noncontroversial, and does not substantively change the proposed rule.

II. What are the corrections to the proposed rules (75 FR 63260)?

In this notice, we are clarifying the scope of the proposed affirmative defense for exceedance of an emission limit or standard during a malfunction. See proposed regulatory text at 75 FR 63260. Specifically, we are clarifying the regulatory text to reflect that the affirmative defense is available only against claims for civil penalties. The preamble to the October 14, 2010 (75 FR 63283), notice stated this position, as did other portions of the proposed regulatory text. See 75 FR 63299 proposed § 60.4861(b) and 75 FR 63323 proposed § 60.5181(b). However, one sentence in the regulatory text created a potential ambiguity that may not have reflected the Agency's intent. Therefore, we are clarifying this in the proposed regulatory text to explain that a facility may assert an affirmative defense to a claim for civil penalties for exceedances of the standards that are caused by a malfunction, as defined in 40 CFR 60.2, but may not assert such a defense to a claim for injunctive relief.

EPA is soliciting public comment on the proposed SSI rule published on October 14, 2010, until November 15, 2010, unless a public hearing is held. If a public hearing is held, then comments on the proposed SSI rule published on October 14, 2010, must be received by November 29, 2010. Members of the public may also comment on this technical correction during that time, and should submit any such comments to the docket for that proposed rule. Submit your comments, identified by Docket ID Number EPA-HQ-OAR-2009-0559, by one of the following methods identified in 75 FR 63260.

III. Statutory and Executive Order Reviews

EPA's compliance with relevant statutes and Executive Orders for the proposed SSI rule is discussed in the October 14, 2010, Federal Register notice titled "Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Sewage Sludge Incineration Units." (75 FR 63260). This technical correction does not affect the analyses contained in the October 14, 2010, notice.

List of Subjects in 40 CFR Part 60

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements. Dated: October 29, 2010.

Gina A. McCarthy,

Assistant Administrator.

For the reasons stated in the preamble, FR Doc. No. 2010–25122, published in the **Federal Register** on October 14, 2010, at 75 FR 63260 is corrected as follows:

- 1. Beginning on page 63298, in the third column, remove the second sentence in § 60.4861 introductory text and add the following two sentences in its place: "Appropriate penalties may be assessed, however, if the respondent fails to meet its burden of proving all of the requirements in the affirmative defense. The affirmative defense shall not be available for claims for injunctive relief."
- 2. On page 63323, in the center column, remove the second sentence in § 60.5181 introductory text and add the following two sentences in its place: "Appropriate penalties may be assessed, however, if the respondent fails to meet its burden of proving all of the requirements in the affirmative defense. The affirmative defense shall not be available for claims for injunctive relief."

[FR Doc. 2010–28002 Filed 11–4–10; 8:45 am] BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 152

[EPA-HQ-OPP-2009-0456; FRL-8424-8] RIN 2070-AJ58

Pesticides; Satisfaction of Data Requirements; Procedures To Ensure Protection of Data Submitters' Rights

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to revise its regulations governing procedures for the satisfaction of data requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These provisions include, among other things, procedures for the protection of exclusive use and data compensation rights of data submitters. The proposed revisions would update the regulations, which have not been revised since issuance in 1984, to accommodate statutory and procedural changes that have occurred since that time. The revisions would also make minor changes to clarify the regulations. The revisions would simplify the procedures and reduce burdens for certain data submitters.

DATES: Comments must be received on or before January 4, 2011.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2009-0456, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the on-line instructions for submitting comments.
- Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2009-0456. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at http:// www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available

at http://www.regulations.gov. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at http:// www.regulations.gov, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT:

Cameo G. Smoot, Field and External Affairs Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5454; fax number: (703) 305–5884; e-mail address: smoot.cameo@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you produce pesticide products that require registration with EPA (NAICS code 32532).

This listing is not all-inclusive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 152.81 of the regulatory text. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

- B. What should I consider as I prepare my comments for EPA?
- 1. Submitting CBI. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then

identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

- 2. Tips for preparing your comments. When submitting comments, remember to:
- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/ or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. Statutory Authority

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq., EPA regulates the sale, distribution and use of pesticides, and the allowable levels of such pesticides in or on food under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA regulations covering activities under these statutes are located in 40 CFR parts 150–180.

The process of registering a pesticide begins with submission to EPA of an application package and required data. In reviewing applications for pesticide product registration under FIFRA, EPA must determine, among other things, whether the pesticide generally causes unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice. If EPA determines

that a pesticide product meets the registration standard of FIFRA section 3(c), EPA registers (or licenses) the product for distribution and sale in the United States (U.S.). Pesticides must be registered or exempted by EPA's Office of Pesticide Programs before they may be sold or distributed in the U.S. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labeling.

B. Data Requirements

FIFRA section 3(c)(2) directs EPA to publish guidelines specifying the kinds of data that applicants and registrants must submit to support EPA regulatory determinations under FIFRA. These data requirements are set forth in 40 CFR part 158 and 40 CFR part 161. The data allow EPA to evaluate whether a pesticide has the potential to cause harmful effects on certain nontarget organisms and endangered species that include: Humans; wildlife; plants; and surface water or ground water.

C. Satisfaction of Data Requirements

EPA regulations in 40 CFR part 152. subpart E prescribe a variety of means by which applicants may satisfy EPA's data requirements. These include submitting new studies, but they also allow an applicant to cite to data previously submitted by another person that are relevant to that applicant's product. When the latter option is selected, an applicant may be required to either obtain permission or offer compensation to cite the data, depending upon whether the data at issue are subject to the exclusive use or data compensation provisions of FIFRA section 3(c)(1)(F). In addition, the regulations in 40 CFR part 152, subpart E spell out the circumstances under which certain applicants are exempt from data submission or citation obligations (i.e., the formulators exemption provided by FIFRA section 3(c)(2)(D).

D. Protection of Data Submitters' Rights

The bulk of the regulations in 40 CFR part 152, subpart E address those situations in which applicants for registration choose to satisfy data requirements by citation to existing data submitted by other persons. In that respect, the regulations prescribe:

1. The means by which a pesticide data submitter can protect and document his/her exclusive use and compensation rights in data submitted to the Agency. Generally, persons submitting data must request inclusion on an Agency-maintained Data Submitters List as the means for

asserting their rights to offers of compensation from applicants who cite their data.

- 2. Procedures that applicants who cite to data submitted by others must follow to ensure that data submitters' rights are protected. The procedures apply to new and amended registrations, as well as maintenance of existing registrations under the reregistration and registration review programs.
- 3. Procedures for the transfer of data rights to other persons. Data rights are separate from the registration of the pesticide, and therefore may be transferred to another person separate from the registration.
- 4. The procedures that a data submitter may use to seek redress when the submitter believes he/she has been deprived of data rights accorded under FIFRA.

III. Today's Proposed Revisions

EPA is proposing to update certain aspects of 40 CFR part 152, subpart E regulations governing satisfaction of data requirements and the associated data rights procedures. The regulations were promulgated in 1984 and have served satisfactorily since then. EPA has, however, identified the need to update the provisions to reflect changes in the statute and related practices over time. For example, the scope of the protections has expanded by statute to include both new protections and new decisions that are subject to data rights protection procedures, including reregistration under FIFRA section 4, and registration review under FIFRA section 3(g). In addition, EPA's needs and practices have changed.

A. Applicability (40 CFR 152.81 and 40 CFR 152.46)

EPA proposes to replace the limited listing of actions to which the subpart does not apply (excepted actions) with a single reference to actions that may be accomplished by notification or nonnotification under 40 CFR 152.46. EPA's intention is first to simplify the exception provisions. At the same time, however, the revision highlights the underlying principle that an action that does not require scientific review of data also does not require satisfaction of data requirements, and is not subject to the requirements in 40 CFR part 152, subpart E. While the current regulation contains this proviso in 40 CFR 152.81(b)(4)(xvi), the proposed revision gives prominence to this fundamental precept, and provides a firm basis for future determinations of the applicability of 40 CFR part 152, subpart E to specific actions.

1. Applicability (40 CFR 152.81). 40 CFR 152.81 describes the applicability of the provisions of subpart E to applications of various types, and more important to today's proposal, those actions to which the procedures do not apply. Some actions are not covered by the provisions of FIFRA section 3(c)(1)(F), including actions such as emergency exemptions under FIFRA section 18, experimental use permits under FIFRA section 5, and State registrations under FIFRA section 24(c). These exceptions would not change.

However, the bulk of the exceptions listed in current 40 CFR 152.81(b) rely not on statutory exceptions, but on the principle that if EPA does not need to review scientific data in order to make its regulatory determinations, it need not require that applicants address the satisfaction of data requirements at all. Accordingly, current 40 CFR 152.81(b) identifies a detailed set of amendments to registration that do not require review of scientific data. These include, among other things, minor amendments to composition and labeling, deletion of uses, clarifications of labeling content and presentation, and other actions of an essentially administrative nature. The list was not intended to be allinclusive when promulgated, and is in fact only illustrative, given the wide variety of possible revisions to registration. EPA reserved the right to make determinations on the need for scientific data on a case-by-case basis, and either to require the procedures if scientific data are needed, or excuse the applicant from the procedures if scientific data are not needed (see 40 CFR 152.81(b)(4) and 40 CFR 152.81(b)(4)(xvi) respectively).

2. Notifications and non-notifications (40 CFR 152.46). In a major restructuring of its procedural regulations in 1988, EPA introduced the concept of revisions to registration that could be accomplished by notification (40 CFR 152.46(a)) or non-notification (40 CFR 152.46(b)). Further, in 1996, those regulations were amended (61 FR 33039, June 26, 1996) (FRL–5372–8) to permit the Agency to issue procedures (generally issued using Pesticide Registration (PR) Notices) to implement actions by notification or non-notification.

The notification and non-notification processes are intended to provide a streamlined means for registrants to make registration changes that have no potential to cause adverse effects. As the terms suggest, changes identified in these procedures may be accomplished without the need for Agency approval. EPA regards an action that will "have no potential to cause unreasonable adverse

effects" as used in 40 CFR 152.46 as equivalent to a determination that no scientific data are needed to make the change within the meaning of 40 CFR 152.81(b)(4)(xvi). In the latest PR Notice that addresses revisions that may be made by notification and nonnotification (i.e., PR Notice 98–10, October 22, 1998), EPA expanded the list of eligible actions considerably. Note that EPA has also permitted certain specific labeling changes to be made through notification or non-notification in other PR Notices (see, e.g., PR Notices 2007-1 and 2008-1) and in case-by-case registration actions.

3. Comparison of actions (40 CFR 152.81 and 40 CFR 152.46). EPA has reviewed the list of actions in 40 CFR 152.81(b)(4) against those permitted by notification or non-notification under 40 CFR 152.46, as expressed in PR Notice 98–10, to determine whether the changes are comparable. PR Notice 98–10 represents an additional 14 years of evolving Agency regulations and policy from the 1984 promulgation of 40 CFR 152.81, and is considerably more detailed in its description of actions. Thus comparisons between the two are not exact.

In a number of cases, the types of amendments excepted under 40 CFR 152.81(b)(4) are covered by the provisions of 40 CFR 152.46, as expressed in PR Notice 98-10, and thus the proposed revision would have no effect on applications of those amendments (for example, minor changes in labeling having no substantive impact). In other cases, statutory, regulatory and policy changes since 1984 have resulted in excepted actions no longer being eligible for exception under 40 CFR 152.81(b). For example, addition or deletion of an active ingredient is now generally regarded as a new formulation requiring new registration. Finally, some types of excepted actions have been rendered moot as they are no longer treated as "applications" for the purposes of subpart E, and are governed by other regulations (e.g., supplemental distribution, name and address changes, label splitting for marketing purposes).

EPA regards the determinations under 40 CFR 152.46, as expressed in PR Notice 98–10 and in other notices implementing notification or non-notification procedures, as the Agency's written finding under 40 CFR 152.81(b)(4) as to whether scientific data (and thus compliance with subpart E) are required to evaluate an application. Today's proposal simply articulates this principle in the text of the regulations.

EPA will generally make these determinations in connection with its

review of applications. However, applicants and registrants may seek EPA's determination as to whether subpart E procedures will apply to their actions in advance of submission of their applications.

The proposed revision would broadly apply to future actions that EPA determines can be implemented through notification or non-notification procedures. Changes to the actions permitted by notification or nonnotification in the future may change the applicability of the procedures in subpart E. Excepted actions not addressed specifically in the regulation or that are not subject to notification and non-notification procedures would continue to be subject to subpart E unless EPA determines, on a case-bycase basis, that such actions do not require scientific review of data.

Accordingly, EPA proposes to eliminate the limited listing in 40 CFR 152.81 in favor of a reference to any action that may be implemented by the notification or non-notification procedures under 40 CFR 152.46.

B. Update Definition of Exclusive Use Study (40 CFR 152.83)

EPA proposes to update and restructure the existing definition of "exclusive use study" to incorporate the additional exclusive use criteria added by the Food Quality Protection Act (1996). In that act, Congress expanded the exclusive use provisions of FIFRA section 3(c)(1)(F) in two circumstances:

- Congress amended section 3(c)(1)(F)(ii) to allow for the extension of an original 10-year exclusive use provision for a period of up to an additional 3 years when the registrant adds minor uses meeting certain criteria to the original registration for which the exclusive use data were submitted.
- 2. Congress added a new section 3(c)(1)(F)(vi) that creates exclusive use rights in data submitted by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, provided such data relate solely to a minor use of a pesticide. These provisions would be incorporated into the new definition.

Because of the complexity of the new definition of exclusive use, EPA proposes to create a separate provision in the regulation to define "exclusive use study." To do so, EPA proposes to move the existing definitions from 40 CFR 152.83 into 40 CFR 152.82, and to add a new 40 CFR 152.83.

C. When Materials Must Be Submitted (40 CFR 152.84)

EPA proposes to revise 40 CFR 152.84 to conform to the requirements of FIFRA section 33(f)(4) (as amended by the Pesticide Registration Improvement Renewal Act, Public Law 110-94, commonly called PRIA II).

Current 40 CFR 152.84 allows an applicant to submit required documents, forms, and other materials related to satisfaction of data requirements at any time before the Agency approves the application, although it recommends submission at the time of application. Some of the required information must be submitted with the application, e.g., a request for waiver of a data requirement, because the Agency must make a determination as part of its review process. Other information has routinely been provided on forms supplied by the Agency, such as the Formulators' Exemption Statement or the General Offer to Pay Statement, and typically is submitted with the application.

Under FIFRA section 33(f)(4)(B), EPA must determine during the initial screen (within 21 days after receiving an application and the required registration service fee) that "the application contains all the necessary forms, data, and draft labeling, formatted in accordance with guidance published by the Administrator." Information and forms required by subpart E pertaining to satisfaction of data requirements are covered by this provision. Furthermore, the Agency must reject applications that do not pass the initial 21-day content screen. Accordingly, the information and forms required by subpart E are no longer permitted to be submitted at any time prior to approval of the application, but must be submitted at

the time of application.

In addition to the above reasons, EPA believes that the primary rationale for the provision of 40 CFR 152.84 that allows applicants to satisfy subpart E requirements after submission of an application no longer exists. In the preamble to the existing regulations (49) FR 30884, at 30897, August 1, 1984), EPA identified the 60-day waiting period for data gap certification letters as the primary example of timeconsuming activities that could unduly delay the submission of an application were applicants are required to submit completed subpart E materials at the time of submission of their applications. Because this proposed regulation will eliminate the requirement for applicants to send data gap letters in order to claim a data gap under the selective method of data support (see Unit III.G.), EPA

sees no compelling reason for maintaining the existing provision even in the absence of the requirements of PRIA II.

Accordingly, EPA proposes to revise 40 CFR 152.84 to specify that the necessary forms and information pertaining to satisfaction of data requirements must be submitted at the time of application.

D. Addition of Electronic Means of Contacting Data Submitters (40 CFR 152.86 and 40 CFR 152.95)

EPA proposes to revise 40 CFR 152.86 and 40 CFR 152.95 to include the use of electronic methods of communication, such as e-mail, in addition to regular mail. This change would update communication methods between applicants.

E. Selective Method (40 CFR 152.90)

EPA proposes to eliminate the requirement that applicants use a Registration Standard as the default source of the listing of data requirements under the selective method in 40 CFR 152.90.

Under the provisions of subpart E, an applicant may choose between two methods to address data compensation for cited data: Cite-all or selective. The cite-all method (40 CFR 152.86) permits an applicant to cite collectively all data in the Agency's files that might pertain to his/her product, provided, among other things, the applicant certifies that he/she has obtained the original data submitter's permission to cite any exclusive use data for the chemical, makes an offer to pay each person listed on the Data Submitters List for each active ingredient in his/her product and makes a general offer to pay other persons to the extent required by FIFRA section 3(c)(1)(F). The cite-all method, while easier to use and less burdensome procedurally, potentially subjects the applicant to an unknown or uncertain compensation liability.

In contrast, under the selective method (40 CFR 152.90), an applicant must provide a list of data requirements that would apply to his/her product if it were being proposed for registration under FIFRA section 3(c)(5) for the first time, and must choose an acceptable method of satisfying each data requirement individually. If the applicant chooses to cite to existing data to satisfy an individual requirement, the applicant will need the permission of the original data submitter if the data are entitled to exclusive use treatment under FIFRA, or will need to make an offer to pay compensation to the original data submitter if the data are subject to the compensation provisions of FIFRA.

Because this method allows the applicant to select the data to be relied upon to meet EPA data requirements, the applicant under the selective method may thereby limit the scope of the required offers to pay.

Currently, 40 CFR 152.90(a) requires that an applicant use an issued Registration Standard (the EPA reregistration decision documents issued prior to 1988) as the source of his/her list of data requirements for the selective method. If the Registration Standard does not address all required data or there is no Registration Standard, the applicant must refer to 40 CFR part 158 data requirements as the alternate source of his/her list of data requirements.

The form of EPA decision documents has evolved since the 1984 regulations were promulgated. Registration Standards were superseded beginning in 1988 by Reregistration Eligibility Decision documents (REDs) as the Agency implemented the reregistration requirements of FIFRA section 4. In turn, REDs will likely be superseded or updated by determinations made under the new Registration Review program required by FIFRA section 3(g) and 40 CFR part 155. Given the growth and evolution of the program's systematic review of existing pesticides, EPA believes it should no longer identify by regulation a specific type of decision document as the source of data requirement listings. These documents are a snapshot of the data requirements at a particular review period, and are likely to become outdated over time as EPA's risk assessments evolve and new types of data are needed.

EPA also notes that on October 26, 2007 ((72 FR 60934) (FRL-8106-5); (72 FR 60988) (FRL-8109-8)), EPA significantly amended its data requirements in 40 CFR part 158 for conventional, biochemical and microbial pesticides. 40 CFR part 158 and 40 CFR part 161 represent the most up-to-date iteration of data requirements for pesticides, and are likely to be updated in the future when appropriate to meet changing data needs. For example, EPA proposed revisions to the data requirements for antimicrobial pesticides (73 FR 59381, October 8, 2008), and other amendments are under development. In general, EPA believes that the regulations in 40 CFR part 158 and 40 CFR part 161 should be the primary source of the data listings needed for the selective method.

Thus, EPA proposes to remove from 40 CFR 152.90 the requirement that any specific Agency listing of data requirements serve as the basis for the selective method listing. Instead, EPA would refer applicants to the data requirements in 40 CFR part 158 and 40 CFR part 161.

Notwithstanding, consideration of existing decision documents such as REDs will continue to provide useful guidance to applicants and registrants in determining how EPA has applied the data requirements to individual products and uses. However, such documents do not represent a binding Agency determination regarding the data requirements that must be fulfilled to satisfy the requirements of any individual registration.

F. Data Waivers (40 CFR 152.91)

EPA proposes to make minor revisions in the data waiver provisions in the selective method in 40 CFR 152.91 to conform to current policy concerning waivers, and to update them to accommodate Reregistration and Registration Review programs.

When the regulations were initially promulgated, the Agency's program for the systematic review and maintenance of existing registration was called the Registration Standards program, and the program had not fully matured. EPA anticipated that data waivers would be evaluated, granted and documented in the context of that program. 40 CFR 152.91 allows an applicant to rely on a previously granted waiver that has been documented in a Registration Standard.

As indicated previously, the Registration Standards program was replaced in 1988 by the reregistration program mandated by FIFRA section 4, which, in turn will be succeeded by the Registration Review program. These second- and third-generation pesticide review programs use different terminology for the decision documents that result. Applicants may rely on these later program documents to identify and document an existing waiver.

Accordingly, EPA proposes to add Reregistration Eligibility and Registration Review decision documents as additional Agency records that applicants may refer to. This revision does not change the substance of the provision, as the current listing of applicable documents is merely illustrative.

EPA also proposes to specify that a denial of a waiver decision is a final Agency action. Similar language is already included in the Agency's regulations on waivers found in 40 CFR 158.45, and this proposal would simply modify 40 CFR 152.91 to reflect the Agency's existing position.

G. Elimination of Certification and Documentation Procedures for Data Gaps (40 CFR 152.96)

As touched upon in Unit III.E., when the regulations were initially promulgated in 1984, EPA was in the midst of establishing procedures for the review of existing registrations. The purpose of reregistration was to update and modernize the scientific database supporting pesticide registrations. At the time, EPA was also on the verge of promulgating for the first time the data requirements supporting registration. Shortly after subpart E was promulgated in August 1984, EPA promulgated a final rule on data requirements (October 24, 1984; 49 FR 42881) (FRL–2591–5).

In acknowledgement of the fact that many of these data requirements were to be satisfied during the reregistration process, the data compensation provisions of subpart E explicitly provide a procedure to satisfy a data requirement for which data have not yet been submitted—the data gap procedures in 40 CFR 152.96. In essence, an applicant can satisfy a data requirement by documenting that no data have been submitted to fulfill the data requirement. The applicant does so by writing to data submitters and requesting verification that they have not submitted data to satisfy the data requirement. Data submitters are not required to respond to such requests, but lose the right to later challenge the applicant's data gap claim if they do not respond.

As noted, however, the processes for review of existing pesticides have evolved significantly over the years, and most data gaps have been eliminated by the submission of data under the reregistration program. Few, if any, applicants can legitimately claim a data gap for a pesticide that has undergone reregistration. The absence or availability of data is evident because the data are likely to be listed in an Agency decision document such as a RED. Moreover, in EPA's experience, the data gap procedures are rarely used, even when data gaps were much more common.

Although there may be circumstances when an applicant may legitimately claim that a data gap exists, EPA believes the required data gap documentation process is no longer needed because: (1) As noted above, most data gaps have been eliminated; and (2) EPA is in a much better position today to evaluate the legitimacy of data gap claims because of its reregistration program. Consequently, EPA proposes to eliminate 40 CFR 152.96(b) and 40 CFR 152.96(c).

EPA will continue to allow a claim of a data gap to satisfy an initial screen of an application, but will not require the submission of the certification of data gap procedures. EPA will also scrutinize such claims carefully, as it believes that few such claims can be supported given the significant amounts of data now available for most pesticides. EPA's current regulations in 40 CFR 152.115(a) provide that any data requirement that remains legitimately unfulfilled at the time of registration is established as a condition of the registration under FIFRA section 3(c)(7), and the new registrant is required to fulfill the data requirement whenever existing registrants of similar products must do

Under the proposed rule, a data submitter would no longer routinely receive requests from applicants to confirm a data gap. However, under 40 CFR 152.119, EPA will make available 30 days after registration the means by which an applicant satisfied the data requirements, including whether, under the selective method, the applicant claimed a data gap. A registrant thus has the means to ascertain whether he/she has submitted data that might fulfill a data requirement for which the applicant has claimed a data gap exists.

Since EPA would no longer require the data gap procedures, EPA also proposes to revise the petition procedures in 40 CFR 152.99 such that a data submitter may petition for redress on the basis of a false or improper data gap claim rather than failure to comply with the data gap procedures. EPA also proposes to eliminate 40 CFR 152.97(b) (Obligation to respond to data gap letters) since that provision will serve no purpose with the elimination of the data gap letter procedure as proposed today.

IV. FIFRA Mandated Reviews

In accordance with FIFRA sections 25(a) and (d), the Agency submitted a draft of this proposed rule to the Committee on Agriculture in the United States House of Representatives, the Committee on Agriculture, Nutrition, and Forestry in the United States Senate, the Secretary of Agriculture, and the FIFRA Scientific Advisory Panel (SAP). The SAP and the Secretary of Agriculture waived review of this proposed rule.

V. Statutory and Executive Order Reviews

A. Regulatory Review

This action is not a "significant" regulatory action under the terms of Executive Order 12866 entitled

Regulatory Planning and Review (58 FR 51735, October 4, 1993), and is therefore not subject to review by the Office of Management and Budget (OMB) under Executive Order 12866.

B. Paperwork Reduction Act

The information collection activities related to the submission of data to EPA in order to register a pesticide product are already approved by OMB under the Paperwork Reduction Act (PRA) 44 U.S.C. 3501 et seq. This action does not impose any new information collection burden. The information collection requirements, i.e., the paperwork collection activities, contained in this proposal are already approved by OMB under the following information collection requests (ICRs):

1. The activities associated with the application for a new or amended registration of a pesticide are currently approved under OMB Control No. 2070–0060 (EPA ICR No. 0277).

2. The activities associated with the generation of data for the Pesticide Data Call-In Program are currently approved under OMB Control No. 2070–0174 (EPA ICR No. 2288.01).

Copies of these OMB-approved ICRs may be obtained from Susan Aby, Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Ave., NW., Washington, DC 20460; or by calling (202) 566–1672.

Under the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number, or is otherwise required to submit the specific information by a statute. The OMB control numbers for EPA's regulations, after appearing in the preamble of the final rule, are listed in 40 CFR part 9 and 48 CFR chapter 15, and included on the related collection instrument (e.g., form or survey). EPA

has determined that this proposed rule imposes no additional information collection and paperwork burden.

These existing ÎCRs cover the paperwork activities contained in this proposal because these activities already occur as part of existing program activities.

These program activities are an integral part of the Agency pesticide program and the corresponding ICRs are regularly renewed. The total estimated average annual public reporting burden currently approved by OMB for these various activities ranges from 8 hours to approximately 3,000 hours per respondent, depending on the activity and other factors surrounding the particular pesticide product.

Comments are requested on the Agency's need for this information, the accuracy of the burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques. Send comments to EPA as part of your overall comments on this proposed action in the manner specified in Unit I. In the final rule, the Agency will address any comments received regarding the information collection requirements contained in this proposal.

B. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., after considering the potential economic impacts of this proposed rule on small entities, the Agency hereby certifies that this action will not have a significant adverse economic impact on a substantial number of small entities.

Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's proposed rule on small entities, a small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any notfor-profit enterprise which is independently owned and operated and is not dominant in its field.

This action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the

regulatory flexibility analyses is to identify and address regulatory alternatives "which minimize any significant economic impact of the rule on small entities." 5 U.S.C. 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

EPA believes that this proposed rule would not have any adverse impacts on affected small entities, because it does not alter the scope of existing pesticide data submission or citation obligations. Further, small business entities already receive the benefit of the statutory "formulators' exemption" provision which exempts qualifying applicants and registrants from most data submission and citation obligations. No changes to this provision are proposed in this action.

The proposed changes discussed in this document are expected to simplify the procedures and reduce burdens on certain data submitters. EPA has therefore concluded that this proposed rule will not have any adverse impacts on affected small entities. Of course EPA continues to be interested in the potential impacts of the procedures on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) Public Law 104–4. Therefore, this action is not subject to the requirements of UMRA.

E. Federalism

Pursuant to Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999), EPA has determined that this proposed rule does not have "federalism implications," because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in the Order. Thus, Executive Order 13132 does not apply to this proposed rule.

F. Tribal Implications

Under Executive Order 13175, entitled *Consultation and Coordination* with Indian Tribal Governments (65 FR 67249, November 6, 2000), EPA has determined that this proposed rule does not have tribal implications because it will not have any effect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in the Order. Thus, Executive Order 13175 does not apply to this proposed rule.

G. Children's Health Protection

Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997) does not apply to this proposed rule because this action is not designated as an "economically significant" regulatory action as defined by Executive Order 12866 (see Unit V.A.), nor does this action establish an environmental standard that is intended to have a disproportionate effect on children.

H. Energy Effects

This proposed rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

I. Technology Standards

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed regulation does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Environmental Justice

This proposed rule does not involve special considerations of any environmental justice related issues as delineated by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 152

Environmental protection, Administrative practice and procedure, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 18, 2010.

Lisa P. Jackson,

Administrator.

Therefore, it is proposed that 40 CFR part 152, subpart E, would be amended as follows:

1. The authority citation for part 152 continues to read as follows:

Authority: 7 U.S.C. 136–136y; subpart U is also issued under 31 U.S.C. 9701.

- 2. The title of subpart E is revised to read "Satisfaction of Data Requirements and Protection of Data Submitters' Rights."
- 3. Section 152.81 is revised to read as follows:

§ 152.81 Applicability.

- (a) Except as provided in paragraph (b) of this section, the requirements of this subpart apply to:
- (1) Each application for registration of a new product.
- (2) Each application for amended registration of a currently registered product.
- (3) Each submission in response to a Data Call-In under FIFRA section 3(c)(2)(B) for an existing registration, including, but not limited to, a product subject to reregistration under FIFRA section 4 or registration review under FIFRA section 3(g). If the Data Call-In establishes procedures for protection of data submitters' rights, recipients must comply with the specific requirements of the Data Call-In rather than the generic procedures set forth in §§ 152.85 through 152.96.
- (b) This subpart E does not apply to any of the following:
- (1) An application for registration submitted to a State under FIFRA section 24(c).
- (2) An application for an experimental use permit under FIFRA section 5.
- (3) An application for an emergency exemption under FIFRA section 18.
- (4) A request for cancellation of a registration, or a request for deletion of one or more existing uses, in accordance with FIFRA section 6(f).
- (5) A modification to registration of a currently registered product that may be accomplished under the notification or non-notification provisions of § 152.46 and any procedures issued thereunder. Notwithstanding the preceding sentence, compliance with this subpart is required if the Administrator has, by written notice under § 152.46, determined that the modification may

not be accomplished by notification or non-notification.

- (6) Any type of amendment if the Administrator determines, by written finding, that Agency consideration of data would not be necessary in order to approve the amendment under FIFRA section 3(c)(5).
- (7) Compliance with Agency regulations, adjudicatory hearing decisions, notices, or other Agency announcements that unless the registration is amended in the manner the Agency proposes, the product's registration will be suspended or canceled, or that a hearing will be held under FIFRA section 6. However, this paragraph does not apply to amendments designed to avoid cancellation or suspension threatened under FIFRA section 3(c)(2)(B) or because of failure to submit data.
- 4. Section 152.83 is redesignated as § 152.82 and the introductory text of newly redesignated § 152.82 is revised to read as follows:

§ 152.82 Definitions.

For the purposes of this subpart, the definitions set forth in the Federal Insecticide, Fungicide, and Rodenticide Act, in § 152.3, and in this section apply. In addition, the term "exclusive use study" shall have the meaning set forth in § 152.83.

5. Section 152.83 is added, to read as follows:

§ 152.83 Definition of exclusive use study.

- A study is an exclusive use study if it meets the conditions of either paragraph (a) or paragraph (b) of this section.
- (a) Initial exclusive use period. A study submitted to support the registration of a product containing a new active ingredient (new chemical) or new combination of active ingredients (new combination) is an exclusive use study if all the following conditions are met:
- (1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978.
- (2) The study was submitted in support of, or as a condition of approval of, the application resulting in the first registration of a product containing such new chemical or new combination, or an application to amend such registration to add a new use.
- (3) Less than 10 years have passed (or up to 13 years, if the period of exclusive use protection has been extended under FIFRA section 3(c)(1)(F)(ii)) since the issuance of the registration for which the data were submitted.

(4) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B).

- (b) Exclusive use period for certain minor use data. A study submitted by an applicant or registrant to support an amendment adding a new minor use to an existing registration that does not retain any period of exclusive use under paragraph (b)(1) of this section is an exclusive study under FIFRA section 3(c)(1)(F)(vi) if all the following conditions are met:
- (1) The study relates solely to a minor use of a pesticide.
- (2) The applicant or registrant at the time the new use is requested has notified the Administrator that any exclusive use pesticide for the period has expired and that the study is eligible for exclusive use treatment.
- (3) Less than 10 years have passed since the study was submitted to EPA.
- (4) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B).
- (5) The minor use supported by the data has not been voluntarily canceled nor have such data been used to support a non-minor use.
- 6. Section 152.84 is revised to read as follows:

§ 152.84 When materials must be submitted to the Agency.

Information and materials required by this subpart must be submitted at the time of application, unless the application is determined not to be subject to the requirements of this subpart.

7. Section 152.86 is amended by revising paragraph (b)(2)(iv) to read as follows:

§ 152.86 The cite-all method.

(2) * * *

(iv) The applicant's name, address and contact information, including a telephone number and e-mail address.

8. Section 152.90 is amended by revising the reference in the last sentence of the introductory text from "demonstrating" to "claiming," and by revising paragraphs (a) and (b)(6) to read as follows:

§ 152.90 The selective method.

* * * * *

- (a) List of data requirements. (1) Each applicant must submit a list of the data requirements that would apply to his/her pesticide, its active ingredients, and its use patterns, if the product were being proposed for registration under FIFRA section 3(c)(5) for the first time.
- (2) The applicant must list the applicable requirements, as prescribed

by part 158 of this chapter or part 161 of this chapter, as applicable. All required (R) studies, and any studies that could be conditionally required (CR) based upon composition, use pattern, or the results of required studies, are to be listed. The applicant need not list data requirements pertaining to any ingredient which qualifies for the formulators' exemption.

- (b) * * *
- (6) Claim of a data gap. Refer to $\S 152.96$.
- 9. Section 152.91 is amended by revising paragraphs (a) and (c), to read as follows:

§ 152.91 Waiver of a data requirement.

(a) Request for extension of an existing waiver. An applicant may claim that a waiver previously granted by the Agency also applies to a data requirement for his/her product. To document this claim, the applicant must provide a reference to the Agency record that describes the previously granted waiver, such as an Agency list of waivers or an applicable Registration Standard, Reregistration Eligibility Decision document or Registration Review decision document, and explain why that waiver should apply to his/her product.

(c) Effect of denial of waiver request. A decision by the Agency to deny a written request for a new waiver or an extension of an existing waiver is a final Agency action. Following denial, the applicant must choose another method of satisfying the data requirement.

10. Section 152.95 is amended by revising the introductory text and by revising paragraph (b)(2)(v), to read as follows:

§ 152.95 Citation of all studies in the Agency's files pertinent to a specific data requirement.

An applicant normally may demonstrate compliance for a data requirement by citation of all studies in the Agency's files pertinent to that data requirement. The applicant who selects this cite-all option must submit to the Agency:

- (b) * * *
- (2) * * *
- (v) The applicant's name, address and contact information, including a telephone number and e-mail address.
- 11. Section 152.96 is revised to read as follows:

§ 152.96 Claim of data gap.

- (a) When a data gap may be claimed. Except as provided in paragraph (b) of this section, an applicant may defer his/her obligation to satisfy an applicable data requirement until the Agency requires the data if no other person has previously submitted to the Agency a valid study that would satisfy the data requirement in question.
- (b) When a data gap may not be claimed—(1) Product containing a new active ingredient. An applicant for registration of a product containing a new active ingredient may not defer his/her obligation by claiming a data gap unless he/she can demonstrate to the Agency's satisfaction that the data requirement was imposed so recently that insufficient time has elapsed for the study to have been completed and that, in the public interest, the product should be registered during the limited period of time required to complete the study. Refer to FIFRA section 3(c)(7)(C).
- (2) Product not containing a new active ingredient. An applicant for registration of a product under FIFRA section 3(c)(7)(A) or (B) (a product not containing a new active ingredient) may not defer his/her obligation by claiming a data gap if the data are:
- (i) Data needed to determine whether the product is identical or substantially similar to another currently registered product or differs only in ways that would substantially increase the risk of unreasonable adverse effects on the environment.
- (ii) Efficacy data specific to the product, if required to be submitted to the Agency.
- (iii) If a new use is proposed for a product that is identical or substantially similar to an existing product, data to demonstrate whether the new use would substantially increase the risk of unreasonable adverse effects on the environment.
- (c) Approval of application with a data gap claim. (1) In accordance with § 152.115(a), any registration that is approved based upon a data gap claim shall be conditioned on the submission of the data no later than the time that the data are required to be submitted for similar products already registered.
- (2) Notwithstanding paragraph (c)(1) of this section, the Agency will not approve an application if it determines that the data for which a data gap claim has been made are needed to determine if the product meets the requirements of FIFRA section 3(c)(5) or 3(c)(7).
- 12. Section 152.97 is revised to read as follows:

§ 152.97 Rights and obligations regarding the Data Submitters List.

(a) Each original data submitter shall have the right to be included on the Agency's Data Submitters List.

(b) Each original data submitter who wishes to have his/her name added to the current Data Submitters List must submit to the Agency the following information:

(1) Name and current address.

- (2) Chemical name, common name (if any) and CAS number (if any) of the active ingredient(s), with respect to which he/she is an original data submitter.
- (3) For each such active ingredient, the type(s) of study he/she has previously submitted (identified by reference to data/information requirements listed in part 158 of this chapter or part 161 of this chapter as applicable), the date of submission, and the EPA registration number, file symbol, or other identifying reference for which it was submitted.
- (c) Each applicant not already included on the Data Submitters List for a particular active ingredient must inform the Agency at the time of submission of a relevant study whether he/she wishes to be included on the Data Submitters List for that pesticide.
- 13. Section 152.99 is amended by removing paragraph (a)(2)(iv), redesignating paragraphs (a)(2)(v) and (a)(2)(vi) as (a)(2)(iv) and (a)(2)(v), and revising newly redesignated paragraph (a)(2)(iv) to read as follows:

§ 152.99 Petitions to cancel registration.

(a) * * * (2) * * *

(iv) The applicant has falsely or improperly claimed that a data gap existed at the time of his/her application.

[FR Doc. 2010–27906 Filed 11–4–10; 8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 450

[EPA-HQ-OW-2010-0884; FRL-9222-3]

Proposed Rule Staying Numeric Limitation for the Construction and Development Point Source Category

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to stay the numeric effluent limitation of 280 NTU and associated monitoring requirements

for the Construction and Development Point Source Category. This action is necessary so that EPA can reconsider the record basis for calculating the numeric effluent limitation. EPA plans to take final action to recalculate the numeric effluent limitation by June 29, 2011. EPA proposes to stay the 280 NTU limit and associated monitoring requirements until it takes final action to recalculate the numeric limitation.

DATES: Comments must be received on or before December 6, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2010-0884, by one of the following methods:

- http://www.regulations.gov: This is EPA's preferred approach, although you may use the alternatives presented below. Follow the on-line instructions for submitting comments.
 - E-mail: OW-Docket@epa.gov.
- Mail: USEPA Docket Center, Environmental Protection Agency, Docket Number EPA-HQ-OW-2010-0884, Mailcode 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- Hand Delivery: USEPA Docket Center, Public Reading Room, 1301 Constitution Ave., NW., Room 3334, EPA West Building, Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OW-2010-0884. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at http:// www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http:// www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through http:// www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your