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POLITICS AND ECONOMICS OF MAINTAINING PESTICIDE REGISTRATIONS

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ABSTRACT: The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to require the reregistration of all pesticides registered before 1984 within 9 years. The FIFRA 88 required that all pesticide active ingredients must meet current registration standards, suspended the previous fee structure, and imposed a one-time registration fee and annual maintenance fees. New data generated because of FIFRA 88 must conform to EPA's Good Laboratory Practice Standards and animal studies must follow guidelines of the Animal Welfare Act. FIFRA 88 has significantly increased data requirements, data costs, and other pesticide registration and reregistration costs for most pesticides. The increased financial burden has caused industry and governmental agencies to drop minor-use registrations that could not generate sufficient profit to pay for reregistration. During 1989, over 19,000 pesticide registrations were canceled because of the imposition of annual maintenance fees levied by FIFRA 88. More registrations will be canceled in 1990 as registrants find that it is not cost-effective to provide data for many minor-use pesticides. This will result in the loss or further use restrictions on chemicals critical to manage vertebrate pests. In addition, the reregistration process will divert funds from research on alternative pest management practices at a time when that research is critically needed.

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HISTORICAL BACKGROUND

The history of pesticide regulation dates back to the turn of the century, when the Insecticide Act of 1910 made it unlawful to sell adulterated products (Bean 1977). The primary purpose of this Act was to protect purchasers of insecticides and fungicides from fraud. The act was difficult to enforce because it contained no provision for registration of pesticides prior to sale. In 1947, registration of pesticides was first required (licensing before sale or distribution) when the Insecticide Act was repealed and replaced by the Federal Insecticide, Fungicide, and Rodenticide Act, which was administered by the U.S. Department of Agriculture (USDA). With FIFRA, labeling requirements and warnings of hazards were also put into effect.

FIFRA was amended in 1959, and again in 1964, to permit the Secretary of Agriculture to cancel or refuse to register pesticides which posed a threat to humans or nontarget wildlife. The amendments also provided a means for private citizens to compel the Secretary through legal proceedings to take action against hazardous pesticides. In 1970, registration functions were transferred from USDA to the newly created Environmental Protection Agency (EPA).

In 1972, FIFRA was amended by the Federal Environmental Pesticide Control Act (FEPCA), which increased EPA's authority to regulate the storage, sale, and use of pesticides. Also, a system of registration was established which classified pesticides as "general use" or "restricted use"; only applicators certified as competent can apply a restricted-use pesticide. FEPCA established more definitive criteria for pesticide registrations. It specified that a pesticide can be registered if: 1) its composition warrants the proposed claims for it (it is efficacious); 2) the labeling complies with FIFRA requirements; and 3) the pesticide will perform its function without "unreasonable adverse effects" on human health or the environment. As a result of these changes, registration data requirements became much more comprehensive.

Three lesser amendments were made to FIFRA after 1972 (McKenna et al. 1987). A 1975 Amendment mandated that EPA consider impacts on agriculture before cancelling pesticides and established the FIFRA Scientific Advisory Panel to review proposed cancellations and regulations. In 1978, Congress amended FIFRA to provide data submitters with the right to 10 years of exclusive use of data and granted conditional registration authority to allow EPA to process registration applications in the absence of full supporting data. A 1980 amendment refined the role of the Scientific Advisory Panel and specified procedures for reviewing studies performed by EPA.

In 1984, the EPA published a notice in the Federal Register (40 CFR Part 158 of FIFRA) that specified and expanded the kinds of data that must be submitted to EPA to support a registration. Data requirements were listed by primary use pattern (such as terrestrial or aquatic), and then by secondary use (e.g., nonfood or food use) for each active ingredient and end-use product. Requirements are comprehensive but are especially numerous and costly for pesticides used on food items or in water. The basic data requirements for all pesticides fall into several broad categories: 1) Product Chemistry studies provide a profile of the physical and chemical characteristics of the pesticide product and address impurities in the product and in the manufacturing process. 2) Wildlife and Aquatic Organisms studies are used to determine toxicity to nontarget species, primarily in the laboratory but also in actual field studies. These tests include studies such as avian toxicity and reproduction, fish toxicity, and invertebrate toxicity. 3) Toxicology or Human Health Hazard studies assess hazards according to duration and route of exposure to the pesticide. These tests include a number of basic LD_{50} tests and also some extremely expensive, chronic, reproductive teratogenicity or carcinogenicity tests with domestic animals. 4) Nontarget Plant Hazard Evaluation studies determine pesticide effects on seed germination and vegetative vigor. 5) Environmental fate studies monitor the movement, degradation and/or metabolism of the pesticide in soil, water, and air. 6) Residue Chemistry studies are used to determine pesticide residues in plants or animals leading to requests for tolerances that specify acceptable residue levels on all food items.

1988 AMENDMENTS TO FIFRA

The 1972 Amendments to FIFRA mandated that all pesticides must meet registration data requirements (be reregistered) within a 5-year period. Under the process established in 1972 and refined in subsequent amendments, Registration Standards were issued to establish data requirements for individual pesticides. These standards were issued for 194 pesticides of greatest concern to EPA. In addition, Data Call-Ins were issued for other pesticides of concern including vertebrate pesticides like strychnine and 1080. By 1987, despite submission of reams of data by registrants, fewer than 5 chemicals (out of 611 active ingredients) had been reregistered (all data provided, and all registration and tolerance decisions completed). As a consequence, public pressure to speed up the reregistration process prompted Congress to pass the 1988 Amendments to FIFRA, which were signed into law on October 25, 1988, and became effective December 24, 1988. This version of FIFRA is frequently called "FIFRA 88" or "FIFRA LITE" (the latter term used by some groups because the final amendment carried fewer provisions than these groups had anticipated). However, there is nothing "LITE" about FIFRA 88. This act is having a profound effect on all pesticide manufacturers, registrants, and users.

Under FIFRA 88, all pesticides containing an active ingredient first registered before November 1984 must be reregistered within a 9-year period. The only exceptions are those pesticides determined to have no outstanding data requirements. FIFRA 88 specifies a 5-phase Reregistration process for approximately 600 active ingredients which are used to produce about 35,000 end-use products.

Phase 1 of the reregistration process is a listing of the active ingredients of the pesticides that will be reregistered on 4 lists (A, B, C, and D). List A includes the 194 products for which Registration Standards were already issued. The data requirements and data due dates specified in the Registration Standards continue to apply until a new Data Call-In is issued, and these chemicals are not subject to the remaining reregistration phases. Lists B, C, and D include all other pesticides in order of descending concern. Phase one was completed in October 1989.

In Phase 2, registrants must submit a notice of their intention to seek reregistration of their pesticides, identify missing and inadequate data for the technical product, and commit to supplying missing or inadequate data within specified time periods of 1 to 4 years. Data are considered inadequate if they do not meet Good Laboratory Practice Standards, if the registrant does not have access to all of the raw data, or if the study was submitted to EPA prior to 1970. Phase 2 ended in January 1990.

During Phase 3, registrants must submit the newly committed data to EPA, must summarize and reformat most previously submitted data, and must identify any adverse effects of the pesticide. Much of the data must be submitted to EPA within a year from the Phase 2 Response due date.

During Phase 4, EPA will review submissions from Phases 2 and 3, identify outstanding data and issue Data Call-ins for additional data. Phase 5 involves the final review of data by EPA, followed by a regulatory action (such as reregistration or cancellation).

FIFRA 88 also established two types of fees (Reregistration and Maintenance) to fund the reregistration process. The Reregistration fee is a one-time fee of between $75,000 and $150,000 split among all the registrants of each active ingredient according to their share of the market. Some registrants will be eligible for minor-use, low volume, or small business waivers that will allow this fee to be reduced. In addition to the one-time fee, Congress estimated that EPA would need $14 million/year to deal with the increased workload mandated by the reregistration process of FIFRA 88, and included an annual maintenance fee for every technical or end-use registration in the legislation. In 1989 this fee was set at $425 per registration (up to 50), $100 registration from 50 to 200, with no additional fees assessed for more than 200 registrations. To maintain the $14 million income for EPA after more than half of all registrations had been cancelled, 1990 maintenance fees were increased to $650 for 1, $1300 each for 2 to 15, and $1,150 for 16. There is no cost for the 17th to 50th registrations ($20,000 per registrant for 50 registrations), but beginning with number 51, the fee is $1,300 each through 61, $700 for 62, and nothing thereafter, for a maximum of $35,000 per registrant.

OTHER REGULATIONS IMPACTING PESTICIDE REGISTRATIONS

In addition to FIFRA, two other recent regulations have impacted research on vertebrate pests by increasing the cost of that research. The Good Laboratory Practice Standards (GLPs) were issued by EPA in 1983 to ensure that testing for Human Health Hazards was conducted properly and that all raw data were retained. GLP standards require that: 1) Studies are defined by an approved protocol; 2) Qualified personnel are in charge of the study; 3) The study is conducted according to written Standard Operating Procedures; 4) Equipment is properly calibrated and maintained; 5) Data is properly gathered and recorded; 6) Raw data are saved for a future review or EPA audit; and 7) A Quality Assurance Unit is established at each laboratory to assure that the standards are met. As of October, 1989 GLPs are now required for all data used to support pesticide registrations.

The Animal Welfare Act (AWA) was enacted in December 1985 and requires that the Secretary of Agriculture provide regulations and standards for humane handling, housing, care, treatment, and transportation of animals. The act requires that animal facilities have an attending veterinarian, and that a committee be established to review every protocol that deals with the use of animals. The act also sets standards for housing and care of animals and provides for periodic inspection of facilities holding animals.

IMPACT OF NEW REGULATIONS

General Impact on Research Organizations-DWRC Example

The recent regulations have had and will continue to have a major impact on vertebrate pest control research. The impact on the research program of the Denver Wildlife Research Center (DWRC) is an excellent example of effects of regulatory decisions. The DWRC is the research organization in the Animal and Plant Health Inspection Service (APHIS); its primary responsibility is to support the animal damage control program and provide APHIS and the public with the knowledge and tools to reduce wildlife conflicts with agriculture and other human endeavors. To comply with the required regulations, the DWRC has reorganized and made personnel and internal structural changes to accommodate the regulations and the resultant shift in research priorities toward reregistration of pesticides.

The documentation required by Good Laboratory

Practice Standards has greatly increased the time and effort required to conduct research studies. To comply with GLP Standards, an independent Quality Assurance (QA) Officer and assistant have been appointed to develop and monitor the GLP program at the DWRC. For every GLP research study a formal study protocol is written, a unique number is assigned, and the study is inspected by the QA office. Verification of personnel qualifications and personnel training are required for participation in a research study, and records of training must be maintained. Standard Operating Procedures (SOPs) are written for every research component (i.e., instrument, technique, method) that could affect the integrity of the study. Logbooks are maintained for all equipment used (i.e., refrigerators, freezers, chromatographs, telemetry equipment). Logbooks and laboratory notebooks are kept according to standards (i.e., permanent black ink, with errors crossed-out and initialed) and measuring equipment (i.e., chromatographs, telemetry receivers, analytical balances, syringes, pipettes, thermometers, etc.) are calibrated according to specific schedules.

A series of chain-of-custody and storage safeguards have been established to monitor the location and amount of every chemical or sample. Validated analytical chemistry methods are being developed for each pesticide active ingredient and for any matrix to which a pesticide is applied (i.e., baits, water, soil). Purity of chemicals is being established for every study of an active ingredient or end-use product, meaning that all sample analyses must be conducted by the validated analytical methods. To meet the increasing demand for validated methods, DWRC chemistry staff had to grow from 3 to 15 in less than 2 years. Procedures for labeling every piece of correspondence, data, sample, instrumentation recording, computer analysis, etc., have been instituted for archival purposes. All raw data and nonperishable samples from a GLP study must be placed in a permanent archive for use in the event of an EPA audit. Access to archives is severely limited.

To meet Animal Welfare Act requirements, an Animal Care Section was established at the DWRC under the supervision of a veterinarian. DWRC is requiring all Animal Care personnel to be certified by the American Association for Laboratory Animal Science (AALAS). An Institutional Animal Care and Use Committee (IACUC) has been established that reviews every protocol dealing with animals and ensures compliance with AWA requirements. Because the research facilities at DWRC require major renovation and the indoor and outdoor animal research areas need to be modernized to comply the AWA and GLP standards, plans are under way for construction of new facilities in Fort Collins, Colorado.

In addition to the personnel and facilities changes, the massive data mandated by GLP and AWA requirements imposed by FIFRA 88 have forced DWRC to shift research priorities. A new Section of Chemical Development/ Registration was formed in 1988 to coordinate all EPA-mandated registration research at the DWRC. In addition, a full-time Registration Coordinator was appointed in 1988 to facilitate registration activities between APHIS, DWRC, and EPA. Under FIFRA 88, APHIS has committed to supplying EPA with over 200 studies for 8 active ingredients within the next 4 years (most are required within 1 year). Because reregistration data requirements are extensive and costs of generating the data are high, the current APHIS budget allows for research at DWRC to be conducted only on currently registered pesticides. Research on nonlethal alternatives for animal damage control has been curtailed despite a growing public opposition to use of toxicants and an increased public need for new and innovative animal damage control tools.

Impact of Regulations on Registration Costs

Increasing data requirements because of GLP, AWA, and FIFRA 88, and the associated costs of generating those data, have made it uneconomical for many private and public registrants to maintain any but the largest volume vertebrate pesticide uses. The following examples will serve to illustrate the wide range of costs associated with generating data for various pesticide-use patterns.

The indoor, nonfood-use pattern has the fewest and least costly data requirements. The indoor nonfood pattern includes pesticides used within enclosed areas (i.e., for rat and mouse control) or around the periphery of structures in a manner that precludes most environmental hazards. EPA guidelines require a minimum of 34 individual studies with an estimated cost of about $53,000 for registering an indoor nonfood use. These studies include Product Chemistry, Human Health Hazards, and Genotoxic Effects. Starlicide® (a bird toxicant registered by Purina Mills, Inc., St. Louis, Missouri) is an example of an indoor nonfood use when used to control starlings in feedlots.

For a terrestrial nonfood-use pattern, Avian and Aquatic Organisms Toxicity, Nontarget Plant Hazards, and Environmental Fate tests are also required, bringing the minimum number of required tests to 57, at a cost of about $670,000. Terrestrial nonfood uses are those uses where pesticides are placed outdoors in nonagricultural areas, in underground burrows, or on rangeland on bare ground around burrows (broadcast baiting on rangeland is considered to be a food use because of the potential for livestock consumption). Almost all USDA/APHIS pesticides are classified as terrestrial nonfood. For example, APHIS has a number of terrestrial nonfood uses for Starlicide® (raven, pigeon, and gull control) that Purina Mills is not supporting; therefore, APHIS will have to provide the additional required data, which will cost between $110,000 and $300,000. APHIS also has a conditional registration for technical 1080 (sodium monofluoroacetate) for use only in the Livestock Protection Collar (LPC) for coyote control. APHIS has requested waivers for most data for this registration because use in a collar around the neck of a sheep allows only negligible exposure of 1080 to nontarget wildlife or the environment and because 1080 is a low volume minor use, with less than one pound sold for this use each year. APHIS has committed to conducting 11 studies to reregister the technical product at a cost of about $16,000. Additional studies are being conducted on the LPC to assess nontarget hazards. The technical registration for use in the LPC is currently the only technical registration for 1080. The technical registration supporting rodenticide uses has been canceled and funds have not been generated to reregister it. EPA may soon begin cancelling all end-use rodenticide products.

Strychnine is another example of a terrestrial nonfood use. Even prior to FIFRA 88, it was clear that none of the technical registrants could afford to produce the data required by EPA. Prior to a 1988 District Court injunction banning aboveground uses, technical registrants of strychnine jointly sold about 200,000 ounces of strychnine per year at a cost of about $2.00 per ounce. Because of concern about the

potential loss of strychnine as a vertebrate pest management tool (particularly for underground baiting of pocket gophers), a consortium of private, state, and federal registrants of strychnine was formed in 1988 to provide funds to meet EPA requirements. The consortium consists of over 20 members, each of which contributed $2,000 initially, plus $1,000 per year over 3 years, and also agreed on a $0.50/oz. charge to be levied on the technical product. A Settlement Agreement was signed by consortium members and EPA in 1989 and the consortium has agreed to supply 31 studies that will be conducted at a cost at about $275,000.

Registration costs for food uses are considerably higher than those for nonfood uses. As an example, Mesurol® (methiocarb) is registered for a variety of uses, including use as an effective bird repellent on a variety of crops. Mobay Corporation previously registered Mesurol for use on blueberries, cherries, and seed corn but has discontinued these uses because of the low volume of use compared to the high cost of data requirements. Mobay Corporation has generated a considerable amount of data for its insecticide, acaricide, and molluscicide uses but has not generated data on dietary risk. Because residues remain on crops, chronic feeding, oncogenicity, reproduction, and metabolism studies are required by EPA to maintain food-use registrations. These studies would cost about $1 million. Mesurol is also highly toxic to some aquatic species. Thus EPA is requiring additional data on fish early-life cycle, bioaccumulation in fish, and aquatic residues at a cost of about $1.6 million. Funds are not currently available to pursue food uses for Mesurol so those uses will probably be lost.

Impact on Number of Pesticide Registrations

Registration cancellations occurred at a high rate during 1989 as registrants were initially required to pay maintenance fees. EPA estimated that of the 44,000 to 45,000 Federal registrations held in 1989, approximately 19,300 (about 13,400 Section 3 and 5900 State or 24 (c) registrations) had been canceled by October 1989. Half of the cancellations were voluntary by the registrant because of the maintenance fee and half were cancellations by EPA for failure to respond to the maintenance fee request. Of the 600 or so active ingredients, 124 were canceled. More registrations are expected to be canceled in 1990 as registrants find data requirements and time frames for generating data too costly to meet.

The active ingredients for which Registration Standards had been issued (List A) include more than 85% of the total volume of pesticide use in the United States. Many of these pesticides have low volume, minor crop uses that are being dropped by registrants because of additional data costs. An incomplete 1989 survey indicated that all crop uses will be dropped for 31 of the 194 active ingredients on List A, and some crop uses will be dropped for 44 active ingredients. One or more crop uses will be dropped for 9 active ingredients of the 149 active ingredients on list B. Specific data on List B & C chemicals are not available.

SUMMARY

Most vertebrate pesticides are minor-use pesticides with low-volume use compared to most insecticides, fungicides, and herbicides. Because of the low volume, minor use, large numbers of currently registered vertebrate pesticide uses of importance to the agricultural community, the public, and governmental animal damage control and public health personnel will be voluntarily or involuntarily canceled or have their uses restricted because of FIFRA 88. Manufacturers will drop low-volume pesticides that cannot economically justify the cost of registration fees, annual maintenance fees, and data generation. Vertebrate control chemicals are especially vulnerable to cancellation because some companies are reluctant to deal with the unfavorable public opinion that these chemicals often evoke. If low volume, minor use vertebrate pesticides are to be retained, then producers, sellers, and user groups may have to look at innovative ways to help technical registrants generate the funding base required to maintain these registrations. Possible funding sources include user groups and registrants of end-use products. Funding could be by assessment of fees or by assessment of a surcharge on products sold. A less well documented problem with the new regulations is that reregistration requirements are diverting funds from research on alternative pest management practices at a time when this research is critically needed.

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