ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 152 and 162

[OPP-30076; FRL 2618-8]

Pesticide Programs; Pesticide Registration and Classification Procedures; Application Procedures To Ensure Protection of Data Submitters' Rights

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule describes methods that applicants for registration, amended registration, and reregistration of pesticides can use to comply with the provisions of FIFRA sec. 3(c)(1)(D) with respect to submission or citation of data. The rule establishes procedures intended to protect the economic interests of pesticide data submitters. At the same time, the rule gives applicants a wide choice of ways in which to comply with FIFRA sec. 3(c)(1)(D). These procedures are adopted following the publication of a proposed rule in the Federal Register of December 27, 1982 (47 FR 57624), an additional request for comments on several topics set forth in the notice extending the comment period, published in the Federal Register of March 30, 1983 (48 FR 13196), and recent Supreme Court decisions on data submitters' rights.

DATE: This rule becomes effective at the end of 60 calendar days of continuous session of Congress from the date of promulgation as provided in FIFRA sec. 25(a)(4). After that period has elapsed, the Agency will issue for publication in the Federal Register a notice announcing the effective date of this rule.

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SUPPLEMENTARY INFORMATION: OMB Control Nos. 2000-0012 and 2000-0468.

This preamble is organized according to the following outline:

I. Background

Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) authorizes EPA to regulate the sale, distribution, and use of pesticides in the United States. With certain minor exceptions, FIFRA requires that all pesticides must be registered by EPA before they may be sold or distributed in commerce. To obtain a registration, an applicant is required, among other things, to submit or cite data in support of his application. Specifically, FIFRA section 3(c)(1)(D) states that the application must contain "a full description of the tests made and results thereof or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator " Section 3(c)(1)(D), however, also imposes limitations on an applicant's right to cite data submitted by another person without the data submitter's permission (see Unit II.B of this preamble). The purpose of these limitations is to protect the economic interests of data submitters by preventing an applicant from relying on data submitted by another unless the applicant has first made an offer to pay reasonable compensation for the right—or in certain cases, unless the applicant has obtained permission—to cite the data.

These statutory provisions, as well as EPA's interpretation and implementation of them have been the subject of numerous lawsuits. A court decision issued in January 1983 led EPA to reconsider its previous interpretation of the relationship of FIFRA section 3(c)(1)(D) to other sections of FIFRA. A review of the Agency's previous interpretation, the court decisions, and subsequent developments will aid in understanding the rules which the Agency is currently promulgating to implement FIFRA section 3(c)(1)(D).

A. The 1978 Data Compensation Approach

In 1978, Congress extensively amended FIFRA section 3(c)(1)(D) and other sections to allow EPA to implement a new approach to registration of pesticides. Under that approach, EPA interpreted FIFRA section 3(c)(1)(D) to require an applicant to cite in support of his application any item of data which the Agency might review or use in deciding whether to register his product, *i.e.*, all relevant data in the Agency's files. In 1979, the Agency issued as an interim final rule its so-called "cite-all" regulation, published in the Federal Register of May 11, 1979 (44 FR 27932), and codified at 40 CFR 162.9-1 through 162.9-8, which embodied this interpretation of the Act. In order to cite data submitted by another, EPA required the applicant to extend an offer to pay reasonable compensation to the data submitter. The consequences of this requirement were far-reaching to applicants, since it required them to offer to pay compensation for an often substantial, but sometimes ill-defined body of data previously supplied by others.

Until 1983, EPA's registration program operated efficiently under that regulation. The regulation required most applicants to cite in their applications all relevant data previously submitted to EPA, regardless of the amount of their own data they provided with their applications. The regulations contained a limited exception, called the "alternate method," under which certain applicants seeking to register end-use products could comply with the data compensation regulations by submitting data they themselves had developed on their own products to satisfy each applicable data requirement. This alternate method was permitted because data on end use products would normally apply only to the product for

which the data were developed (or very closely similar products), and ordinarily would not be pertinent to the review of other products containing the same active ingredients. Moreover, data on the exact product formulation proposed for registration would allow the Agency to better judge the registrability of the product than would data on a similar formulation. See 40 CFR 162.9–8.

B. The Mobay Decision

Mobay Chemical Co. challenged the 1979 interim final regulations in court, claiming, among other things, that the cite-all regulations were procedurally deficient because they had not been promulgated in accordance with the requirements for notice and opportunity for comment in the Administrative Procedure Act. In June 1982, following an initial ruling in favor of the Agency at the district court level, the U.S. Court of Appeals for the Third Circuit held that the Agency had failed to follow required procedures in issuing the data compensation regulations. *Mobay Chemical Co.* v. *Gorsuch*, 682 F 2d 419 (3d Cir. 1982). The court, therefore, declared the regulations invalid. The court stayed its order, however, to permit the Agency to repromulgate the rule. In response, on December 27 1982, the Agency reproposed its 1979 cite-all regulations essentially unchanged with a 60-day comment period (47 FR 57624). The proposal's preamble contained an extensive discussion of, and request for comment on, possible alternatives to the cite-all procedures, specifically procedures which would provide a means for applicants to identify the specific data requirements for the proposed product and to cite or submit a specific study to meet each such requirement. Commenters were urged to address not only the methods by which such procedures would be implemented but also the means by which disputes arising under them could be resolved. 47 FR 57638–57640, 57645–57646.

C. The NACA Decision

In January 1983, a decision by the District Court for the District of Columbia (*National Agricultural Chemicals Association* v. *U.S. Environmental Protection Agency*, 554 F Supp. 1209 (D.D.C. 1983) (*NACA*) rejected EPA's interpretation of the statute contained in the cite-all regulations, and held the 1979 regulations invalid insofar as they required an applicant to cite every study in the Agency's files relevant to the applicant's product. The district court enjoined EPA from requiring applicants to submit or cite more data than needed to meet the "statutory criteria for registration."

EPA's response to the *NACA* decision was (1) to discontinue requiring applicants to follow the cite-all regulations; (2) to allow applicants who did not wish to wait until new procedures were in place voluntarily to follow the "cite-all" regulations; and (3) to start development of procedures employing a selective method as an alternative to cite-all. The Agency extended the original comment period on its December 1982 proposal until May 6, 1983, as published in the Federal Register of March 30, 1983 (48 FR 13196). In extending the comment period, the Agency also specifically requested comment on each of the major issues related to the alternative procedures under development: (1) The means by which product specific data requirements should be identified, including the role of waivers of requirements; (2) the effect of "data gaps" in the Agency's files reflecting the fact that previous registrants have not yet complied with certain applicable requirements; (3) the question of whether and how a selective method would implement the mandatory data licensing provisions of section 3(c)(1)(D); and (4) the process by which disputes arising under such procedures should be resolved either before or after the issuance of registrations under them.

D. The Monsanto District Court Decision

While EPA was developing alternative procedures to respond to the *NACA* decision, another U.S. District Court ruled that FIFRA section 3(c)(1)(D) was unconstitutional and enjoined the Agency from implementing, in any way, FIFRA section 3(c)(1)(D). *Monsanto Co.* v. *Acting Administrator*, 564 F. Supp. 552 (E.D. Mo. 1983) (*Monsanto*).[1] The injunction immediately rendered the mandatory licensing scheme upon which the cite-all regulations depended inoperable, even on a voluntary basis. (The *NACA* decision had permitted the continued use of cite-all as long as it was not the only option available to applicants.) As a result, the Agency was effectively prohibited from permitting applicants to cite data in support of registration without the original submitter's permission. The Agency halted registration under the "voluntary cite-all" approach except in the very few cases where EPA could determine that only the applicant had submitted any relevant data. Moreover, the *Monsanto* injunction, coming as it did before the Agency was able to issue its alternative procedures even on an interim basis, left the Agency with no regulations that could legally be used to implement the data citation/submission requirements of FIFRA.

The combination of the *NACA* and *Monsanto* decisions, therefore, brought the registration process to a virtual halt. In the absence of a set of procedures to replace the cite-all regulations, EPA could not instruct applicants about the information they were required to provide in order to be registered, nor could the Agency efficiently determine whether an applicant had satisfied the statutory requirements for registration. The Agency's inability to issue new registrations prevented applicants from obtaining approval to market new, potentially safer and more effective products. In view of the time needed to obtain final resolution of the court challenges and to promulgate final regulations, and the urgent need to have some means for applicants to satisfy data requirements, EPA elected to issue interim alternative procedures and to permit applicants to use them immediately. On June 29, 1983, EPA issued PR Notice 83–4 (and 83–4A, containing several minor amendments). This notice was provided to all registrants and applicants, and a notice of availability of the PR Notice to the general public was published in the Federal Register of July 13, 1933 (48 FR 32012). That notice stated in part that the interim procedures "would remain in effect only until issuance of final, effective rules in the Agency's pending rulemaking proceeding to modify 40 CFR 162.9–1 through 162.9–8. See proposal at 47 FR 57635 (December 27, 1982); extension of comment period at 48 FR 13196 (March 30, 1983)."

The alternative procedures set out in the PR Notice are substantially similar to the "selective method" in this rule, except that this rule permits applicants to rely on data without the original submitter's permission. This selective method represents EPA's resolution of the issues identified for specific comment in the notice extending the comment period on the proposal which initiated this rulemaking. The "cite-all"

[1] Another district court later found unconstitutional the parts of section 3(c)(1)(D) which provided that disputes between data submitters and applicants about the amount of compensation owed can be resolved through binding, non-reviewable arbitration. *Union Carbide Agricultural Products, Co., Inc.* v. *Ruckelshaus*, 571 F. Supp. 117 (S.D. N.Y. 1933) (*Union Carbide*). The court enjoined EPA from "implementing any use of data" in which the amount of compensation due could be determined through arbitration. The *Union Carbide* decision and injunction did not prohibit any activity that was not also forbidden by the *Monsanto* injunction. Thus, as a practical matter, the issuance of the *Union Carbide* order had no immediate impact on EPA's registration program.

procedures established in the 1979 regulations (and contained in the December 27, 1982 proposal) have also been retained. Differences between this rule and the PR Notice are identified and discussed in Unit X of this preamble.

E. The Supreme Court Decisions in Monsanto and Union Carbide

On June 26, 1984, the United States Supreme Court decided EPA's appeal from the *Monsanto* decision. *Ruckelshaus* v. *Monsanto Co.*, 52 LW 4886. The Supreme Court's opinion upheld the constitutionality of the mandatory data licensing provisions of section 3(c)(1)(D) of FIFRA, and its order vacated the judgment of the district court. Shortly thereafter, on July 2, 1984, the Supreme Court ruled on EPA's appeal from the *Union Carbide* decision. In a decision without opinion, the Court vacated the judgment of the district court and remanded the case for further consideration in light of its *Monsanto* holding. *Ruckelshaus* v. *Union Carbide Agricultural Products Co.*, 52 LW 3928. The effect of these two Supreme Court decisions, therefore, was to remove the bar on EPA's implementation of the mandatory licensing provisions of section 3(c)(1)(D).

F Promulgation of This Final Rule

Now that the Supreme Court has issued its decisions in *Monsanto* and *Union Carbide*, EPA has determined that it is appropriate to issue this final rule, which fully implements the mandatory data licensing provisions of FIFRA section 3(c)(1)(D) and culminates the rulemaking process initiated by the December 27, 1982, Notice of Proposed Rulemaking, 47 FR 57624. This rule provides two alternative systems by which applicants for registration actions may comply with the compensation requirements of section 3(c)(1)(D). One of these systems allows applicants to cite (and offer to pay for) all relevant data in EPA's files which are available for data licensing and for which submitters are entitled to compensation under section 3(c)(1)(D). This alternative is designated the "cite-all method." The other system provides a means by which an applicant can identify the data requirements that apply to his product and can selectively cite previously submitted data or submit new data to satisfy each applicable data requirement, instead of citing all relevant data in EPA files. This alternative is identified as the "selective method." This final rule, like the proposal, addresses the basic issues necessarily raised by any selective approach: How to identify the applicable data requirements, how applicants may satisfy each requirement, and how disputes between data submitters and applicants who rely on the selective method may be resolved. This final rule also contains procedural regulations to implement each of these approaches.

The December 1982 proposal set forth the details of the cite-all method, which the Agency then believed was the preferred means of implementing FIFRA section 3(c)(1)(D), and discussed necessary components of any section 3(c)(1)(D) approach, such as the types of registration applications which must comply with the data protection scheme. In addition, the proposal described in detail and solicited comment on two versions of the selective method approach, one submitted to the Agency by Rhone-Poulenc, Inc. (47 FR 57646) and the other contained in a bill (HR 5203) which had been passed by the House of Representatives (47 FR 57638–57641). Both the Rhone-Poulenc proposal and HR 5203 envisioned allowing an applicant to submit or cite only enough data to satisfy the minimum data requirements applicable to his product. The House bill's approach was broader, and spelled out in detail all the elements of the selective method. Under it, the application would include "a list of the applicable data requirements, a list of the data the applicant is submitting or citing to satisfy each such requirement, and a certification that the applicant is not precluded by" the requirement that the applicant either obtain the prior permission of the original data submitter (in the case of exclusive use data) or enter into appropriate cost-sharing arrangements. The House bill also set forth a mechanism for resolving disputes between applicants and data submitters which the rule promulgated today resembles. Key portions of that mechanism were set forth in the proposal.

The preamble quoted Rhone-Poulenc with regard to its proposal as follows:

> The principal difference between our proposal and the current cite-all regulation is that under our proposal a subsequent applicant relying entirely on its own data would no longer be blocked by the combined effect of the FIFRA exclusive use provision and the cite-all regulation from obtaining a registration or permit, and would no longer be required to offer to pay compensation to other registrants with similar data on file. However, under our proposal, as at present, no applicant could obtain the benefit of another registrant's data, rely on them, or cite them without full compliance with any exclusive use and data compensation provisions.

Rhone-Poulenc's proposal thus addressed primarily a subset of the HR 5203 approach, i.e., those situations where the applicant has developed a complete data set. Rhone-Poulenc also argued that EPA could by regulation establish dispute resolution procedures under the then-existing FIFRA that paralleled those in HR 5203.

The 1982 proposal also set forth, and sought comments on, correspondence urging the implementation of a selective method under the the existing law which EPA had received from the Secretary of Agriculture and the House Subcommittee on Department Operations, Research, and Foreign Agriculture of the Committee on Agriculture.

Timely comments on the proposal were received from the Pesticide Producers Association, four pesticide producing firms, and an environmental group, and are addressed in Unit XI of this preamble, Response to Comments. All of the industry commenters emphasized their support for the Rhone-Poulenc proposal or otherwise urged the adoption of a selective method of data support.

During the period alloted for comments on the December 1982 proposal, the *NACA* decision was announced. It required that EPA implement section 3(c)(1)(D) in a manner which assured the availability of a selective method of data support. In light of the fact that EPA could no longer require the use of the cite-all approach identified in the December 27 proposal as the preferred option, the Agency issued a notice, which was published in the Federal Register of March 30, 1983, which extended the period of comment on the December 1982 proposal. That notice specifically sought comments addressed to the alternative selective approach identified in the December 1982 proposal. Further, that Notice identified the issues related to each element of a selective method: (1) How to identify the data requirements for each application, including the treatment of waivers of such requirements in the section 3(c)(1)(D) context; (2) the effect of the failure of previous registrants of identical or substantially similar pesticide products to meet applicable data requirements (data gaps); (3) the extent to which applicants should be able to rely on data previously submitted by others to fill data requirements, and the mechanisms to be used; and (4) the means by which disputes over compliance and data submitters' rights should be resolved. The Agency received comments from the National Agricultural Clemicals

Association (NACA) and from three pesticide producers after the notice of extension of the comment period. NACA indicated that the Agency had been misinterpreting FIFRA in certain respects (See Unit XI of this preamble), while the three producers all expressed support for a selective method of complying with section 3(c)(1)(D) as mandated by the *NACA* decision. Those comments also are addressed in Unit XI of this preamble.

As a consequence of the *Monsanto* district court injunction, EPA decided to develop interim procedures for processing registration applications which assured that applicants could identify applicable data requirements and meet those requirements, either by selecting previously submitted data they had obtained permission to use or by submitting new data. The mechanics of those interim procedures are substantially similar to the selective method set forth in this final rule, except that the removal of the district court injunctions [2] permits the Agency to allow selection of previously submitted data without permission of the original data submitter, provided an offer to pay is made when required. Before the interim procedures were made effective, the Agency consulted with trade associations concerned with pesticides, individual pesticide companies, interested environmental groups, governmental agencies, and any other person expressing interest. Various participants in this development process returned reworked drafts, attended meetings with Agency representatives, and supplied correspondence detailing their opinions on the procedures. After EPA's consideration of all of these views, the interim procedures were implemented (see 48 FR 32012) and have been used for the past year.

EPA is now issuing its final rule concluding this administrative process and resolving the issues raised to date. The proposal documents raised as one of EPA's major concerns with the selective approach the administrative difficulties potentially associated with the resolution of disputes between data submitters and applicants. The proposal and extension notice expressly solicited comment on this basic approach to dispute resolution adopted in this rule—permitting exclusive use data submitters to petition for denial of a registration application and other data submitters to petition for cancellation of a registration upon an allegation that the registration applicant improperly relied on their submitted data or improperly avoided reliance on (and submission of the offer to pay for) their submitted data. As the preamble spells out in detail elsewhere, and as the commenters urged, EPA has determined that the methods of dispute resolution identified for comment in the proposal documents for this rule can be implemented satisfactorily under current law. Further, EPA's particular concerns about potential disputes involving exclusive use data submitters have benefitted from the exchange of drafts during the development of PR Notice 83-4. EPA now believes, based on the comments received and on discussions with data submitters during the development of PR Notice 83-4, that those concerns are adequately resolved by the provisions of this rule allowing for challenges to applications for pesticide products on which relevant exclusive use data have been submitted previously.

The proposal documents for this rule also solicited comments on the two other basic topics which must be dealt with in designing any selective data support scheme—how the data requirements are determined and how the applicant is to demonstrate compliance with those requirements. The final rule adopts the approach to determining data requirements suggested in the March 1983 notice, namely, to require reliance on the EPA regulations (40 CFR Part 158) establishing data requirements for registration. The rule permits applicants to demonstrate that they have met the requirements by any method which the statutory scheme allows—generating their own new data, citing their own previously submitted data, citing data previously submitted by others, relying on public literature, seeking a "waiver," or showing the existence of a "data gap." Specific comment on each of these latter means of complying with data requirements was also requested in the March 30 proposal.

This final rule, therefore, completes the data compensation rulemaking by implementing the already largely familiar procedures necessary to provide for both a cite-all and a selective method of supplying the required data to support applications for pesticide registration actions pursuant to the provisions of FIFRA section 3(c)(1)(D).

II. The Statutory Scheme

A. Agency Review of Data

After reviewing the statute in detail in light of the *NACA* decision, the Agency concluded in 1983 that there is an important distinction in the statute between (1) EPA review under FIFRA section 3(c)(1)(D) to determine whether the applicant has satisfied the requirements that specify how an application must be supported by the submission or citation of data, and (2) EPA review of data to determine whether to approve a properly supported application on risk/benefit grounds.[3] EPA's review of applications is governed by sections 3(c)(5) and 3(c)(7) of the Act. Section 3(c)(5)(B) governs the first step in EPA's review of materials submitted in support of applications by stating that EPA may register a pesticide only if "its labeling and other material required to be submitted comply with the requirements of the Act." The "labeling and other material required to be submitted" consist of the various items listed in section 3(c)(1), one of which is "a full description of the tests made and the results thereof , or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator." (Section 3(c)(1)(D).)

The types and amount of data an applicant must submit or cite to obtain a registration are specified in 40 CFR Part 158. That rule implements the requirement of FIFRA section 3(c)(2)(A) that EPA "publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide . . "

FIFRA section 3(c)(1)(D) imposes limitations on the extent to which an applicant may satisfy requirements by

[2] The formal docketing of the Supreme Court's *Monsanto* and *Union Carbide* orders in the district courts may follow publication of this rule by a few days. However, this rule cannot become effective until after the 60-day congressional review period; therefore, its effective date clearly will follow the effective dates of the Supreme Court decisions.

[3] The Agency's previous interpretation, as set forth in the December 1982 proposal (47 FR 57633) was that these two functions arguably were indistinguishable, because the Agency's ability to review all relevant data in its files in order to make a risk/benefit decision depended on the applicant's supplying or citing all such data. The *NACA* court rejected this interpretation, saying (554 F. Supp. at 1211):

> While it is commendable that the EPA does not intend to limit its inquiries to the data submitted by applicants, the plain language of the statute does not support the EPA's conclusion that the applicants are required to provide all the information the EPA would like to review.

The Agency then reexamined the statute and developed its current interpretation. This interpretation was set forth in the preamble of the regulations concerning conditional registration (a parallel rulemaking also necessitated by the *Mobay* decision), see 48 FR 34000, 34002 col. 3 (July 26, 1983), and in PR Notice 83-4. Industry comments disagreeing somewhat with this interpretation and the Agency's response are discussed in Units II and XI of this preamble.

citing studies submitted by others. FIFRA section 3(c)(5)(B) states, in effect, that an application may not be approved unless the applicant has submitted a complete and properly supported application. Thus, section 3(c)(5)(B), together with sections 3(c)(1)(D) and 3 (c)(2)(A), defines the first step of EPA's review of applications.

Sections 3(c) (5) and (7) also require that, before a product may be registered, the Agency must make a second, risk/benefit determination: Either that the product and its uses will not cause unreasonable adverse effects on the environment (see sections 3(c)(5) (C) and (D) and 3(c)(7) (C)), or that use of the product will not significantly increase the risk of unreasonable adverse effects on the environment (see section 3(c)(7) (A) and (B)). Nothing in either FIFRA or the court decisions mentioned above limits the range of data which EPA may consider in making these risk/benefit decisions. To the contrary, the intent of Congress that the Agency review data other than those submitted by applicants is evident in several sections of the Act.

Under FIFRA section 2(bb), the term "unreasonable adverse effects on the environment" is defined to require a consideration of economic and social, as well as environmental, costs and benefits of use. This definition clearly contemplates that the Agency will examine information beyond that which applicants are required to provide. Moreover, FIFRA section 3(c)(2)(A) requires that the Administrator make available to the public after registration not only the "data called for in the registration statement," but also, " such other scientific information as he deems relevant to his decision." The "other secientific information" clearly refers to information distinct from that submitted by the applicant.

In sum, EPA must engage in two separate data review functions—one for the purpose of determining the sufficiency of the applicant's submissions under FIFRA section 3(c)(1)(D), the other for the purpose of evaluating the pesticide itself against the statutory risk/benefit criteria. In the latter review, EPA may consider any relevant data without regard to who submitted the data, for what purpose, or when the data were submitted. In contrast, very specific limitations apply to the Agency's consideration of data in the first review.

B. Protecting the Economic Interests of Data Submitters

FIFRA section 3(c)(1)(D), which is primarily concerned with protecting the economic interests of data submitters, limits the extent to which an applicant may reference another person's data to satisfy the Agency's data requirements. The Act does so in two ways: (1) For a pesticidal active ingredient never before registered (a "new chemical"), section 3(c)(1)(D)(i) grants the data submitter "exclusive use" of data he has generated in support of the first registration of a new chemical for a 10-year period after that registration; (2) for all other pesticides (and for new chemicals after the expiration of the 10-year exclusive use period), section 3(c)(1)(D)(ii) establishes a "mandatory licensing" scheme under which a data submitter's permission is not necessary to permit the citation of his post-1969 data by another applicant if the applicant has made an offer to pay compensation to the data submitter. The period of such compensation protection is 15 years after the submission of the data to the Agency. After the expiration of both of these time periods, the data may be cited freely by any applicant.

1. Exclusive Use Protection

The purpose of the exclusive use provision in FIFRA section 3(c)(1)(D)(i) is to encourage continued research and development of new, more effective, and safer pesticides by giving producers—who often devote many years and millions of dollars to developing a new pesticide—a period of protection against competition. Section 3(c)(1)(D)(i) achieves this purpose by prohibiting the Agency from allowing any subsequent applicant to cite "exclusive use" data in support of his application for registration without the express written authorization of the first registrant of the new chemical. Since the original registrant can withhold authorization to cite his data, he can make it quite difficult for subsequent applicants to obtain registration. Theoretically, a second applicant could obtain registration by independently developing the entire set of data required under FIFRA, but few producers are likely to be willing to take this course, because of the cost and delay. In addition, a later registrant may be reluctant to enter a new market because he would not be eligible for exclusive use protection for his data, and thus would be more vulnerable to competitors. Each later registrant would, however, be guaranteed the opportunity to claim compensation from subsequent applicants under the mandatory licensing provisions of the Act.

FIFRA section 3(c)(1)(D)(i) and the legislative history of that section carefully circumscribe the set of data that is eligible for exclusive use protection. In this rule, a study entitled to exclusive use protection is called an "exclusive use study," a term defined in § 152.83. Two specific conditions must be met before a study is eligible for exclusive use protection: (1) The data must pertain to a new active ingredient (or new combination of active ingredients), i.e., not registered before September 30, 1978; and (2) the data must be submitted in support of the "original registration" of the product containing that ingredient or amendments for new uses of that product. Moreover, there is a time limitation placed upon exclusive use rights, and an exclusion for "defensive data" (newly submitted studies required in connection with new registrations of "old" chemicals or to maintain an existing registration in effect). Each of these is discussed below.

First, the data must pertain to, or have been derived from testing on, a new active ingredient (commonly referred to as a "new chemical"). For the purposes of FIFRA section 3(c)(1)(D)(i), a new active ingredient means any pesticide active ingredient that is contained in any product that was not registered before the date of enactment of that section, September 30, 1978. The legislative history of the 1978 amendments further clarifies that exclusive use protection extends to data that pertain solely to a new combination of active ingredients, any or all of which may have been registered prior to September 30, 1978. With respect to a new combination, only those data that pertain solely to the new combination acquire exclusive use protection; data that pertain to the individual constituents of the combination that are not new chemicals acquire no exclusive use protection. This point is important because the types of data that the Agency requires to be submitted on the combination, as distinct from its components, are relatively limited.

Second, the data must have been submitted in support of the first registration of the new chemical or new combination. As EPA reads the statute, data are not protected because they pertain to the new chemical, but because they are submitted in support of a particular product registration. Thus, data submitted to support an application for the second (and later) registration(s), by whatever applicant, of a product containing the same new chemical acquire no exclusive use protection. (This interpretation has been disputed by industry commenters and is discussed further in Unit XI of this preamble.)

If the first registration of the new chemical is issued conditionally under

the authority of FIFRA section 3(c)(7)(C), those data whose submission was deferred at the time of registration are eligible for exclusive use protection when later submitted. Additionally, data in support of subsequent amendments to add new uses to the first registration of a product containing the new chemical gain such protection. In this latter case, protection is limited to data that pertain solely to the new use.

In no circumstance does the protection last more than 10 years from the date of first registration of the product containing the new chemical. If a new use were approved after eight years of registration, the data supporting that use would gain exclusive use protection for only two years. Likewise, conditionally required data would be protected only for the duration of the 10-year period from first registration.

Finally, the statute expressly specifies that exclusive use protection shall not be available for studies that the Agency requires to maintain registration in effect under FIFRA section 3(c)(2)(B), or that are currently required for registration of a product containing an active ingredient initially registered before September 30, 1978.

The prohibition against unauthorized citation of an exclusive use study applies only to an applicant's right to cite another's study in his application for registration, not to the Agency's review of data to determine whether or not the pesticide should be registered on risk/benefit grounds. The Agency's review of data for this purpose in no way negates or compromises the rights of the exclusive use data submitter or undermines the intent of Congress in providing such protection. A second applicant who wishes to cite the exclusive use study must obtain the written authorization of the exclusive use data submitter. If permission is denied, the second applicant is not precluded from entering the market, but must first replicate the necessary data or obtain it from another source. Thus, the exclusive use data submitter is assured that no competitor enters the market without either having his permission to cite data submitted to EPA (which he may condition upon the payment of royalties or compensation) or having generated (or otherwise acquired) at least the equivalent set of data required for registration.

2. Mandatory Licensing and Data Compensation

A second type of protection is established for data submitters by FIFRA section 3(c)(1)(D)(ii). This section provides that an applicant must offer to pay reasonable compensation for the right to cite another person's data. In including this provision, Congress intended to allow data submitters who have spent money for data development to receive payment from subsequent applicants who cite those data to obtain registration for competing products. Congress did not intend, however, that a scheme for compensation should function to exclude new products and producers from the marketplace. Accordingly, seciton 3(c)(1)(D)(ii) establishes a mandatory licensing scheme: once an applicant has extended a proper offer to pay compensation to a data submitter, the applicant may freely cite the other person's study. Unlike exclusive use protection, data submitters do not have the right to block competitors lacking their own data from entering the market; rather, they only have the right to receive compensation. The right to compensation, however, is limited in four ways: (1) Compensation is required only with respect to applicants who rely on the data during the 15-year period starting with submission of the data; (2) compensation is not required for data submitted before January 1, 1970,[4] (3) compensation is not required if the data are exempted from registration data requirements by the formulator's exemption (see Unit IV.B. of this preamble); and (4) compensation is not required for data from the "public literature."

Under the mandatory licensing provisions of FIFRA section 3(c)(1)(D)(ii), Congress also provided that disputes about the amount and terms of the compensation actually to be paid were to be settled either by negotiation between the data submitter and the applicant, or by binding arbitration under rules promulgated by the Federal Mediation and Conciliation Service.

[4] Beginning in 1985, the "non-compensable" date will advance as the 15-year "window" for compensation shifts forward. Thereafter, the January 1, 1970, date will be irrelevant, and compensation rights will be governed solely by the application of the 15-year calculations.

III. Summary of This Rule

This rule establishes procedures by which applicants will be able to demonstrate their compliance with the procedural requirements of FIFRA section 3(c)(1)(D), and thereafter for the Agency to determine under FIFRA section 3(c)(5)(B) that an application "complies with the requirements of the Act." The Agency's determination that an application has been properly supported under section 3(c)(5)(B) does not in any way imply that the Agency has reviewed, that an applicant has provided, or even that the Agency possesses a study that could be used by the Agency in its risk/benefit determination under FIFRA section 3(c)(5)(C) or (D) or 3(c)(7).

Certain data requirements must be satisfied by the submission of data that are unique to the applicant's own product. These are primarily requirements for product composition, efficacy, and certain acute toxicity data. For all other data requirements, the procedures an applicant may use to supply required supporting data will depend on two factors: (1) The data base to which he chooses to refer; and (2) the method by which he would actually demonstrate compliance with the requirements of FIFRA section 3(c)(1)(D).

With respect to the first factor, an applicant has the choice either of citing all relevant data in the Agency's possession that would satisfy any applicable data requirements (cite-all method), or of selectively identifying one or more studies to satisfy each individual data requirement (selective method). Having chosen which set of data to rely on in his application, the applicant will then have to decide the means by which he will obtain the right to rely on those data as part of his application. If he elects the cite-all method, the applicant's choice is limited to two methods: making offers to pay for the right to cite the data, or obtaining permission to cite the data. If he picks the selective method, he may choose one of these, or several other ways to demonstrate compliance. The table below is designed to assist readers in understanding the various procedures that could normally be used under each method.

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TABLE--COMPARISON OF THE CITE-ALL AND SELECTIVE METHODS

If an applicant chooses this method-- ---------->		Cite-all	Selective
He can satisfy a data requirement by this means ↓			
1. Requesting and obtaining a waiver		NO	YES
2. Submission of a new study		NO	YES
3. Citation of his own study		NO	YES
4. Citation of another person's exclusive use study	a. With permission	NO	YES
	b With offer to pay	NO	NO
5. Citation of another person's study that is not exclusive use	a. With permission	NO	YES
	b With offer to pay	NO	YES
6. Citation of public lit. study		NO	YES
7. Citation of all pertinent studies in Agency files--exclusive use studies involved	a. With permission	YES	YES
	b. With offer to pay	NO	NO
8. Citation of all pertinent studies in Agency files--no exclusive use studies involved	a. With permission	YES	YES
	b. With offer to pay	YES	YES
9. Documentation of a data gap		NO	YES

Under the cite-all method the applicant may choose to make an offer to pay each original data submitter who has previously submitted data that may be pertinent to his product, its ingredients, and its uses. These persons are generally identified on the Agency's list of "Pesticide Data Submitters by Chemical" (abbreviated as the "Data Submitters List"). The applicant would not be able to demonstrate compliance by making offers to pay to all previous data submitters, however, if any pertinent data in the Agency's files are exclusive use data.

The only alternative to offers to pay compensation under the cite-all method would be for the applicant to obtain the written permission of each person who has previously submitted data pertinent to his product.

An applicant under the selective method has a greater number of acceptable ways of satisfying section 3(c)(1)(D) requirements. Under the selective method, the applicant is required to identify the specific data requirements applicable to his product by reference to a Registration Standard for the active ingredient(s) in the product or to the Agency's data requirements in 40 CFR Part 158. He is then required to satisfy each data requirement by one of the methods listed below (note that his choices are broader than simply making offers to pay or obtaining permission from data submitters). The numbers are keyed to the table in this unit.

1. Requesting and obtaining a waiver of the data requirement. (See Unit VI.C.1.)

2. Submitting his own new study. (See Unit VI.C.2.)

3. Citing his own previously submitted study. (See Unit VI.C.3.)

4. and 5. Citing another person's individual exclusive use or non-exclusive use study. If the study is an exclusive use study, permission must be obtained. (See Unit VI.C.3.)

6. Citing a public literature study. (See Unit VI.C.4.)

7 and 8. Citing all pertinent studies in the Agency's possession. If exclusive use studies are involved, permission must be obtained from the exclusive use data submitter. (See Unit VI.C.5.).

9. Demonstrating that no study has been submitted to the Agency (a "data gap"), permissible under the conditional registration provisions of FIFRA section 3(c)(7). (See Unit VI.C.6.)

It should be noted that applicants under the cite-all method will not be precluded from obtaining waivers, or submitting or citing their own studies (1. through 3. in the table), but that taking these actions would affect neither their obligation to cite all data, nor the procedures that require offers to pay or in certain cases, permission of each previous data submitter. Therefore, as the table indicates, none of these actions would suffice, in and of itself, to demonstrate compliance under the cite-all method.

Under the procedures of this subpart, requesting a waiver would be of concern primarily to those who choose the selective method of demonstrating compliance. An applicant under the cite-all method might, nonetheless, wish to establish that a data requirement has been waived in order to reduce the amount of data needed for an incremental risk assessment, or to limit his obligation to pay compensation (as

contrasted to his obligation to tender offers to pay compensation).

Similarly, the submission of a new study or the citation of a previously submitted study will be of most interest to applicants under the selective method, which involves meeting individual data requirements rather than referencing all previously submitted data. While no applicant is precluded from submitting his own data, under the cite-all method submission of a new study or citation of an old study would be in addition to the citation of all other relevant data in EPA's files. Under the selective method, however, the applicant submit his own study to satisfy a data requirement and thereby can avoid the need to offer to pay compensation for other studies in EPA's files that satisfy the same data requirement.

Both the cite-all and selective methods are subject to the requirement of FIFRA section 3(c)(1)(D)(i) that applicants must obtain written permission to cite exclusive use data. The existence of exclusive use studies would directly affect an applicant's choice of methods. Because an applicant who uses the cite-all method must rely on every relevant study in EPA's files, an applicant could not use that method if an exclusive use data submitter denied the applicant permission to cite his relevant data. The applicant could obtain registration only by using the selective method to demonstrate compliance with section 3(c)(1)(D).

In addition, when the Agency's files contain exclusive use data relevant to an applicant's product, this rule requires the Agency to provide notice to exclusive use data submitters if the Agency decides to register the product (regardless of the method of support chosen by the applicant). This special notification procedure is designed to give exclusive use data submitters the opportunity to oppose a proposed registration if the data submitter contends that the applicant has improperly relied on his exclusive use data without obtaining prior permission or has supported his application in a manner that improperly avoided citing the exclusive use data.

Pre-registration notification is neither necessary nor appropriate for other data submitters who are not entitled to prevent an applicant from citing their studies so long as the applicant has made an offer to compensate. The rule does, however, allow such previous data submitters to raise their objections after registration. An original data submitter who believes that an applicant had failed to follow the procedures of this subpart, or had not supported his application properly, can petition the Agency to cancel the registration.

IV Scope and Applicability

A. Which Applications Are Subject to the Requirements

Under FIFRA section 3(c)(5)(B), the Agency must determine, as part of its decision whether to register a pesticide product, that the applicant has properly supported his application for registration with material that complies with the requirements of the Act. That determination must be made for each application (for new or amended registration or for reregistration), and requires that the Agency review the application to determine that all items listed in FIFRA section 3(c)(1) have been submitted and are in compliance with the Act. The procedures in this rule, however, apply only to applications which are subject to FIFRA section 3(c)(1)(D). The Agency has carefully considered which applications should be subject to the requirements of that section and this rule.

There are cogent arguments for broadly defining the scope of registration actions to which the requirements of section 3(c)(1)(D) apply. A literal reading of the statute would support the view that all applications of any type (new, amended or reregistration) under section 3 are subject to that section. (It should be noted that the strictest reading has never been used: The 1979 regulations contained a number of exemptions for certain amended applications for which review of scientific data was not necessary to approve the application.) Additionally, it can be argued that a broad interpretation of scope of actions subject to the data compensation provision of the statute would ensure the most consistent and equitable treatment of all producers in the marketplace. Each producer would have to comply with the exclusive use or compensation provisions of the Act whenever he sought any change in his registration. This would promote more rapid redistribution of the costs incurred by previous data submitters among all producers in the marketplace who now benefit or have benefitted from those data.

There are equally persuasive policy reasons why EPA should not adopt such a broad interpretation of section 3(c)(1)(D). First, if all applications were subject to its requirements, the Agency, as well as applicants and data submitters, would be inundated by large amounts of paperwork that would rapidly render the Agency's review process unmanageable. A significant portion of this paperwork burden would be applications for amended registration of a minor administrative nature, whose approval would have no effect on the product's competitive market position.

A secondary result would be that registrants faced with the necessity for section 3(c)(1)(D) compliance with each amendment, would be disinclined to request amendments to their registrations unless these amendments would improve their competitive position in the market. Registrants might choose not to pursue amendments not of direct economic benefit (but which are often in the public interest), such as improved labeling or composition changes to reduce hazards, given the possible compensation consequences. When this would lead to decreased public protection, the provisions of section 3(c)(1)(D) would clearly be contrary to the Agency's primary goal of protection against unreasonable adverse effects. EPA does not believe that Congress intended that the economic protections afforded by section 3(c)(1)(D) should be interpreted in a manner that could undermine the Agency's mandate for protection of public health and the environment.

A less obvious but similar situation might arise if the Agency proposes to cancel or suspend the registration of a product unless the registrant amends his registration in some manner directed by the Agency. Such "involuntary" amendments may be the result of the special review process, the classification process, or the Label Improvement Program. If the registrant's choice is either to comply with the provisions of section 3(c)(1)(D) in order to avoid cancellation or suspension actions that would remove him from the market, or to challenge the action and remain on the market, certainly there would be greater incentive to dispute or litigate the Agency's action. Such challenges not only are costly for the Agency, but also delay corrective measures intended to reduce risks to public health or the environment.

The Agency believes it may be appropriate to restrict the application of FIFRA section 3(c)(1)(D) to circumstances where an applicant needs EPA approval to enter or expand the market for his product, and where approval of the application potentially changes the competitive structure or balance of the market in the applicant's favor. Accordingly, EPA may later propose to modify this rule to limit the registration actions to which section 3(c)(1)(D) applies to applications for new registrations, applications for amended registrations to add a new use

for the product, applications to change the source of active ingredient from a registered supplier to an unregistered supplier and applications for reregistration. Because comment on this issue was not solicited in the 1982 or 1983 proposal notices for this final rule, however, this rule retains the provision defining the kinds of applications which must comply with 3(c)(1)(D) which is set forth in the 1979 regulations and the December 1982 proposal.

B. Which Data Requirements Must Be Satisfied

FIFRA section 3(c)(2)(A) requires the Administrator to publish guidelines specifying the types of data needed to support a registration. The Agency's registration data requirements are found in 40 CFR Part 158. That rule describes the types of data that the Agency must have to determine that the standards of FIFRA section 3(c)(5) are met. No application may be approved unless the Agency has this data, except that in some cases, FIFRA section 3(c)(7) permits the Agency to approve registrations conditionally if the data required under section 3(c)(5) have not previously been submitted to the Agency.

The list of requirements in Part 158 is the basis for determining which data an applicant must cite or submit to comply with section 3(c)(1)(D). Units V.B. and VI.B. discuss the need for and methods of determining data requirements under the cite-all and selective methods respectively.

C. The Formulator's Exemption

1. Purpose of the Exemption

FIFRA section 3(c)(2)(D) provides that any applicant who purchases a registered pesticide product from another producer and uses it to formulate an end use product need not submit, nor offer to pay for, data on the safety of the purchased product. This provision is commonly referred to as the "formulator's exemption." Since the costs that FIFRA section 3(c)(1)(D) is intended to recoup for producers are generally included in the purchase price of the pesticide they sell, that section would have the effect of requiring producers who purchase those pesticides in effect to pay data development costs twice—once as a condition of obtaining registration, and thereafter as part of the price of the pesticide they purchase to make their products.

Although section 3(c)(2)(D) specifies that only end use producers are eligible for the formulator's exemption, the legislative history of the statute offers additional guidance on the intent of Congress. The Report of the House Committee on Agriculture states:

> [The House bill] would obviate the need for formulators to furnish certain registration data by providing authority for "generic" registration. Under the "generic" registration plan, detailed submissions and evaluations of the basic chemical need not be repeated with each formulation. . . Applications will be simplified and formulators relieved of the need to offer to pay for the registration data except in the purchase price of the basic pest control chemical. [H. Rep. No. 95-663, 95th Congress, 1st Session, p. 19.]

It seems clear that the purpose of the formulator's exemption was to eliminate duplicative payment of data development costs. The same rationale that underlies the exemption for end-use products would also hold true for any other product whose active ingredients were purchased from another producer in the form of a registered product.

By limiting the exemption to end use products, FIFRA section 3(c)(2)(D) fails, perhaps unintentionally, to acknowledge the substantial body of products that are neither technical grade chemicals nor end use products, and that logically could or should be included within the formulator's exemption. Thus the language of the statute is constraining both upon the Agency and upon applicants for registration of other types of products whose ingredients are both registered and purchased. The Agency, therefore, interprets FIFRA section 3(c)(2)(D) to apply to any product whose ingredients are both registered and purchased, without limitation as to the intended use of the product. Products that are eligible for the formulators' exemption under this interpretation include not only end-use products but also so-called "formulation intermediates" or "technical concentrates," whose producers purchase registered products which are technical grade active ingredients and reformulate them into a less concentrated intermediate product that is sold for reformulation into an end use product.

As a result of the formulators' exemption, an applicant who qualifies need not list (and need not submit or cite data to fulfill) as many data requirements as an applicant for a similar registration who is not eligible for the exemption. Since the majority of data requirements in Part 158 require studies on active ingredients of the type that are often purchased and used to make end use products, and since the majority of applications are for end use product registrations, the formulators' exemption can result in a substantial reduction in the number of data requirements that must be listed for a significant number of applicants.

Under the cite-all method of support (and its variation within the selective method, see Unit VI.C.5 of this preamble), the formulator's exemption currently functions largely to limit the actual compensation paid for the use of data, not to reduce the amount of correspondence between applicants and data submitters. If certain data requirements are eliminated by the formulator's exemption, the applicant for registration of an end use product should, theoretically, also be able to eliminate correspondence to persons who have submitted only data that fulfill those requirements. In reality, however, the Data Submitters List is not sufficiently detailed that an applicant can ascertain which data submitters may be omitted. Thus he is compelled to write to all persons listed. He is not obligated, however, actually to pay any compensation for a study that would fulfill a data requirement for which he is not responsible.

Under the selective method of data support, on the other hand, the formulator's exemption would limit or simplify the transactions between applicants and data submitters required to comply with the procedures of this rule. The selective method requires that applicants write to previous data submitters with respect to individual data requirements they wish to satisfy (to obtain permission to use a specific study, to offer to pay compensation, or to verify a data gap). The reduction in the number of data requirements that must be satisfied would directly result in letters to fewer data submitters, in less complicated correspondence, or both.

2. Procedures for Formulator's Exemption

Section 152.85 describes the formulator's exemption. In order to prove that he is eligible for the formulator's exemption, the applicant would be required, at the time of filing for initial registration (or at the time the exemption is first claimed for the product), to submit a certification identifying which active ingredients in his product meet the requirements of FIFRA section 3(c)(2)(D). (In a product containing several active ingredients, the exemption might apply only to some ingredients.) The Agency provides a form for this purpose, on which the applicant would list each active ingredient that qualifies for the exemption. In addition, the Agency would have to receive, or have on file, an up-to-date Confidential Statement of Formula that lists the source(s) of each

active ingredient by name and, if registered, by EPA Registration Number.

Once this information is on file with the Agency, the applicant or registrant would not be required to resubmit it with succeeding applications for amendment, provided that he made no change in the source of his active ingredients. In all cases, a registrant who changes his source of supply of an active ingredient is required to file an application for amended registration with the Agency. If the change in source would disqualify the applicant from the formulator's exemption, the applicant must also comply with the requirements of this subpart. For example, if the applicant changes his source of active ingredient to one that was unregistered or begins to produce his own technical material rather than purchasing it (whether or not the technical material was also registered), he will no longer qualify for the exemption for data concerning that ingredient. On the other hand, a registrant who changes from an unregistered source to a registered and purchased source might wish to take advantage of the formulator's exemption and file a formulator's exemption statement, but he is not required to do so.

V The Cite-All Method

A. Overview

This rule retains, as an option instead of a requirement, the essential features of the 1979 cite-all regulation. See former 40 CFR 162.9–4 and 162.9–5. The cite-all procedures fully protect the rights of data submitters under FIFRA section 3(c)(1)(D). The procedures require a direct offer to pay reasonable compensation to each original data submitter by the applicant for registration, as well as a general offer to pay filed with the Agency under which data submitters may claim compensation even if direct notice is not provided. Further, although the procedures require a potentially large volume of correspondence, they are straightforward and easy for applicants to follow and do not require that the applicant determine data requirements as a prerequisite to application. For the same reason, they are also easy for the Agency to administer. Moreover, most disputes are resolved outside of the registration process and delays in obtaining registration are thereby avoided. Finally, the procedures were used from 1979 to 1983 by applicants and data submitters alike, and thus are widely understood.

The primary disadvantage of the cite-all method to the applicant is that he may be compelled to pay for the more than the minimum set of data required by Part 158. Also, uncertainty about the amount of compensation that will ultimately have to be paid has been of major concern to many applicants.

The cite-all method contained in § 152.86 requires that the applicant acquire the right to cite all relevant data previously submitted to EPA by other persons. An applicant can establish his right to cite all relevant data by either getting permission from, or making an offer to pay to, each person on an Agency list of pesticide data submitters. Whether the applicant must obtain permission or may simply make an offer to pay is governed by whether the data are entitled to exclusive use protection under FIFRA section 3(c)(1)(D)(i).

B. Determination of Data Requirements

In order to file an application under the cite-all method, an applicant is not required to determine which data requirements actually apply to his product. By securing the right to cite all relevant data in EPA's files, the applicant obviates the need for identifying specific data requirements, specific studies, or data submitters for specific studies.

C. Demonstrating Compliance Under the Cite-All Method

Procedurally, the cite-all method set forth in § 152.86 is identical to that contained in 1979 regulations (see former §§ 162.9–4 and 162.9–5). Simply stated, the applicant must write to each previous data submitter and either obtain written authorization or make an offer to pay for the right to cite all of his relevant data.

The Agency maintains a list entitled "Pesticide Data Submitters by Chemical," (the "Data Submitters List) which contains, by chemical, the name and address of each previous data submitter who has indicated that he wished to be so listed. The list distinguishes by broad categories what type of data the person has submitted to the Agency (e.g., acute toxicity, efficacy), and whether the person has submitted any data that are entitled to exclusive use protection. The list does not associate studies with specific data requirements, nor does it characterize a study as to its validity or sufficiency.

If the Data Submitters List indicates that the person has submitted data entitled to exclusive use protection, the applicant must obtain a written authorization to cite the exclusive use data. If the applicant is unable to secure written authorization from any exclusive use data submitter, he would be precluded from using the cite-all method.

Section 152.86(a) lists the elements of an acceptable written authorization. The written authorization must grant the named applicant permission to use specified studies. The exclusive use data submitter could limit such permission, for example, only to a single application (by naming the product), or for a specified period of time. Regardless of the form and conditions of the written authorization, it must grant permission to use the study or studies at least for the application in question, such that the applicant can certify in good faith to the Agency that he has received permission to rely on the study. The Agency will rely on the applicant's certification that permission to use the exclusive use studies has been granted.

The Agency notes that the exclusive use data submitter may give broader permission than is required by the Agency. The data submitter may grant permission to cite his data with no time limitations; he may permit citation of the studies for future amendments to the same product, or for different products using the same active ingredient. The Agency requires only that the applicant certify (and be able to prove if challenged) that he has obtained the permission of the exclusive use data submitter for each individual application he submits.

If the Data Submitters List does not indicate that the person has submitted exclusive use data on the ingredient in question, the applicant must, at a minimum, make an offer to pay that person compensation for the right to cite any pertinent data in the Agency's files. Nothing would prohibit the applicant, however, from requesting written authorization to cite the data in addition to, or instead of, making an offer to pay. The data owner, in turn, is not obligated to give permission, but the fact that he did not authorize the applicant to cite his data will not preclude the applicant from demonstrating compliance with the cite-all requirements by having made the offer to pay in the correct form.

Before the Agency will approve his application, the applicant must certify that he has obtained the authorization of, or made appropriate offers to pay to, each person on the Data Submitters List. Moreover, since the Data Submitters List is constantly changing as new data submitters are added, but is reissued only about twice a year, the applicant will be required to extend a general offer to pay as a safeguard against inadvertent omission of a person from the Data Submitters List. Offers to pay to persons on the Data Submitters List must be made directly to those persons, and the applicant must certify to the

Agency that he has complied with this requirement. The general offer to pay must be submitted to the Agency as part of the certification. The Agency will make available to applicants a form for this purpose.

As in the past, the applicant will be permitted to submit his certification and general offer to pay at any time before registration is approved. The Agency will not delay the review of the application pending receipt of these statements, but will not approve the application until they are received and determined to be in compliance.

Thereafter, if the Agency identifies any exclusive use data submitter whose permission is a prerequisite to demonstrating compliance with requirements for the application in question, EPA will notify the applicant and require that he obtain written authorization from that person. This will only be necessary if the omitted person is an exclusive use data submitter; other data submitters are protected by the general offer to pay statement and may pursue any claims for compensation pursuant to that offer.

Section 152.86(d) requires the application to contain a statement that for purposes of FIFRA section 3(c)(1)(D), the application relies on all data in Agency files that concern his product, other similar products, or any of the active ingredients of his product, and that are of the kinds that would be relevant to an Agency risk/benefit evaluation under FIFRA section 3(c)(5). Similar language was contained in the 1979 regulation and the 1982 proposal.

VI. The Selective Method

A. Overview

As required by the *NACA* decision, EPA has developed alternative procedures to the cite-all method for meeting the requirements of FIFRA section 3(c)(1)(D), called the "selective method." These procedures are more flexible than the cite-all method, and allow an applicant to demonstrate compliance in a number of different ways. This flexibility exists because the applicant can address data requirements on an individual basis rather than collectively as in the cite-all method. The table in the Summary enumerates the options available to the applicant, each of which will be discussed further in this Unit. Further, the selective method should reduce or eliminate some of the unknowns associated with the cite-all method, since the applicant can, under the selective method, know with reasonable certainty the identity of each person whom he might have to compensate. The selective method will also reduce the potential for having to pay compensation for several similar studies satisfying the same data requirement, since the applicant can generally demonstrate compliance by citing a single specific valid study for each individual data requirement. Finally, this method permits applicants to comply with the requirements of FIFRA section 3(c)(1)(D) in circumstances when the existence of exclusive use data might preclude the use of the cite-all method altogether.

The selective method has some disadvantages when compared to the cite-all procedures. While the magnitude of these disadvantages is unknown, the Agency expects that a decision to use the selective method will involve heavier paperwork burdens on the applicant, and will require the Agency to devote more resources to reviewing the application to determine that the submitted materials comply with the Act, with a concomitant increase in time and cost of registration reviews in general.

Nonetheless, the Agency believes that the selective method is the only workable alternative available to comply with the *NACA* decision, and that applicants may find it advantageous with certain applications, such as those for which they intend (or are required) to develop and submit the bulk of the data themselves.

The selective method requires that the applicant identify each data requirement that potentially applies to his product, and demonstrate compliance with each. The selective method is summarized in § 152.90, and the various means of satisfying the requirements are described in §§ 152.91 through 152.96.

B. Determination of Data Requirements

Section 152.90 requires the applicant who chooses to use the selective method to identify and list the data requirements that apply to his products, its ingredients and uses. For an application for amended registration to add a use, the applicant must list requirements for all current uses of the product he seeks to register, as if the product were being proposed for its initial registration. This usually will not be a significant burden, however, since the applicant for a limited amendment can repeat the data requirements from his initial registration; only those pertaining solely to the amendment would be a new listing after the first such listing for that registration.

Most applicants will use 40 CFR Part 158, Data Requirements for Registration, to determine their data requirements. Part 158 consists largely of a series of tables of data requirements, grouped according to the broad category of data covered. Product chemistry, environmental fate, residue chemistry, toxicology, effects on fish and wildlife, effects on non-target plants and insects, reentry protection, and efficacy data are among the topics covered in Part 158. There is a separate compilation of the requirements that apply to biochemical and microbial pesticide products.

Subpart B of Part 158 describes how to use the tables to determine the data requirements applicable to a specific product. Under the selective method, the applicant must include in his list each data requirement that potentially applies to his product. Thus, he must list each requirement for his product (those denoted with an "R" in the tables), and the appropriate requirements among those that are conditional based on the product's use patterns, composition, physical characteristics or the results of the other tests (denoted "CR" in the tables). [In each case the footnotes to the tables explain the "R" or "CR" requirement more explicitly, and should be consulted.] In some cases, the applicant will not be able to determine from Part 158 whether the results of one test leads to a second required test because he does not have access to the test results in Agency files. The Agency will not adequately protect the data submitters' interests, however, if it permits an applicant to list, and satisfy, only the initial set of required ("R") tests. Either the Agency must require that the applicant list all possible data requirements, or the Agency must assume a burden of reviewing studies on an *ad hoc* basis to determine whether they trigger further data requirements, and notifying the applicant so that he may satisfy the added requirements. The Agency does not intend to review studies already in its possession on this case-by-case basis except when it chooses to, such as when a Registration Standard for an active ingredient is prepared. Consequently, EPA is requiring that applicants assume that all possible requirements apply and proceed accordingly.

An applicant who wishes to determine absolutely whether a conditional data requirement applies to his product may write to each person on the Data Submitters List (for his active ingredients) and ask whether that person has previously submitted a study that would satisfy the conditional data requirement. If any response is "yes," the applicant can assume that the data requirement had been imposed on another registrant, and therefore presumably will be imposed on him when the Agency reviews the data in its

possession. If no one responds that he had ever submitted such a study, the applicant would not know definitively whether the data requirement would apply to his product; but it would not matter, for present purposes, since the existence of a "data gap" would be sufficient to demonstrate compliance under the selective method "Data gap" procedures are discussed further in Unit VI.C.6 of this preamble.

In an ever-increasing number of cases, the Agency will have already conducted its comprehensive review of a chemical as part of the Registration Standards process. In that process, the Agency reviews all data in its possession on the chemical, and determines, based on the results of the various tests, whether secondary data requirements have been triggered. Thus, if the Agency has issued a Registration Standard on a chemical, that Standard will list each applicable data requirement, including those that are listed as conditional in Part 158. In this case the applicant need only (indeed he will be required to) recite the list of data requirements from the Standard for that active ingredient.

It should be noted that early Registration Standards cover both manufacturing use and end use products containing a chemical; later ones (generally those issued after April 1982) generally address only manufacturing use products. In the former case, the applicant for an end use product may list from the Standard the data requirements applicable to his end use product. In the latter case, he still must refer to the Part 158 tables to determine data requirements for his end use product and its uses.

One further consideration bears upon the applicant's list of data requirements. The formulator's exemption, as discussed earlier in Unit IV.C of the preamble, might eliminate a large number of data requirements for those who qualify. If an applicant qualifies for the formulator's exemption for one or more of the active ingredients in his end use product, he is not required to list data requirements applicable to the safety of those ingredients. If all of his active ingredients were eligible for the exemption, his list of data requirements will be reduced to those that apply to his end use product as formulated, a relatively short list. The applicant must, of course, file his formulator's exemption certification.

C. Demonstrating Compliance Under the Selective Method

Once the list of data requirements has been determined, the applicant must demonstrate compliance with each requirement by using one of the following options (summarized in § 152.90):

1. Data Waiver Request (§ 152.91)

Any applicant (not limited to those under the selective method) may claim the existence of or request a waiver of a data requirement. A waiver is an Agency action excusing an applicant from having to fulfill a data requirement that would normally apply to his product, based on arguments that the requirement would not be useful to the Agency in evaluating the risks and benefits of the product.

Only under the selective method can the applicant, by submitting information verifying the existence of a waiver, satisfy a data requirement. If the applicant can determine that a waiver has been granted previously by the Agency, either from published lists of waivers or from waivers noted in a Registration Standard, he can comply by simply noting the waiver, together with the Agency reference, and explaining briefly why the waiver should apply to his product. EPA will make available to applicants under Freedom of Information procedures any existing lists of waivers it has generated. However, few such lists exist, and the Agency generally will not systematically review pesticide data requirements for the purpose of developing lists of waivers except as part of its Registration Standards review. The Agency intends to explore methods of organizing the waivers granted on an *ad hoc* basis (outside of the Registration Standards process), so that they will be more readily accessible to applicants.

Requests for new waivers will be entertained as part of the application review. An applicant who wishes to request a waiver should refer to 40 CFR 158.45 for information on the procedures for submitting waiver requests. The applicant should note that a request for waiver will require more extensive review by the Agency to determine whether the waiver is justified, which could delay the approval of the application. Moreover, if the waiver request is denied, the applicant will have to choose a different method of demonstrating compliance, or appeal the denial through administrative channels.

2. Submission of a New Valid Study (§ 152.92)

An applicant may submit a new valid study to satisfy a data requirement. When the Agency refers to a "new" study, it means one that has not previously been submitted to the Agency.

A new study should contain the following: (1) A title page containing certain identifying information about the study; (2) a statement concerning its trade secret status under FIFRA section 10, and any claims of confidentiality made under that section; (3) a certification concerning compliance with the Good Laboratory Practice standards of Part 160; and (4) an English translation if written in a foreign language. In addition, each submission of one or more new studies should be accompanied by a transmittal document and bibliography of its contents.

3. Citation of Previously Submitted Valid Studies (§ 152.93)

Any valid study already in the Agency's possession can be cited to demonstrate compliance with a selective data requirement. The applicant should not submit another copy of such a study, but may simply reference it appropriately. If the study was originally submitted by the applicant himself, that is all he is required to do. Further, if the applicant owned the section 3(c)(1)(D) rights in a study as a result of a transfer of the rights from the original submitter of the study, he need only certify his legal ownership of the study for that purpose.

In all other situations, the applicant must determine whether the study falls into the category of exclusive use data, compensable data, or non-compensable data under FIFRA section 3[c][1][D] in order to determine the procedures for proper citation of the data. For exclusive use data and compensable data, the procedures in § 152.93(b) (1) and (2) for obtaining permission or making an offer to pay are exactly the same as those under the cite-all method, except that the applicant will write to a specific data submitter concerning a specific study rather than to all data submitters on the Data Submitters List.

When an applicant using the selective method has made an offer to pay to the owner of a specific study that he wishes to cite, he is not required to submit with his application to the Agency a general offer to pay.

4. Citation From the Public Literature

FIFRA section 3[c][1][D] specifically allows an applicant to cite data that "appear in the public literature" to satisfy a data requirement. Under the procedures set out by PR Notice 83-4, an applicant is permitted to cite freely any article in a journal. EPA will continue this policy, and § 152.94 so states.

Studies generated by or at the expense of any government agency, or paid for with public funds, may be cited by any applicant on the same basis as studies from the public literature. It is

the Agency's opinion that such studies fall into the same category as studies from the public literature.

The legislative history of the 1978 FIFRA amendments shows that Congress did not intend that merely being the first submitter of such a study should confer any rights under FIFRA section 3(c)(1)(D) to exclusive use or compensation. The Conference Committee Report states in relevant part that " the conferees intend that the exclusive use and data compensation provisions of FIFRA should apply only to those data submitters who are entitled to exclusive use or compensation, either because they generated the data, paid for its generation, or otherwise have legal ownership of the data." (Sen. Rep. No. 95-1188, 95th Cong. 2d Sess. 29.) The same Report states:

> [A]s an alternative to describing tests made and results thereof, the applicant may cite data (1) that appear in the public literature, or (2) that previously had been submitted to the Administrator by the original data submitter if the exclusive use and data compensation provisions are met. [*Id.* at 14.]

The Agency believes that in the case of both public literature articles and government-generated studies, no ownership interest of the sort that was contemplated by the Congress has been acquired simply by submission or citation of the journal article or study to satisfy a data requirement.

The Agency is aware that many articles in journals are the results of research conducted by individuals working for, or supported by, a pesticide producer. Producers often arrange for research to be performed by universities, extension services or other extra-industry sources. Reports from some of these studies are submitted to the Agency in support of registration, and, in addition, published in scientific journals. Publication of scientific results is a means of disseminating information on pesticides and encouraging further research, which the Agency does not wish to discourage. If data submitters believe that, by publishing research in which they have a substantial monetary investment, they would forfeit or jeopardize their right to exclusive use or compensation, they will be inclined to forego publication and reserve their research studies for submission to the Agency. In that way they could clearly preserve their right to compensation or exclusive use. Thus free access to public literature studies arguably may discourage publication.

The Agency does not believe that its interpretation creates a loophole in economic protection afforded data submitters or stifles publication of research. EPA's experience in reviewing both data submitted directly by applicants, and journal articles from the public literature, shows that most such articles do not contain sufficient information, in themselves, to satisfy a registration data requirement. Published research typically describes the test methods and presents the results of the research in summary form. Such articles, however, rarely offer the detailed information (such as raw data results) needed by the Agency to reach sound conclusions about the risks and benefits of the pesticide, and to judge the validity of the study. This is particularly true of long-term studies, where the expense of the research would be most likely to cause concern about economic protection. When long-term studies are involved, journal articles alone will rarely suffice for registration purposes. Thus, the Agency sees no policy considerations that would compel a broader application of section 3(c)(1)(D) than currently used.

5. Citation of All Studies (§ 152.95)

Under the selective method, the applicant can choose to follow the cite-all procedures with respect to a single data requirement.

The procedures in § 152.95 are virtually identical to those under the cite-all method. The applicant must write to each person on the Data Submitters List and make an appropriate offer to pay (perhaps, but not necessarily, limited to a single data requirement; a single offer-to-pay letter could suffice for a number of individual data requirements). He then submits to the Agency, either at the time of application or before its approval, his general offer to pay and certification statement. The general offer to pay may also be limited to the specific data requirement(s) for which the applicant chose the cite-all option.

As in all of these procedures, if the Data Submitters List indicated the existence of exclusive use data, the applicant must obtain the written authorization of each such original data submitter instead of merely making an offer to pay. Lacking written authorization, he may not use the cite-all method for that data requirement and must pursue another option under the selective method (such as developing the data himself).

One drawback with using the cite-all procedures for a specific data requirement is that the Data Submitters List does not allow an applicant to determine whether a person on the list has submitted a specific study that would be pertinent to, or fulfill, the data requirement in question. Therefore, while an applicant may limit his request for authorization or offer to pay to studies that fulfilled a single data requirement, he still must write to each person on the list.

EPA is currently preparing a catalog of all of its data, which, when completed, will identify persons who have submitted specific studies, not just data on a particular chemical. The Pesticide Document Management System (PDMS) will catalog each study in the Agency's possession, describe its characteristics, and identify the original data submitter and date of submission. EPA is developing a system (accessible by computer terminal) that will permit users to correlate data requirements by chemical and use with specific data in Agency files that might fulfull those requirements. Once this system is fully operational, applicants should be able to determine whether data gaps exist without the need for extensive correspondence, and also to ascertain whether waivers have been granted. This system will also permit applicants to limit correspondence where appropriate to those persons who have submitted data which may fill a particular data requirement.

6. Data Gap Confirmation (§ 152.96)

In many cases, an applicant may obtain conditional registration even though there are "data gaps" for some of the data requirements for his product. Under FIFRA section 3(c)(7), the Agency is authorized to register some pesticide products conditionally. That section required, in pertinent part, that the Agency determine that " approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment." This "incremental risk" determination can often be made without the full range of studies that would be necessary to permit the overall determination of "no unreasonable adverse effects" required by FIFRA section 3(c)(5) (C) and (D). The finding of no incremental risk is a risk/benefit determination analogous to that under FIFRA section 3(c)(5) (C) and (D), and, likewise, is a separate function from the determination that the amount or type of data made available to the Agency by an applicant meets the section 3(c)(1)(D) data submission requirements.

The same data requirements are imposed under FIFRA section 3(c)(7) as under FIFRA section 3(c)(5), but, for already existing ("old") uses, section 3(c)(7) provides that if the Agency does not already possess data satisfying

those requirements, the applicant for conditional registration is not required to produce such data prior to registration when previous applicants have not had to do so. The applicant for conditional registration is required, however, to produce data that (1) pertain uniquely to his product (e.g., chemical composition, efficacy), or (2) are needed for the Agency's incremental risk determination (e.g., data pertaining solely to a "new" use).

The absence of generic data that do not bear on the incremental risk determination, therefore, is not a bar to the conditional registration of a product. The Agency will not deny conditional registration of a product under FIFRA section 3(c)(7) (A) or (B) solely because an applicable generic data requirement not essential to the incremental risk judgment has never been satisfied.

The procedures used to show that a data gap exists depend on whether EPA has issued a Registration Standard covering the active ingredient(s) in the applicant's product, and on the scope of that Standard. If a Registration Standard for an active ingredient has been issued, and the Standard covers both manufacturing use and end use products (generally those before April 1982), the applicant's task will be comparatively simple, since the Standard will list any data requirements, including those for which the Agency does not possess data. The applicant may rely on such a list of data gaps for the purpose of demonstrating compliance. If the Standard does not cover end use product data requirements, the applicant will have to follow the procedures in § 152.96 if he wishes to demonstrate a data gap for the end use data.

The Agency will track data submissions in response to the issuance of a Standard or other requirement to submit data pursuant to FIFRA section 3(c)(2)(B) and update Agency files promptly when a data requirement has been fulfilled. Nonetheless, there may be occasions when data that eliminate a "gap" have been submitted although a Standard still indicates that there is a data gap. The Agency will assume the responsibility for notifying affected applicants in such cases. The applicant will be required to select another method of demonstrating compliance for that data requirement, such as making an offer to pay for the newly submitted study.

If no Standard has been issued, an applicant can demonstrate a data gap by writing to each person on the Data Submitters List and asking him if he has previously submitted a study that would fulfill the data requirement(s). Data submitters will have 60 days in which to respond to data gap inquiries. If no one responds that he has submitted a study that fulfills the requirement, the applicant can certify to the Agency that a data gap exists. If any person responds within the 60-day period that he has submitted such a study, then the applicant may not claim that a data gap exists.

Failure to respond limits the data submitter's challenge rights after registration. Specifically, he cannot claim that the applicant had improperly claimed a data gap, a limitation which might preclude the data submitter's successfully petitioning the Agency to challenge the applicant's registration. (See Unit IX of this preamble for a discussion of a data submitter's rights to challenge a registration.)

If a data submitter indicates that he has submitted such a study, then the applicant can use the procedures in § 152.93 for citing that specific study. If more than one person responds that he had submitted such a study, the applicant can choose either to cite one of the studies or to cite all studies by following the procedures in § 152.86. It is unlikely, but not impossible, that exclusive use data would be the subject of a data gap search, since the Data Submitters List would normally alert the applicant to its existence. If, however, correspondence reveals the existence of exclusive use data that satisfies the requirement, the applicant must obtain the requisite written authorization if he wishes to cite the study.

The data gap procedures may not be used in certain instances. First, an applicant for conditional registration of a new active ingredient under FIFRA section 3(c)(7)(C) may not use the procedures. The applicant for registration of a new active ingredient is expected to submit all data necessary to make a full risk/benefit determination under FIFRA section 3(c)(5). Failure to submit any needed study at the time of application is not acceptable unless the Agency has so recently imposed a data requirement that the applicant has not had time to produce the data. In this case, the applicant may comply not by demonstrating a data gap, but by demonstrating the recentness of the data requirement, and then, only by persuading the Agency that, in the public interest, the product should be registered for the limited period of time before the study is completed.

Second, the data gap procedures may not be used for data requirements for which each applicant must develop and submit data on his own product. Such data include basic product composition data and, in some cases, certain efficacy data (e.g., efficacy data for antimicrobial products and for vertebrate control products formulated as baits).

Finally, the data gap procedures may not be used for a data requirement if the data are needed to make an incremental risk assessment under FIFRA section 3(c)(7)(B), typically for a new use. 40 CFR 158.30 describes the basic rule of thumb for determining whether this is the case. An applicant must determine the data requirements that apply to the product and its existing uses, and compare that list with the data requirements which apply to the product with the addition of the new use. Any differences in requirements are attributable solely to the new use, and data to satisfy them must be submitted at the time of application.

VII. Agency Review to Determine Compliance

Under FIFRA section 3(c)(5)(B), the Agency must review applications to determine whether the materials required to be submitted, including those that are required by this Subpart E, comply with the requirements of the Act. This part of the review need not take place before the Agency begins to review the application for compliance with other statutory requirements, but must occur before the registration is approved. EPA recognizes that the correspondence requirements of this subpart may take some time, and that an applicant may not wish to await responses in all cases before filing his application. A notable example is data gap certifications: if a data gap is suspected, the applicant can not claim that the gap exists until he has waited 60 days after corresponding with data submitters. EPA sees no reason why correspondence times and Agency review times may not run concurrently. Section 152.84 therefore provides that applicants may submit materials required by this subpart at any time before registration is granted. The Agency will not delay the review of other information pertinent to the application pending receipt of lists and certification statements, but will not approve the registration until they are received.

Applicants should be aware, however, that if deficiencies are found in materials submitted late in the Agency's review, the registration could be delayed while the applicant corrects the problem. It the Agency completes its review of the application, but has not received the applicant's submissions under this rule, the Agency will send the applicant a rejection letter, which will include a 75-day response time, after which the application will be treated as

though it had been withdrawn. A new application will be required if the applicant wants to pursue registration at some later date.

For all applications, the Agency will review any formulator's exemption statement to confirm that the applicant is eligible for the exemption, based on his Confidential Statement of Formula.

Applications under the cite-all method will be examined primarily to determine that the applicant's certification and general offer to pay have been correctly submitted. (The Agency will not ascertain the data submitters to whom the applicant had written.) This review will not be time-consuming, and the Agency will be able to resolve any problems quickly and directly with the applicant.

Applications under the selective method will be more extensively reviewed. First, the Agency will examine the applicant's list of data requirements to determine that all applicable requirements have been included. The Agency will verify those conditional requirements that depend on use patterns, product composition, or physical or chemical characteristics, but will not attempt to determine whether conditional requirements based on the results of other studies were actually imposed, i.e., EPA normally will not review results of the first-level studies to see if they triggered a conditional requirement.

EPA will then check that the applicant has demonstrated compliance for each listed data requirement by one of the means provided in this subpart, and that his certification reflects that required offers to pay, written authorizations, and data gap claims have been made or obtained in accordance with this subpart.

If the Agency determines that the applicant has failed to list an applicable data requirement, the Agency will notify the applicant, and will refuse to register the product until the applicant had corrected the deficiency. Since adding an omitted data requirement might result in the applicant's having to engage in futher correspondence with data submitters, the registration could be delayed. Approval of an application will not constitute a waiver of any data requirement the applicant may have omitted; a data submitter later may challenge the registration under § 152.99.

The Agency will review any new study submitted by an applicant to determine its validity and sufficiency, but will not necessarily review studies previously submitted. Thus, approval of an application does not mean that the Agency has determined that previously submitted studies are valid or sufficient from a scientific standpoint under present-day standards. As discussed in Unit IX, a data submitter may challenge a registration based on a claim that non-valid studies have been cited. If a challenge is made, the Agency will review a previously submitted study; if it is found to be invalid or insufficient, the applicant's registration could be jeopardized.

In order to protect exclusive use data rights, the Agency will notify each exclusive use data submitter before it grants a registration which may have been supported by exclusive use data. This procedure will not be necessary, however, if the applicant can provide to the Agency a statement from each exclusive use data submitter (in most cases there is only a single exclusive use data submitter) that he was aware of the applicant's application, and does not object to its issuance. In essence, the applicant may anticipate the Agency's 30-day notification and assume responsiblity for it himself.

In the absence of the applicant's taking this step, § 152.116 provides for pre-registration notification at least 30 days before the registration is granted, during which time the exclusive use data submitter can request further information concerning the applicant's means of demonstrating compliance with data requirements, and subsequently petition the Agency to deny the application for failure to comply with FIFRA section 3(c)(1)(D)(i). The Agency will entertain a pre-registration petition only if it concerns the applicant's failure to list, or obtain written authorization for, a study for which the petitioner holds exclusive use rights.

The Agency will periodically make public a listing of registrations issued, including the name and address of the registrant, the name of the product, the active ingredients, and the method of compliance. The Agency currently maintains such a list, and intends to continue this practice.

Moreover, the materials submitted in accordance with this subpart, including the applicant's list of data requirements under the selective method, his means of compliance for each, and his citations of studies in the Agency's possession, will be available to any person after registration upon request under Freedom of Information procedures. The Agency is promulgating § 152.119 to state this policy clearly.

VIII. Rights and Obligations of Data Submitters

Section 152.97(a) describes the right of data submitters to be listed on the Agency's Data Submitters List. As noted earlier, the Agency will use this list as the basic reference for applicants for corresponding with data submitters.

When the list was developed in 1980, its purpose was to identify persons who wished to receive letters from applicants offering to pay compensation for the right to cite their data under the 1979 cite-all regulations. The Agency surveyed its registrants at that time to eliminate from the list any who did not wish to receive such offers. A large number of end use producers chose to forgo potential compensation apparently because of the expense of responding to offers to pay for data that, after negotiation or arbitration, might prove to be non-compensable, or of such low value that the expense was not warranted. Because it is possible that a data submitter might wish to receive offers to pay or to have the opportunity to give or deny permission for the right to cite data, this rule provides, in § 152.97(a), that a data submitter will be able to request that his name be added to the list.

A data submitter may request inclusion on the list at any time, which he may do by submitting pertinent information about his studies to the Agency. The Agency will refuse to include studies submitted before 1970 and studies which each applicant is required to submit on his own product, such as product composition information and certain efficacy studies.

Section 152.97(b) describes the data submitter's obligation to respond to requests for confirmation of a data gap. Data submitters have an interest in responding to requests from applicants to verify the studies they have submitted. This rule does not require that data submitters respond to correspondence from applicants, since the Agency could not enforce such a requirement under FIFRA. The Agency notes, however, that FIFRA section 3(c)(1)(D) was included in the Act specifically to protect the economic rights of data submitters. The data submitter who fails to respond will be affected to the extent that the Agency will not recognize his right to challenge a registration on the grounds that his data was not cited.

Section 152.98 describes the data submitter's right to transfer his section 3(c)(1)(D) rights to another person. Heretofore, the Agency has generally (but informally) assumed that transfer of registration and transfer of data submitted or associated with that registration where linked, and data rights under section 3(c)(1)(D) have been assumed to belong to the person who held the registration. EPA believes that

in the majority of registration transfers, this has been and will continue to be the intent of the parties, although the Agency rarely has been informed specifically that that was the case.

The Agency, however, acknowledges that there may be situations when a data submitter (who may also be a registrant) would wish to retain the rights to exclusive use or data compensation while transferring the registration of the product. Alternatively, there may be situations when a data submitter would wish to sell or transfer those rights while retaining the marketing rights conferred by registration. The Agency's Pesticide Document Management System (PDMS) now being developed will permit the Agency to track items of data independently of the regulatory action in connection with which they were originally submitted, and is thus compatible with a transfer system that functions separately from that for registration. Moreover, the tracking of data under the PDMS and the transfer or registrations are carried out by different units within the Office of Pesticide Programs, and it is logical that a separate transfer be permitted.

Section 152.98 describes the transfer documents required to be submitted to the Agency so that the Agency can fulfill its responsibility under 3(c)(1)(D) to protect the economic rights of data submitters.

IX. Data Submitters' Challenge Rights

A. Exclusive Use Rights

The exclusive use provisions of FIFRA section 3(c)(1)(D)(i) offer full protection only if the Agency provides the exclusive use data submitter the opportunity to keep a competitor's product off the market, i.e., to insure that registration is denied in situations where the data submitter's rights would be violated. Once the product has been registered and enters the market, the exclusive use data submitter, although he has recourse, has lost the protection intended by the Act.

In order to protect against this unlikely occurrence, the rule provides in § 152.116 that the Agency will notify the exclusive use data submitter of its intention to register a product which might possibly have been supported by his exclusive use data. The exclusive use data submitter will have the opportunity to challenge the issuance of the registration on the grounds that the applicant had not obtained his written permission, or had otherwise made an improper certification to the Agency. After 30 days the Agency will proceed to register the product if no challenge has been received.

The applicant may himself notify the exclusive use data submitter, and provide the Agency with evidence of the data submitter's permission to proceed with issuance of the registration, thereby eliminating the 30-day waiting period.

B. Compensation Rights

In administering the compensation provisions of the Act, the Agency intends to rely heavily on data submitters to monitor compliance with the procedures of this subpart. Section 152.99 of this rule establishes a petition procedure by which data submitters can challenge the Agency's issuance of a registration. Certain petition procedures—those preceded by an offer to pay in accordance with FIFRA section 3(c)(1)(D)(ii)—are provided for, and limited by, the Act itself. This rule establishes similar petition procedures to accommodate situations under the selective method for which no offer to pay has been made.

The rule limits challenge rights under the rule to persons who have submitted valid data to fulfill a requirement for which the applicant purportedly has failed to demonstrate compliance. The applicant's failure to comply must be shown to have affected rights that the data submitter actually possesses. The Agency believes that a data submitter who had never acquired such rights by submitting a pertinent study should not be permitted to request cancellation of the registration of a competitor under these procedures.

To assist data submitters in the task of monitoring compliance, the Agency will periodically make public a list of the applications it has approved, including the name and address of the registrant, the product name and registration number, the date of registration, the active ingredient(s) in the product, and the applicant's method of compliance. From this list a data submitter may ascertain whether an applicant under the cite-all method had failed to make the required offer to pay. The data submitter then may write to the registrant and assert his claim for compensation based upon the registrant's general offer to pay.

If the Agency's public notice indicates that the applicant has used the selective method, a data submitter who wishes to determine whether he should have received an offer to pay first must request the applicant's list of data requirements and means of complying with each to determine whether the applicant cited any of the submitter's data. The time period for challenging the registration does not begin until the data submitter has received these materials.

1. Challenges Preceded by Offers To Pay

In contrast to the exclusive use provisions of the Act, which, to offer full protection, must be enforced before registration is granted, an applicant can fully comply with the requirement of the statute by making a general offer to pay under the cite-all method (and the selective cite-all option). The data submitter is adequately protected by this procedure, which preserves the right to compensation even if the registration has for any reason been improperly approved. Compensation may be claimed at any time after the offer to pay has been extended. Provided the offer to pay has been made, the issuance of the registration itself is not of sufficient import to warrant advance notice to data submitters.

The Act does not contemplate that, when offers to pay have been made, disputes over compensation should delay the registration of products. Rather, such disputes are to be handled through negotiation or arbitration without Agency involvement. Therefore, the Act provides, in section 3(c)(1)(D)(ii), that a data submitter may request that the Agency cancel the registration only after an applicant has failed to participate in an agreed-upon procedure for determining the amount of compensation due, has failed to participate in an arbitration proceeding, or has failed to adhere to any agreement or arbitration decision. Section 152.99(a)(1) limits the grounds for petitioning the Agency to those specifically provided by the statute.

FIFRA section 3(c)(1)(D), moreover, provides that if the Agency determines that the applicant or registrant has failed to participate in such an agreement or in an arbitration proceeding, or has failed to adhere to any such agreement or arbitration decision, then the Agency shall cancel (or deny) the registration with 15 days notice without further hearing. Consequently, §152.99(c)(2) provides that the Agency will notify the applicant and the petitioner at least 15 days before any intended cancellation of the product. Within the 15 days, the registrant of the affected product may respond to the Agency, but may not challenge the Agency's action in an administrative hearing forum. If the Agency subsequently cancels the product registration, the registrant can pursue his appeal in an appropriate United States District Court.

2. Other Challenge Rights (Under the Selective Method)

The selective method does not lend itself as readily to monitoring by data submitters, because of the specificity of its procedures and the variety of options available to the applicant to comply with data requirements. A data submitter will not necessarily receive an offer to pay from each applicant, as he would under the cite-all method. Nor will he be able to determine from the Agency's listing of approved applications whether he should have received an offer to pay, since an applicant may have submitted his own study, or cited another data submitter's study.

The Agency's review of selective method submissions primarily will attempt to determine that the applicant has listed each applicable data requirement, and has demonstrated compliance by an appropriate method. Several methods rely on the applicant's certification that he has complied with the procedures. Moreover, the Agency will not review cited data to determine its validity by current scientific standards or sufficiency for regulatory purposes, and thus an applicant may cite a study that, upon review, would no longer be acceptable in support of registration. For these reasons, EPA believes it necessary that data submitters be allowed to challenge selective method registration actions (other than selective cite-all, which would be governed by the general offer to pay) to protect any perceived loss of rights under FIFRA section 3(c)(1)(D). The procedures in § 152.99 will be used for this type of challenge.

Section 152.99(a)(2) lists several types of complaints that might serve as the basis for a petition by a data submitter under the selective method. Among these are failure to satisfy data requirements that should be or have been listed, failure to follow required procedures, improper certification with respect to written authorization, offers to pay, or data gaps, or citation of an invalid study. Where any such failure involved the cite-all option, however, the Agency expects the data submitter to avail himself of the general offer to pay rather than petition for cancellation of the registration.

Section 152.99(b) requires the data submitter to make his challenge in a timely manner, and to assume the responsibility of notifying the registrant of his challenge. A challenge must be filed with the Agency within one year after the Agency makes public its listing of recently approved applications. The registrant is permitted 60 days to respond to the petitioner's complaint.

Thereafter, the Agency will use the procedures for denial or cancellation provided by either FIFRA section 3(c)(6) or 6(b), including the possibility of conducting hearings if it finds the petitioner's arguments or the applicant's response to be persuasive. Any hearings will be conducted in accordance with the procedures of 40 CFR Part 164, with the only issue for resolution at the hearing being whether the applicant had failed to comply with the requirements of this subpart in the manner described by the petitioner.

X. Differences Between This Rule and PR Notice 83-4

This rule contains a number of significant additions to, deletions from, and modifications to PR Notice 83-4, issued June 16, 1983, under which the Agency has been operating for the last year (see Unit I.D of this preamble). These differences are summarized in this unit.

1. Inclusion of Offers To Pay

The most obvious difference is that this rule includes provisions for offers to pay for the right to cite a data submitter's study. Under the *Monsanto* and *Union Carbide* district court decisions, the Agency could not permit an applicant to cite a data submitter's study without the latter's written authorization. The Supreme Court's decisions upholding the constitutionality of FIFRA section 3(c)(1)(D) and vacating the district court judgments have removed that bar. Therefore, this rule includes procedures allowing offers to pay.

2. Reliance on Registration Standard for List of Data Requirements

Section I.A. of PR Notice 83-4 requires the applicant to base his list of data requirements on the Agency's data requirement regulations found in 40 CFR Part 158. This rule provides that, when a Registration Standard has been issued for an active ingredient, the applicant may rely on the list of data requirements contained in the standard, and need not undertake the exercise of determining data requirements from Part 158. This will reduce the burden of listing data requirements for active ingredients for which Registration Standards have been prepared.

3. Restrictions on Waiver Requests Eliminated

Section I.A.3. of PR Notice 83-4 stated that the Agency would not, during the period that the PR Notice was in effect, consider waiver requests except when the applicant would be required to generate new data to fulfill a requirement, i.e., when no person had previously submitted such data. This was included so that the Agency would not have to spend time reviewing requests for waivers of requirements which, although theoretically imposed, as a practical matter did not result in actual economic burden upon applicants. The Agency's data requirement regulations in 40 CFR Part 158 permit requests for waiver without restriction. Consequently, this rule allows waiver requests without restrictions as to whether data relevant to the requirement have been previously submitted.

4. Certification With Respect To Written Authorizations

Section I.B.1.c. of PR Notice 83-4 required an applicant to submit to the Agency the written authorizations obtained from other data submitters. EPA does not believe that written authorizations should routinely be submitted to the Agency, and does not wish to receive such paperwork which would have to be processed and filed in substantial volume. Accordingly, this rule provides that an applicant merely must certify to the Agency that he has in fact received such authorizations. Only if the registration were subsequently challenged would the Agency ordinarily expect the applicant to present the written authorizations to verify compliance with the requirement.

5. Reliance on Registration Standard for Data Gaps

Section I.B.2. of the PR Notice required that an applicant who wishes to demonstrate a data gap write to each person on the Data Submitters List. In cases where a Registration Standard has been issued, however, EPA believes that the applicant can rely on the data gap listings in that Standard. The Agency will assume the responsibility of notifying applicants if a data gap has been filled, so that the applicant can select another method of demonstrating compliance with that data requirement.

6. Notice to Prior Data Submitters

Section I.D. of the PR Notice provided an optional procedure whereby applicants could write to exclusive use data submitters concerning the data requirements for an active ingredient. Under that section, the exclusive use data submitter could provide the applicant (and the Agency) with his list of applicable data requirements. In Section II.B. the opportunity to provide lists of data requirements to the Agency