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FEASIBILITY OF PRESCRIPTION PESTICIDE USE IN THE UNITED STATES

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SUMMARY

Chemical exposure has been a major concern of the general public for many years. This concern has resulted in regulation of food additives, drugs, cosmetics, and pesticides. In 1996, Congress enacted the Food Quality Protection Act (FQPA), which established a health-based standard for all pesticide residues in food and mandated that the U.S. Environmental Protection Agency (EPA) determine that there is reasonable certainty of no harm from aggregate exposure to a pesticide from various sources, including the diet, drinking water, and residential use. Under the law, all existing pesticide tolerances will be reassessed in a process that is scheduled to be completed by August 2006.

The outcome of the process could result in the cancellation of some pesticide registrations important to production of several crops. The medical profession uses a model where relatively low-risk chemicals may be self prescribed, but high-risk chemicals are prescribed only by a trained and licensed professional. A similar model could be applied to pesticides where exposure control is an issue. Prescription use could be a mechanism by which certain valuable but high-risk pesticide uses could be maintained while addressing the public's concern for safe use of those products. However, it should be understood that prescription pesticide use will require a new level of infrastructure in terms of personnel qualified to issue prescriptions. Such an infrastructure would take time to put in place and considerable resources to maintain. Careful analysis of the costs of prescription use should made before such a step is taken.

INTRODUCTION

Managing pests, including weeds, insects, plant diseases, and nematodes, has always been a challenge in both agricultural and nonagricultural environments. In modern agriculture, pesticides are used to protect animal health and to enhance plant production. They have an inseparable role in the evolution of agricultural production to a highly mechanized system using modern plant breeding, fertilization, and irrigation methods. Unfortunately, the increases in productivity have been accompanied by some unintended social and environmental consequences. In the case of pesticides, these consequences include documented cases of pest resistance and pesticide-induced pest outbreaks and public concern for

environmental contamination, human exposure, and residues on food.

Pesticides are chemical substances used to control pests. They are legally classified as economic poisons and are defined as substances used for controlling, preventing, destroying, or mitigating any pest. In addition to synthetic organic compounds, pesticides include inorganic products like sulfur, natural botanical products like pyrethrum, and biological products such as *Bacillus thuringiensis* and *Trichoderma harzianum*, which occur in nature, but also are produced commercially for pest control. The general public seems most concerned with the use of synthetic pesticides, particularly those with broader activity and those with which they are unfamiliar. Agricultural uses of pesticides in particular are not well understood by the public, so questions and concerns exist about the safety of these products and the need for their use, especially when food supplies are abundant and inexpensive.

Pesticide Use in Integrated Pest Management

During the 1950s, entomologists working in pest control initiated the concept of integrated control, intended primarily to reconcile the use of insecticides with biological controls (Michelbacher and Bacon, 1952; Smith and Allen, 1954; van den Bosch and Stern, 1962). The concept was expanded to include economic thresholds by Stern et al. (1959), which added the components of pest monitoring and risk assessment before justifying the application of therapeutic measures like insecticides. As the philosophy of integrated pest management (IPM) matured, an appreciation developed for integrating the management of weeds, pathogens, and nematodes as well as insects in a cropping systems context. At its highest level, IPM incorporates knowledge of interactions among pests, the crop, and the environment within the context of a social, political, and economic matrix.

Adoption of IPM systems normally occurs along a continuum from being largely reliant on prophylactic control measures and pesticides to using multiple-strategy biologically intensive approaches, and is not usually an either/or situation (Sorenson, 1994). The U.S. Department of Agriculture (USDA)formalized this concept in quantifying IPM adoption by creating categories that represent progressively greater use of biological or cultural practices instead of conventional pesticides (Vandeman et al., 1994). Others have accepted and expanded this approach (Hoppin et al., 1996; Benbrook et al., 1996; Kogan, 1998). In the continuum, the threshold for a minimum IPM level being practiced is field scouting for both pests and natural enemies and using action thresholds to make pesticide use decisions. It is important to note that the practice of IPM is site-specific in nature and individual tactics are determined by the particular crop/pest/environment scenario.

Integrated pest management strategies include prevention, avoidance, monitoring, and suppression of pest populations. Prevention is the practice of keeping a pest population from infesting a crop or field and should be the first line of defense. It includes such tactics as using pest-free seeds and transplants, preventing weeds from reproducing, scheduling irrigation to avoid situations conducive to disease development, cleaning tillage and harvesting equipment between fields or operations, using field sanitation procedures, and eliminating alternate hosts or sites for insect pests and disease organisms.

Avoidance is practiced when pest populations exist in a field or site but their impact on the crop is avoided through some cultural practice. Examples of avoidance tactics include crop rotation such that the crop of choice is not a host for the pest, choosing cultivars with genetic resistance to pests, using trap crops, choosing cultivars with maturity dates that may allow harvest before pest populations develop, using fertilization programs to promote rapid crop development, and simply not planting certain areas of fields where pest populations are likely to cause crop failure. Some tactics for prevention and avoidance may overlap.

Monitoring and proper identification of pests through surveys or scouting programs, including trapping, weather monitoring, and soil testing where appropriate, should be performed as the basis for any suppression activities. Records of pest incidence and distribution should be kept for each field. Such records form the basis for crop rotations, cultivar selection, economic thresholds, suppressive actions and other management decisions.

Suppression of pest populations may become necessary to avoid economic loss if prevention and avoidance tactics are not successful. Suppressive tactics may include cultural practices such as altered row spacings or optimized in-row plant populations, alternative tillage approaches such as no-till or strip-till systems, cover crops or mulches, or using crops with allelopathic potential in the rotation. Physical suppression tactics may

include cultivation or mowing for weed control, baited or pheromone traps for certain insects, and temperature management or exclusion devices for insect and disease management in confined areas such as grain storage. Biological controls, including mating disruption for insects, may be considered as alternatives to conventional pesticides, especially where long-term control of an especially troublesome pest species can be obtained.

Chemical pesticides are important components of pest suppression systems. In many cases, pest outbreaks occur in spite of the best efforts at prevention or avoidance. If effective biological or other controls do not exist, chemical pesticides may be the only alternative for saving a crop. Pesticide use is appropriate in IPM systems that include the following sound management approaches.

1. The cost:benefit ratio should be confirmed prior to use (using economic thresholds where available).
2. Pesticides should be selected on the basis of least negative effects on beneficial organisms, the environment, and human health in addition to efficacy and economics.
3. Where economically and technically feasible, precision agriculture or other appropriate advanced technologies should be utilized to limit pesticide applications to areas where pests actually exist or are reasonably expected.
4. Sprayers or other application devices should be calibrated prior to use and periodically during the use season.
5. To avoid resistance development, chemicals with the same mode of action should not be used continuously on the same field.

FQPA Impacts on Pesticide Registrations

In 1996, Congress enacted the Food Quality Protection Act (FQPA) which established a health-based standard for all pesticide residues in food. In addition, the FQPA mandates the EPA to determine that there is reasonable certainty of no harm from aggregate exposure to a chemical from various sources, including the diet, drinking water, and residential use. Under the FQPA, all existing pesticide tolerances will be reassessed in a process that is scheduled to be completed by August 2006. The outcome of the process could result in cancellation of some pesticide registrations important to production of several crops. Additionally, the application of new standards for review could make the registration of new products more difficult.

The EPA uses the analogy of a "risk cup" to represent the total level of acceptable risk from lifetime exposure that will not result in increased probability of long-term health effects. Each registration (tolerance) for a pesticide potentially contributes to estimated dietary risk. When dietary intake for a pesticide is combined with estimated nondietary exposure, the total risk for that pesticide can be calculated. Once the "risk cup" for a pesticide is full, no additional uses of that chemical can be approved unless others are removed. Aggregate risk estimates could dictate the pattern of registered uses for many common products. For example, insecticides such as chlorpyriphos, malathion, diazinon, and carbaryl are used to control pests in turf and ornamental crops, in and around homes, or for institutional uses. These uses will contribute to filling the "risk cup" of such products and could preclude other uses such as those for agricultural crops.

The tolerance reassessment schedule announced by the EPA is divided into three groups of chemicals, each with about a third of the tolerances to be reassessed over three successive 3-year periods. The first group to be reassessed includes carbamates, organophosphates, Class B1 and B2 carcinogens, chemicals that exceed reference doses, and high hazard inert ingredients. The second group includes Class C carcinogens and pesticides subject to re-registration. The third group includes biological pesticides, the remaining inert ingredients, and pesticides registered after November 1994.

There is particular concern for minor-acreage crops where typically fewer pesticides of any kind are registered, and many of the Group 1 pesticides provide the base for chemical control. In these minor-acreage crops, small market size might result in the reluctance of registrants to defend these uses or to register new products in order to maintain more profitable large-acreage crop uses when the tolerance evaluation requires a risk reduction. Often, the minor-acreage crop uses are significant contributors to dietary risk values and a registrant may be forced to drop these uses. Even when they are not, a minor use registration could trigger an aggregate risk assessment for all uses, which presents a business or resource demand that a registrant may not wish to take. Even the alternatives to conventional pesticides often are lacking for minor-acreage crops or involve greater expense.

The lack of proven alternatives for existing materials that might be lost on all crops is a general concern for many producers. The cost of alternatives also is an issue. There remains a need for a systematic and realistic appraisal of the availability, cost, and risks of potential alternatives to the available materials at greatest risk of being lost. Because of the pace at which reassessment decisions must be made, there is concern on the part of growers that proven alternatives, chemical or nonchemical, may not be in place quickly enough to prevent severe economic losses.

The EPA's recent experience with the review or setting of tolerances in the emergency exemption (FIFRA Section 18) process has resulted in radically different opinions in what state officials and the EPA consider as "emergencies." The tensions created in this process between growers, suppliers, and agencies are not yet resolved, but serve as an example of how the FQPA is affecting urgent-need situations.

Public Perception of Pesticide Use

Chemical exposure has been a major concern of the general public for many years. This concern has resulted in regulation of food additives, drugs, cosmetics, and pesticides. Stringent regulation is essential to protect the public and to provide public confidence. Pesticides which present the greatest risk to human health or the environment have various restrictions placed on their use. Pesticides believed to be "safe" may be put on a fast track for registration. In spite of extensive regulation of their registration and use, pesticides remain a major public policy issue.

What makes pesticides different from other regulated chemicals in the eyes of the public? Former U.S. Food and Drug Administrator Donald Kennedy once characterized the public outcry his agency endured demanding that it maintain the availability of saccharine, a known carcinogen used as a food additive and slated for removal under the Federal Food Drug and Cosmetic Act, as being "run over by a train" (Kennedy, 1988). He went on to conclude that the public will demand that cancer-causing products be removed from the market except when people enjoy them. The public also seems to have confidence in the regulation and use of pharmaceutical drugs. Medicines posing less risk to consumers are available over-the-counter and can be self-prescribed. In contrast, those posing a greater risk must be prescribed by physicians who presumably are trained in diagnosis, understand potential alternative treatments, and can provide an educated assessment of the benefits and risks of recommending a particular health therapy.

At present, growers practice a form of self-prescription with pesticides, controlling the choice of chemicals and treatment schedules. As long as they are used according to label restrictions, there are few additional restrictions on their availability or use. There is no requirement that alternative treatments are considered or that knowledge of alternative treatments exist. Increasingly more stringent regulations will likely lead to the loss of certain higher risk pesticides or to uses of pesticides for which there are no known alternatives or which provide other benefits for growers.

The Issue

The medical profession uses a model where relatively low-risk chemicals may be self prescribed, but high-risk chemicals are prescribed only by a trained and licensed professional. A similar model could be applied to pesticides where exposure control is an issue. Prescription use could be a mechanism by which certain valuable but high-risk pesticide uses could be maintained while addressing the public's concern for safe use of those products.

Prescription Use Classification of Pesticides

Implementation of a program that allows for pesticide use by prescription would require the cooperative and parallel development of efforts within the regulated (users and suppliers) and regulatory (federal and state) communities. Imbedded in such a program is a long list of questions that must be asked and answered, and the process of working through these questions would need to be efficient to provide the mechanisms necessary to both institutions. Understanding the commonality of what seem to be different goals can enable rapid implementation of a program to address those commonalities. While the regulated community seeks to maintain use options for certain compounds that otherwise might be eliminated by other regulatory actions such as the FQPA, the regulatory community seeks to provide alternatives for those compounds that present unacceptable risks. A key factor is how one evaluates and controls risk. In both environmental and human health risks, control of exposure at increased increments results in control of risk at increased increments. If a general use classification according to the Federal Insecticide, Fungicide and Roden-

ticide Act (FIFRA (3)(d)(1)(B)) is the first tier of regulatory control of risk, then restricted use classification (FIFRA (3)(d)(1)(C)) can be considered the second tier of control. The implementation of prescription uses for those pesticides affected by some of the issues discussed above (e.g., minor use, the FQPA) would then be the next (third) tier of federal control.

Reference to general and restricted use implies that no change in use classification would occur until the FIFRA is amended and new practices are put in place through implementing regulation. However, the restricted use classification process was embraced by the EPA and voluntarily implemented by industry prior to the actual description of these processes by the FIFRA. Such a process can undergo rapid evolution simply by a cooperative agreement between industry and the EPA to embark upon a voluntary campaign that later is validated by the adoption of law. The order of effort, i.e., from voluntary to legal rather than the reverse, will be determined by the willingness of the regulated community to embark on a voluntary program and the willingness of the regulatory community to recognize prescription as a means for exposure control. The order also will be determined by the cost of implementation and enforcement, the achievement of equitabileness among registrants, the ability of the process to provide tangible data on exposure, and the cooperation of multiple levels of government (federal and state, enforcement and monitoring agencies or branches).

The restricted use classification system evolved as state training programs were developed. Progress of adoption differed from state to state when the program was initiated. Federal legislation eventually brought a common denominator to the definition of "restricted use," but earlier EPA pesticide regulation notices and regulatory support at the state level (training and state restricted use implementation) brought the regulated community to a common ground on labeling issues. If there is a voluntary effort, one can envision the industry supporting an educational program and a common labeling process for affected compounds. If there is a legal amendment to the FIFRA, one can envision a struggle similar to the current controversy about certain provisions of the FQPA. But, appropriately provisioned, either alternative could generate use reporting and regional, crop, or "as needed" restrictions that would help the EPA evaluate exposure and thus risk.

On a national level, development of a regional or crop approach should provide predictability to the use of compounds classified as prescriptive. Manufacturers are faced with a logistical nightmare if they must provide small amounts of materials that are "dispensed" on an urgent, as-needed basis. Moving such compounds from point of delivery or distribution to point of need requires time and the assurance that once the product is purchased it can be used when the need arises. Therefore, a prescription process would have to allow the free distribution of materials. Free distribution of materials might require a special definition of "materials in channels of trade," which would exempt prescription pesticides in some manner so that they could be delivered to areas where their use would be most likely.

Prescription practices in themselves could provide multiple levels of protection. It seems safe to say that the EPA over time has attempted to utilize conservative risk assessment as a protection mechanism. The EPA must work with use assumptions unless the registrant provides actual use data. Even then, the EPA must assume that use will be consistent over time or will grow at a given rate. For compounds now under increased "risk pressure," however, the risk equation itself allows one to predetermine how much exposure can be tolerated. If one generates "what if" scenarios in a dietary risk assessment, for example, at some point the volume of compound per crop will meet the acceptable risk criteria. Thus, monitoring volume, through prescription for compounds under risk pressure, could offer a means of assuring the EPA that an appropriate margin of safety is maintained over time. This may also help to give an element of predictability of use, which would allow manufacturers assurance that the logistics of distribution could be managed.

The manufacturer, however, is not in a position to dictate what tools a grower might need, and, in fact, gets considerable pressure from growers to make every effort to maintain those pesticide tools now available or even reinstate labeling that may have been lost or abandoned. It also is not to the manufacturer's benefit to have high costs tied to products that may be increasingly limited in their use. Initiation of prescriptive use would be eased in proportion to the extent that prescription practices could be implemented by mechanisms that do not excessively burden the registrant. Existing programs at the state level may offer such opportunities. All states now have in place certification programs for restricted use and pesticide application licensing. Adding one step—the third tier—to that process would be one mechanism of

implementation of a voluntary program. Most states already have pesticide use record-keeping requirements but few have reporting requirements. Changes would be needed in reporting requirements to give the EPA a mechanism needed to monitor and control exposure.

Comparing pesticides to human medications and the prescription practices embodied by the Federal Food, Cosmetic and Drug Act is a useful exercise, although there are some very basic differences in operational applications. A pharmaceutical product typically evolves from a tightly controlled prescription to a general prescription, and—possibly—to over-the-counter use. Conceptually, all registered pesticides currently are "over-the-counter" use; however, some require dispensing by a "pharmacist" (restricted use). Furthermore, the user community is concerned about the loss of tools for unique, emergency, or minor use situations, not the registration and product maturity process. Pharmacists are licensed according to national standards and also by state testing, licensing, and enforcement programs. This process compares favorably to the manner in which pesticide dealers and consultants are licensed with respect to general use and restricted use compounds. However, in agriculture there is no equivalent to the cure of a serious condition that physicians can provide through their ability to draw from a greater and stronger list of compounds, some of which are controlled expressly because they have potentially serious side effects if not properly managed.

Enhancing existing state programs through voluntary efforts recognized and supported by the EPA and industry may be one way to provide the protection crops need and the protective mechanism that the EPA needs for certain "risk pressured" compounds. Developing such a program would require the definition of qualifications for who could administer those products known to be needed for a certain cure but of concern to the EPA with respect to their potential or aggregated risk.

Qualifications of Prescribers

Currently, each state has requirements for pesticide certification. The programs conform to national standards but include state-developed testing schemes, training programs, and licensing arrangements. Generally, certification depends on the ability of an individual to pass a specific qualifying exam (sometimes by crop or crop group) at various criteria levels (applicator, operator, consultant). Recertification and continued licensing depends on documented attendance at qualifying training sessions for a given amount of time during a one- to five-year period. Meeting these requirements generally precludes the need to identify disciplinary, educational, or experiential qualifications.

As far as the individual source for a "prescriber," there is much debate. The manufacturer's representative has a wealth of product knowledge, but may be perceived as having a conflict of interest under a prescription scenario. U.S. Department of Agriculture or state officials may be a source for prescribers, although state and federal resources to act in this capacity may be limited. Independent crop consultants may be the most logical source of prescribers, but their numbers are relatively small compared to what would be needed under prescriptive use. Growers, regulators, and regulatory agencies are likely to have very different views about who should be a prescriber.

Several options exist for a simple mechanism to provide the third tier of exposure control, through qualified providers. One option could be minimum standards for educational or experiential requirements. Another option could be an increased requirement for continuing education or a more rigorous exam that includes test criteria on compounds identified as prescriptive. A more rigorous exam or even a specific exam for qualification in prescription dispensing would allow those currently recommending curative or preventive measures, through the recommendations of a crop consulting service, to maintain and enhance their practice. Educational or experiential requirements may be more difficult to establish and could have the potential to disqualify otherwise qualified practitioners. Conversely, a phased or dual approach could be established to allow transition to a third tier of prescriptive pesticide consultants.

Just as medicine has moved from general practice to specialization, implementation of a prescription process could impact agricultural practitioners in the same manner. Given the relatively small pool of talent available in the agricultural science area, forcing specialization could be a detrimental limitation to the work force. Also, some degree of specialization naturally occurs because crop management is a local issue depending on climate, crop, pest pressures, and location of the growing area being managed. Recognition of the importance of localized experience is a critical factor to consider in envisioning a pesticide prescription process. There are many human pathogens with strong regional ties. However, the importance of local issues is a component usually not as

common to the medical world—a physician educated in Boston can usually take that knowledge to Los Angeles and begin to save lives. A professional educated in agriculture may not make as easy a transition. Therefore, it may be useful to concentrate on product knowledge and use considerations in such a situation.

Two factors—specialized practice and short or limited supply—could be combined in the strategy for distribution and control of prescription pesticides, and if arranged properly could benefit all parties. In other natural resource areas, certain factors are desired but in short supply, e.g., air pollution credits and specialized hunting tags for large or limited species take. In these resource areas, states (largely) have developed systems of bidding for points, exchanging points, and allowing for the resale of points. It becomes the responsibility of the user to decide if he or she should invest resources in what may be a premium commodity. Perhaps a version of this approach could solve various problems, such as assuring limited distribution, allowing advanced delivery to point-of-sale, or other economic and logistic benefit related to the law of supply and demand. It should be noted, however, that alternatives to some pesticide uses do not presently exist, and partitioning out a limited supply would put those growers not able to obtain the pesticide at risk of losing a crop. In the medical profession, prescriptions are issued largely based on need, and total use is not limited.

Prescriber Functions

The prescriber, in the case of pesticide use by prescription, would have the potential to enhance the current public understanding of crop protection professionalism. The prescriber also could follow a dictated process, which would document or otherwise demonstrate that all control mechanisms are considered in the curative process. For example, in a given situation, a prescriber could consider the evaluation of pest control mechanisms tried to date on the pest of concern and could recommend a prescriptive solution based on the finding that all other mechanisms of control were exhausted, ineffective, or otherwise inadequate for the pest situation at hand. However, pest control nearly always is associated with the urgencies of the crop season; thus, an evaluation process would not be practical if it were burdensome or time consuming.

A prescriber also may be able to provide a service similar to an early alert system, particularly as the science of precision agriculture matures and the ability to forecast pest incidence improves. That is, a prescriber who is networked into information providing real-time pest infestation reports for an area and the effectiveness of treatment options for those pests would be acutely aware of a new outbreak of an exotic pest or an outbreak requiring special tools. From an exposure and human health standpoint, it may be much better to use a preventive, small, controlled volume of a "risk burdened" compound than to use a large volume of an unrestricted compound applied later and more broadly in the infection-and-control process. Early detection and rapid control using a full arsenal of protection mechanisms has long been a sound medical practice and transfers well to the prescriptive pesticide concept.

In a prescription scenario, it is possible that the prescriber may cover a wider geographic area of responsibility than a single pest consultant, or that the prescriber would be a part of a professional society or entity that sets this practice apart from other types of pesticide certification. Such a level of responsibility may encourage education for the users on preventive measures and IPM practices. The medical community not only serves the population by curing, but also by advising how not to contract a condition—whether it be a contagious disease such as meningitis or a condition related to lifestyle such as early onset heart disease. The credibility associated with a physician advising a healthy diet goes further than a layperson's recommendation, even though the practical knowledge of both may be the same. Thus, a practitioner perceived and qualified as a "higher tiered" provider is likely to have more impact on the target audience when it comes to adopting agronomic practices that prevent or minimize the threat of pestilence or disease.

Under any scenario, the use of pesticides by prescription implies limited availability. Economics and good farm management dictate the conservative use of all crop culture practices, e.g., soil fertility, soil erosion prevention, pesticide use, and other cultural and land use practices. Crop protection measures are implemented either to prevent a known circumstance from occurring or to minimize the impact of a pest when it is discovered. In a prescriptive practice, the specialist may be faced with decisions related to pesticide resistance, exotic disease, extreme weather conditions, or other similar challenges. Under such circumstances, the need for verification of the strain of organism being controlled or the confirmation of an exotic target pest's identity can be critical to

successful control. Thus, the need for and availability of experts in pest identification or disease evaluation through laboratory verification will be critical to the prescription provider.

From a regulatory standpoint, one of the qualifying criteria for a prescriptive pesticide practitioner could be not only proving by examination and certification that the provider is qualified, but also by assuring that the provider has a network of diagnostic resources and decision support should it be needed. The prescriptive practitioner could be required, for example, to list the "preferred providers" of diagnostic services in the application process. Preferred providers are used in the medical profession as well. The preferred provider process could imply that freedom of choice is limited only to those providers identified in the application and recertification process. However, limiting that choice would prevent finding a provider for a unique disease or situation and would not allow for alternate sources should the preferred providers be backlogged with work. Thus, a preferred provider system or reporting criteria should not be constructed to limit freedom of choice. Instead, it should be used as a demonstration that the prescriptive practitioner knows where to obtain advice when it is needed.

Working under the assumption that prescriptive pesticides are a third and higher tier of exposure control means that the reporting requirements associated with restricted use compounds would also apply here. That system is already in place and functioning nationally. Reporting on an annual basis could be used to adjust product placement, availability, or "product credits" from one year to the next or from one 5-year period to the next. Again, because the prescriptive practice would deal with compounds in short supply and of special use, the burden of reporting, tracking, and monitoring needs to be minimized for both the regulated and the regulatory community. Use of a reporting systems for restricted use compounds would provide a monitoring mechanism that is already familiar to the regulated community and a consistent means of enforcement and monitoring for the regulatory community.

Legal Issues

Legal issues surrounding prescriptive pesticides are related to product labeling, FIFRA, FQPA, and FFDCA law. Individuals currently involved in pesticide consulting probably would find it difficult to imagine their liability exposure increasing beyond what it is now, even under a prescriptive use program. Companies that manufacture and distribute pesticides are likely to have the same opinion, but the complexity of their involvement in prescriptive practice is associated with product labeling and sales. If product labeling must address prescriptive use, the current regulatory process may present a deterrent to filing an application for this type of labeling. However, if existing (or previously existing) labeling could be "saved" through prescriptive use, then the only change to an otherwise lost use would be associated with a label statement similar to that for restricted use.

Labeling for prescriptive use, however, could present a regulatory burden similar to that of Worker Protection Labeling, a prospect that neither the regulatory nor regulated communities should be anxious to face. There may be some entities within the EPA who would argue that nothing precludes the requirement for exhaustive labeling under a provision for prescriptive use. Legal review of the basis on which certain labeling decisions have been made, and mechanisms by which an exhaustive labeling program could be avoided, should be considered.

An alternative to causing more liability or regulatory burden for the manufacturer on a product with little likely financial return might be to place the burden of an "exception to labeled" use on the prescription writer. This would increase the liability of the prescription writer but would alleviate the need to wait for a large and slow process to address an urgent and minor need. One way to evaluate implementation of a mechanism might be to consider the exposure level that triggers a potential label cancellation or that triggered a dropped use. That level could be reduced to an acceptable risk level by allowing a product quota under a prescriptive use program. Once that quota was identified, the quantity to be released to prescription practice, under the control of a practitioner, would become the responsibility of the practitioner not of the manufacturer. A complicating factor here would be a situation where multiple practitioners are involved in the same area.

Public Education and Outreach

As mentioned earlier, the prescriber may have the potential to enhance the public's understanding of crop protection professionalism currently existing at the field level. The potential for outreach and education would

be increased as the practitioner communicated his knowledge to others. Also, a requirement for certification and qualification for prescription practice in itself provides an added level of credibility. This could inspire confidence by the nonagricultural public.

The concept of "plant doctor" has been successfully used in education and outreach programs by trade organizations. It is well received and understood by K-12 educators and the public who have had experience with these programs. Endorsing this concept to increase the public's comfort level by adopting a prescription program for risk burdened compounds would increase public understanding of the need for and control of restricted use pesticides.

Oversight of the Program

It is clear that, conceptually, prescriptive use of pesticides fits within existing state and federal regulatory programs already empowered to handle restricted use compounds and the certification of pesticide applicators and consultants. Prescriptive use is a logical sequential addition to FIFRA(3)(d)(1) and would allow an implementation process for at least one aspect of the minor-acreage crop provisions intended, but at this point unrealized, under the FQPA. Oversight of the program fits naturally within the licensing and labeling provisions now in place, but concessions to deal with product labeling and distribution would have to be made or jointly negotiated between the regulatory and regulated community and then embodied into law or implementing regulation. Some labeling already lost may be important to minor-acreage crop growers and could provide them with alternatives otherwise not available. However, the mechanism for and means by which a former label could be resurrected are, under the current registration scenario, complex and burdensome for a minor and uncertain use environment.

Potential Impacts

Farmers obviously would be the primary group impacted by prescriptive use of pesticides. Prescriptive use may be a way of assuring continued availability of certain pesticides important in the production of some commodities. If a pesticide, or certain uses of a pesticide, were found to exceed acceptable risk standards, one option under the FQPA is for the EPA to cancel registration of that pesticide or use. If use of such a pesticide only by prescription were considered to fall within acceptable risk parameters, then the availability of that pesticide use could be continued. However, if prescriptions for pesticide use are required, there are at least three issues of major concern to farmers. First, there will be a cost associated with prescriptive use, and it is not clear who would bear that cost. Second, many pesticide use decisions must be made in a very short time after discovery of a pest infestation to avoid unacceptable crop loss. Any delays caused by the necessity for prescriptions may be unacceptable in the context of good pest management practice. Third, introducing another aspect to use could expose the farmer to increased liabilities.

Agribusiness, including pesticide manufacturers, the distribution network, and dealers and suppliers would be impacted by prescriptive use. In addition to the challenge, based on need, of getting appropriate amounts of certain pesticides to the right place at the right time, manufacturers would have to decide the economic feasibility of supporting registrations for prescriptive use. Certainly, no manufacturer could afford to support a pesticide registration based solely on prescriptive use. However, most companies probably would support prescriptive use on their labels if sufficient nonprescriptive uses could be maintained to support profitable production and distribution of the product. Any new or additional registrations for prescriptive use of a product probably would have to be handled through the Interregional Research Project No. 4 (IR-4) because a manufacturer probably could not justify the cost associated with obtaining new registrations for such limited potential use.

Prescription pesticides could be very important for many IPM programs for minor acreage crops. Several pesticides considered high risk, particularly organophosphate insecticides, are important as remedial treatments in circumstances where preventive and avoidance strategies fail to keep insect populations under control. In some crops, there are no known alternatives for these products. If use of such pesticides could be maintained through prescription as an alternative to cancellation of registration, there would be obvious benefits to IPM programs.

Another group impacted by prescriptive pesticide use would be independent crop consultants. There could be increased demand for consultants who choose to become qualified to prescribe. Additional independent crop consultants probably would be needed under a prescriptive use scenario, and training programs would be needed as well as some licensing authority.

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