American Association of Pesticide Safety Educators

IMPACT OF GOOD LABORATORY PRACTICE (GLP) REQUIREMENTS ON STATE AND FEDERAL MINOR USE (RE) REGISTRATION PROGRAMS

Background

Federal and state budgets to support minor crop registrations via USDA's IR-4 Program and the National Agricultural Pesticide Impact Assessment Program (NAPIAP) have been effectively reduced by EPA's GLP requirements. 40 CFR 160.la requires "... good laboratory practices for conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by EPA." This requirement also includes research supported by NAPIAP which is "...intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of pesticide."

IR-4, established in 1963, provides data to support pesticide registrations for minor crops and uses. These minor crops account for about 40 percent of the value of all cash crops and are an important component of a healthy diet. Studies are conducted in accordance with protocols approved by IR-4 in concurrence with EPA and the manufacturer. Prior to implementation of the amended GLP requirements, field and laboratory studies were completed using accepted scientific methodology.

In 1987 EPA estimated that the GLP revisions would increase the cost of ecological effects, environmental and chemical fate, and efficacy testing about 20 percent. The Council for Agricultural Science and Technology (1992) estimated the additional costs at 25 percent. A more recent study by IR-4 (1994) estimated that the cost of complying with EPA's GLP's was nearly 46 percent of IR-4's resources. The addition of full-time quality assurance officers has increased regional office expenses an estimated 56 percent. None of the studies submitted by IR-4, before 1987 or after 1987, have been rejected by EPA because of suspected fraudulent data.

Impacts of EPA's FIFRA GLP Requirements

State and federal funds available to support registration and reregistration are limited. Dollars spent to meet requirements imposed without clear and adequate justification reduce the total number of (re)registrations projects which can be supported.

Very few faculty at land grant universities are willing to become involved in the registration process at least in part because of the severe restrictions GLP's impose on research activities. Faculty who serve as study directors are legally accountable for the conduct of each study, i.e., they may be subject to civil and criminal penalties if violations are found. The threat of such action is a serious deterrent to the faculty's willingness to participate in studies subject to GLP's. Study directors may have limited control of some activities and must depend on the integrity of cooperators. Faculty who serve as study directors also find their productivity diminished due to extensive paperwork. Active participation in the minor crops program can therefore have negative impacts on academic professional advancement and recognition, because promotion and tenure decisions are directly linked to productivity. This lack of support has resulted in decreased research on minor use pesticide resulting in impediments in production of minor use crops.

It is quite clear that the imposition of GLP's has had a negative impact on state and federal efforts to provide data needed to register pesticides for use on fruits and vegetables.

EPA's current GLP requirements negatively impact federal and state governments' ability to provide data to support minor use (re) registrations via the IR-4 and NAPIAP programs. GLP requirements are extremely costly in terms of personnel and operations. In some states, trained quality assurance staff needed to insure compliance are difficult to recruit. Extensive record keeping requirements have reduced the efficiency of existing staff operations. Lack of qualified personnel and reduced efficiency of existing personnel has adversely affected development of efficacy and residue data needed to support registration of new products, alternatives to existing products or more

environmentally benign products. Many of these new registrations could reduce or eliminate the use of currently registered products or provide urgently needed relief for growers who have lost existing products via the reregistration process. Lastly, additional regulatory and research resources are needed to support emergency exemptions directly attributable to the loss of registrations.

Possible Solutions

The negative impacts of GLP requirements on efforts to register pesticides for use on minor crops can be minimized in several ways. AAPSE supports the following solutions: first, many of the problems related to compliance with GLP's are the result of how 40 CFR 160 is interpreted. It is recommended that EPA and USDA appoint a working group to write a Memorandum of Agreement to develop policy statements and interpretive guidance documents which address GLP's as they relate to conducting (re)registration research at land grant universities. Suggested topics include but are not limited to (1) use of instruments, facilities, personnel or other shared university resources, (2) interpretation of personal liability of faculty who serve as study directors, and (3) data collection and management. Members of the working group must include representatives at the state, regional and national levels. By adopting both policy statements and interpretive guidance documents EPA can greatly reduce their own regulatory burden without jeopardizing their mandate to protect the public from unreasonable exposure to pesticide residues. EPA will always have the opportunity (and responsibility) to reject studies it feels are not properly documented or conducted according to good scientific practices.

Second, GLP requirements need to recognize that there are significant differences between toxicity, use patterns, persistence, acres treated, formulation, cropping systems, and application methods and rates of various pesticide products considered for (re)registration. For example, GLP requirements to register glyphosate on taro are not significantly different from those to register glyphosate on a major crop like corn or soybeans. Although Monsanto or other large manufactures may be willing to cover the costs of GLP requirements to obtain a registration for corn, very few manufactures are willing to do so for taro or other minor crops. EPA could base GLP requirements on a system similar to the tier testing requirements published in 40 CFR 158.

Third, EPA currently uses a system of certifying laboratories which conduct enforcement actions or provide monitoring data to support federal asbestos and drinking water programs. EPA should examine the feasibility of establishing a self-certification program for IR-4 and NAPIAP taking into account their mission, past performance, facilities, experience, and training. A self-certification program could be subject to regular review by EPA in partnership with USDA.

EPA, USDA and the state land grant universities have now had nearly six years of experience with GLP's as they relate to pesticide (re)registration programs. The direct costs related to GLP compliance are at least 100 percent more than EPA estimated. The indirect costs to universities are more difficult to measure, because they impact other faculty, graduate students, and programs. EPA and USDA have espoused a new partnership and willingness to work together to achieve mutually agreed to objectives. Both agencies need to take advantage of the Regulatory Review and Reinvention Initiative to modify GLP requirements for the IR-4 and NAPIAP programs.

AAPSE supports the principle of GLP, but also recognizes drawbacks resulting from GLP requirements. Therefore, AAPSE implores EPA to adopt the solutions presented.

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