each point on its outer edge or from its construction site, but may not interfere with the use of recognized sea lanes essential to navigation. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 147

Continental shelf, Marine safety, Navigation (water).

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 147 as follows:

PART 147—SAFETY ZONES

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 14 U.S.C. 85; 43 U.S.C. 1333; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 147.849 to read as follows:

§ 147.849 Safety Zone; Olympus Tension Leg Platform.

(a) *Description.* The Olympus Tension Leg Platform is in the deepwater area of the Gulf of Mexico in Mississippi Canyon Block 807B. The facility is located at 28° 9′35.59″ N, 89°14′20.86″ W. The area within 500 meters (1640.4 feet) from each point on the structure's outer edge and the area within 500 meters (1640.4 feet) of each of the supply boat mooring buoys is a safety zone.

(b) *Regulation.* No vessel may enter or remain in this safety zone except the following:

(1) An attending vessel;

(2) A vessel under 100 feet in length overall not engaged in towing; or

(3) A vessel authorized by the Commander, Eighth Coast Guard District or a designated representative.

Dated: January 10, 2014.

Kevin S. Cook,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 2014–02441 Filed 2–4–14; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 152

[EPA–HQ–OPP–2009–0456; FRL–9904–32]

RIN 2070–AJ58

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revising and updating its regulations governing the procedures for the satisfaction of data requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Specifically, this regulation addresses procedures for the protection of exclusive use and data compensation rights of data submitters, which have not been revised since issuance in 1984. These revisions are now needed to accommodate statutory changes and related changes in practice that have occurred since that time and to make minor changes to clarify the regulations.

DATES: This final rule is effective April 7, 2014.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2009–0456, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Scott Drewes, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–0107; email address: *drewes.scott@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What action is the agency taking?

EPA is revising and updating its regulations governing the procedures for the satisfaction of data requirements under FIFRA. Specifically, these provisions include procedures for the protection of exclusive use and data compensation rights of data submitters. These revisions also provide greater clarity when data compensation procedures do and do not apply, and update the regulations to be consistent with statutory changes and related changes in practice since the regulations were first promulgated in 1984.

B. What is the agency's authority for taking this action?

This action is issued under the authority of FIFRA sections 3 and 25, 7 U.S.C. 136 *et seq.*

C. Does this action apply to me?

You may be potentially affected by this action if you produce pesticide products that require registration with EPA. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include, but are not limited to: Pesticide and other agricultural chemical manufacturing (NAICS code 325320), e.g., pesticides manufacturing, insecticides manufacturing, herbicides manufacturing, fungicides manufacturing, etc.

D. What are the incremental costs and benefits of this action?

EPA did not quantify the potential costs or benefits from these revisions, which are qualitatively discussed in Unit V. EPA has determined that there are minimal incremental costs for industry to comply with the requirement that applicants submit data compensation materials at the time of application for registration. As such, EPA has concluded that the per firm and industry level impact of the rule is not significant. Benefits are derived from the efficiencies in the registration process gained by the timely submission of data compensation materials to EPA, as well as the early resolution of data compensation disputes that may arise. EPA also believes benefits accrue to applicants through the additional clarity regarding when data compensation procedures do not apply.

II. Background

A. Summary of the Proposed Rule

In the **Federal Register** of November 5, 2010 (75 FR 68297) (FRL–8424–8), EPA proposed to revise the regulations governing procedures for the satisfaction of data requirements under

FIFRA. EPA proposed to do the following:

- Replace the limited listing of actions to which subpart E does not apply with a single reference to actions that may be accomplished by notification or non-notification under § 152.46;
- Update and restructure the existing definition of exclusive use period to incorporate the additional exclusive use criteria added by the Food Quality Protection Act (FQPA) of 1996;
- Revise § 152.84 to conform to the requirements of FIFRA section (33)(f), which now requires data compensation materials to be submitted at the time of application; and
- Update the regulations to be consistent with programmatic developments since the regulations were first promulgated in 1984, including eliminating the data gap procedures, removing the reference to Registration Standards, and adding email as a means of contacting data submitters.

B. Public Comments and EPA Responses

EPA has considered the comments received on the proposed rule, and provided responses in a Response to Comments document, which is available in the docket for this rulemaking. Many commenters requested the Agency to make additional revisions that were outside the scope of the proposed rule. Only the key comments within the scope of the proposed rule and the Agency's responses are discussed in this document.

1. *Data submitters rights under a Data Call-In (DCI).* Two commenters questioned how data submitters' rights would be addressed under a DCI. EPA proposed to specify in the applicability section of the regulation at 40 CFR 152.81(a)(3) that when a DCI itself establishes procedures for the protection of data rights, recipients of the DCI must follow the procedures established in the DCI rather than the procedures set forth in subpart E. The commenters argued that the proposed revisions would nullify the protections afforded by the administrative process used to develop subpart E and could result in the establishment of arbitrary procedures.

In response, EPA notes that the Agency did not intend to suggest that the data protections of FIFRA section 3(c)(1)(F) do not apply to data submitted in response to a DCI. The purpose of the proposed amendment to § 152.81(a)(3) was to clarify and codify the Agency's existing practices for ensuring protection of data rights in connection with the issuance of DCIs. EPA's intent in adding the reference to FIFRA section 3(c)(2)(B) was simply to make clear that DCIs are actions subject to the data compensation provisions of FIFRA and to acknowledge that EPA, pursuant to its authority under FIFRA section 3(c)(2)(B), generally establishes compliance procedures in the DCIs it issues. EPA believes it is generally simpler and more efficient to include provisions for the protection of data in the DCIs themselves in order to provide recipients with a single set of instructions for satisfying the terms of a DCI. Further, because the process and timing for complying with DCIs under FIFRA section 3(c)(2)(B) differs from the process for obtaining a new registration, EPA believes it generally makes sense to tailor the instructions for addressing the data protection requirements of FIFRA to fit the structure of the DCI compliance process. As a practical matter, the procedures EPA establishes for the protection of data rights in DCIs track those in subpart E because, as the commenter points out, the protections of FIFRA section 3(c)(1)(F) apply with equal force to data submitted under FIFRA section 3(c)(2)(B). Thus, this provision does not have any substantive impact on the protection EPA extends to data submitted to the Agency under FIFRA.

2. *List of amendments excluded from the scope of subpart E.* A commenter asked the Agency to provide a single source of current, appropriately updated and readily available guidance that specifies actions that do not require compliance with subpart E.

In response, EPA notes that it proposed to revise § 152.81(b) by removing the list of amendments in § 152.81(b)(4) that do not require compliance with subpart E and instead refer to the notification and non-notification provisions of § 152.46. Through proposed § 152.81(b)(6), however, EPA retains its ability to exclude from the provisions of subpart E ''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).''

The proposed revisions to § 152.81(b) would not change the scope of subpart E. As EPA explained in the preamble to the proposed amendments, data submission obligations—and therefore compliance with the data protection procedures of the subpart E regulations—only apply where review of an application requires EPA consideration of scientific data in order to make a FIFRA regulatory determination. Because it would be difficult to create an exhaustive list of possible registration amendment actions that do not require review of data, EPA believes it is simpler and less confusing to make that principle clear in the regulations without also including what, in the existing regulations, was a non-exhaustive list of such amendments. Further, EPA believes the regulation's express exclusion of registration amendments subject to the notification and non-notification provisions of § 152.46 from these data protection procedures effectively addresses the majority of amendment actions not requiring consideration of scientific data. A list of those actions can be found in Pesticide Registration (PR) Notice 98–10, available on the Internet at *http://www.epa.gov/PR_Notices/pr98-10.pdf.* PR Notice 98–10 was developed pursuant to § 152.46 specifically to identify minor registration amendments that may be made by notification or non-notification without the need for Agency review of scientific data and are, therefore, not subject to the subpart E data protection procedures. EPA believes it is appropriate to address other circumstances where scientific review of data is not required on a case-by-case basis in connection with specific amendment requests. EPA is finalizing the language in § 152.81(b) as proposed.

3. *Authorization for use of exclusive use studies for tolerances or tolerance exemptions.* A commenter proposed that EPA require applicants to submit authorizations for use of exclusive use studies to the Agency prior to registration or the Agency's granting of a tolerance or tolerance exemption if the Agency identifies any exclusive use data submitted on the Data Submitter's List.

In response, EPA notes that the regulations at §§ 152.86(a) and 152.93(b) already require applicants for FIFRA registration to certify prior to registration that they have obtained permission for the citation of any exclusive use studies. EPA believes that the certification process under those provisions has been effective in ensuring that necessary authorizations have been obtained and there is no need to require submission of the actual documentation to EPA.

EPA notes that the commenter's request to extend the proposal to apply to the issuance of tolerances and tolerance exemptions goes beyond the scope of EPA's proposal. EPA did not propose to make changes to the portion of the regulations addressing the types of regulatory approvals that are subject to the subpart E procedures. This comment therefore goes beyond the scope of EPA's proposal.

In 2003, EPA addressed the substance of this comment when it announced in the **Federal Register** of April 17, 2003 (68 FR 18977) (FRL–7279–9) the availability of a white paper, ''Proposal for Implementing Data Compensation Rights for Data Submitted in Support of Tolerance or Tolerance Exemption Actions,'' discussing a program to enable the Agency to appropriately implement the new provisions contained in section 408(i) of the Federal Food, Drug, and Cosmetic Act (FFDCA) to address exclusive use and compensation rights for data submitted to EPA in support of tolerance and tolerance exemption actions. In that white paper, EPA made clear that FFDCA section 408(i) extends exclusive use and data compensation rights to data submitted to support or maintain tolerances and tolerance exemptions to the same extent provided by FIFRA section 3. It is, however, important to understand how and when FFDCA data are protected by EPA. While FFDCA section 408(i) bestows protections to data submitted under FFDCA, EPA protects those rights through the FIFRA registration process when an application for a pesticide registration is submitted, not when a tolerance or tolerance exemption is sought. Tolerances and tolerance exemptions are rulemaking actions, not licenses issued to individuals that sell or distribute pesticides or pesticide ingredients. Unlike FIFRA, the FFDCA rulemaking process does not, therefore, provide EPA with a means of ensuring compliance with exclusive use and compensation requirements by all persons who may sell or distribute a product that is covered by a tolerance or tolerance exemption. For this reason, EPA ensures compliance with exclusive use and data compensation obligations in connection with the submission of an application for registration or amended registration under FIFRA and not in connection with the issuance of a FFDCA tolerance or tolerance exemption.

4. *When materials must be submitted.* Several commenters addressed EPA's proposal to amend § 152.84 to require submission of all data compensation compliance information and materials, including evidence of any necessary offers to pay compensation, at the time of application rather than ''at any later time prior to EPA's approval of the application.''

In response, EPA notes that the commenters were split regarding EPA's proposal to require submission of all data compliance information and materials at the time of application. As EPA explained in the preamble to the proposed rule, the Agency proposed this change to conform the implementing regulations with the requirements of FIFRA section 33(f)(4) (as amended by the Pesticide Registration Improvement Renewal Act (PRIA II), Pub. L. 110–94, commonly called PRIA II). Because FIFRA section 33(f)(4)(B) directs EPA to determine during the initial screen (within 21 days after receiving the required registration service fee) that ''the application contains all the necessary forms, data, and draft labeling,'' EPA believes that completed data citation forms must be submitted at the time of application. In addition, EPA also cited a policy rationale in support of this proposed amendment, noting that the Agency's primary rationale for previously allowing data compensation materials to be submitted after submission of the application—the time-consuming data gap certification process—was being eliminated from the regulations.

The commenters objecting to EPA's proposal argued that, contrary to EPA's position, FIFRA section 33(f)(4) leaves EPA with discretion to determine what contents of the application constitute a ''complete application.'' They also argued that the Agency's ability to conduct reviews of applications would not be limited in any way by allowing applicants to submit offers to pay throughout the application review process. This group of commenters' primary concern with the proposed change appeared to be that it may provide a greater opportunity for data submitters to seek compensation and file data compensation petitions before uncertainties involving EPA's ''substantial similarity'' determinations and related data issues have been resolved. To that end, these commenters asked that EPA maintain the current language, or that EPA consider an alternative to the proposed amendment whereby applicants would be required to provide notice to data submitters of their intent to file applications for registration, but would not be compelled to tender any associated offers to pay compensation unless and until EPA reviewed and accepted the applicant's citations to data. They argued that this alternative would not delay EPA's review, since review of the offer to pay certification is merely an ''administrative function'' and they asserted that this alternative could minimize unnecessary and premature data compensation disputes.

The commenters supporting EPA's proposed amendment agreed with EPA's interpretation of PRIA II that completed data compensation materials must be submitted as part of the initial application. They also argued that allowing applicants to delay submitting required offers ''until the eve of registration'' effectively reads the right to petition to deny an application out of EPA's regulations and deprives EPA of the assistance of the original data submitter in meeting EPA's obligation to determine that the applicant has submitted or cited all necessary data, consistent with the requirements of FIFRA section 3(c)(1)(F) and §§ 152.80 through 152.99.

EPA continues to believe that Congress clearly addressed this issue with the passage of PRIA II and must therefore reject those comments seeking that EPA maintain § 152.84 in its current form. There is no dispute that FIFRA section 3(c)(1)(F) requires applicants for registration or amended registration to offer to pay compensation to original data submitters when the application seeks to rely on previously submitted data that are subject to FIFRA compensation requirements. EPA requires applicants to submit a data certification form to demonstrate that any required offer to pay compensation has been made. There can be little question, therefore, that the data certification form is a ''necessary form'' within the meaning of FIFRA section 33(f)(4)(B) and that, consistent with the requirements of that section, these forms must be submitted at the time of application.

With the recent passage of the Pesticide Registration Improvement Act of 2012 (Pub. L. 112–177), Congress has only made it more clear that a completed data certification form must be submitted at the time of application. Specifically, FIFRA section 33(f)(4)(B)(iv)(II) now expressly provides that an application is only considered complete for purposes of the preliminary technical screening required by FIFRA section 33 if the Administrator determines that ''the application, data, or information are consistent with the proposed labeling and any proposal for a tolerance or exemption from the requirement of a tolerance . . . and are such that, subject to full review under the standards of this Act, could result in the granting of the application.'' (emphasis added). Since EPA cannot lawfully grant an application in the absence of ensuring that an applicant has made all necessary offers to pay or received any required letters of authorization to cite data, it is clear that EPA cannot consider as complete applications that do not include a completed data certification form. Consistent with the requirements of FIFRA section 33(f)(4)(B)(ii), EPA is required to reject applications that do not include completed data certification

forms and therefore cannot permit applicants to submit certifications ''at any later time prior to the approval of the application,'' as previously provided in § 152.84.

Further, even if EPA had discretion to consider the alternative approach offered by the commenters, EPA does not believe that approach promotes the efficient and effective review of applications. The notion that certain portions of applications should continue to come in piecemeal to EPA is not consistent with the prompt and efficient FIFRA application process envisioned by PRIA. In addition, ensuring that all necessary offers to pay are made is not simply an ''administrative function,'' but an obligation that lies at the core of EPA's duty to ensure compliance with the data protection provisions of FIFRA section 3(c)(1)(F). EPA believes that providing data submitters with the required offers to pay at the beginning of the application process rather than at the end of that process can serve to assist EPA in ensuring that the Agency meets its FIFRA section 3(c)(1)(F) obligations and can serve to encourage early resolution of data compensation disputes. While EPA understands the reasoning why some commenters would prefer to engage in those disputes after an application has been granted rather than before, EPA does not believe this is a policy objective reflected in FIFRA, nor was it EPA's objective when it promulgated the original regulation that allowed data compensation materials to be submitted after the initial application. The basis for that provision was largely to avoid the delay applicants could encounter as a result of the data gap certification process. And, as noted, EPA has eliminated the data gap process with these amendments.

5. *Electronic means of contacting data submitters.* Two commenters sought clarification as to whether the proposal to require offers to pay to include the applicant's email address applied to data submitters, as the title of this section in the preamble to the proposed rule might have suggested, or whether it was meant to apply only to applicants that are submitting offers to pay compensation. The commenters further asserted that they believe that it would not be appropriate or sufficient to allow electronic notification as the sole method of delivering offers to pay data submitters.

In response, EPA notes that the provision proposed in §§ 152.86 and 152.95 that creates a requirement to include an email address as an additional point of contact is part of the ''offer to pay'' requirement that is applicable to applicants, not to data submitters. EPA agrees that the title of this section in the preamble of the proposed rule may have created some confusion, but EPA believes the proposed provisions of the rule are clear that the obligation to provide an email address is part of the offer to pay requirement. EPA also notes that it inadvertently omitted this language from the offer to pay provision in proposed § 152.93(b)(2)(v) and has included it in the final rule.

In response to the commenters' final point, it was not EPA's intent in the proposed rule to prescribe or limit the means by which an applicant delivers offers to pay to data submitters and the regulations in subpart E have not limited the forms of delivery that may be used. EPA recognizes the efficiencies afforded by email, and the Agency believes that, given advances in technology, it would be inappropriate to preclude email as a means of communication between applicants and data submitters, including submission of offers. Provided the applicant can produce evidence of delivery of the offer to the original data submitter, EPA does not believe FIFRA prescribes a precise method of delivery.

Consistent with this view, in this final rule EPA is amending the language in § 152.99(b)(2) requiring that data compensation petitions be sent by certified mail, to allow the use of any method that provides evidence of delivery.

6. *Source of list of data requirements.* Several commenters requested EPA to clarify when Reregistration Eligibility Decision documents (REDs) and registration review decision documents can be relied on to determine registration data requirements and to determine what data are compensable.

In response, EPA notes that the Agency proposed in the November 5, 2010 **Federal Register** document to eliminate from § 152.90(a) the requirement that an applicant use an issued Registration Standard, the EPA reregistration decision documents issued prior to 1988, as the source of its list of data requirements for the selective method. Further, § 152.90(a) indicated that if the Registration Standard does not address all required data or there is no Registration Standard, the applicant must refer to the data requirements in 40 CFR part 158 as the alternate source of its list of data requirements.

As explained in the preamble to the proposed rule, the form of EPA decision documents has evolved since the 1984 regulations were promulgated. Registration Standards were superseded beginning in 1988 by 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 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 explained that it no longer intends to 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. Accordingly, the Agency concluded that § 152.90(a)(2) should be revised to require applicants to list the applicable EPA data requirements at 40 CFR part 158.

The commenters expressed concern that this amendment could be interpreted to allow selective citations to exclude data requirements that are not explicitly included in EPA's codified data requirements but that may have otherwise been required in connection with registration, reregistration, or registration review actions and reflected in Agency decision documents such as REDs. The commenters, therefore, asked EPA to reinforce that its data regulations are flexible and that the Agency can and often does impose additional requirements beyond those found explicitly in the data tables. EPA agrees with these comments, but does not believe there is any need to alter the language of the amendment as proposed. It was not EPA's intention to suggest that in all cases the data tables in 40 CFR part 158 will constitute the exclusive list of required data that applicants utilizing the selective method of citation must satisfy. In fact, EPA's data regulations make it explicitly clear that the regulations are intended to be flexible and that EPA reserves the right to require additional data, or, in some instances, to waive studies that EPA concludes are not relevant to its registration decision under FIFRA. It is EPA's intention that the reference to 40 CFR part 158 in amended § 152.90(a)(2) incorporate this principle. Accordingly, where EPA has imposed additional requirements beyond those listed in the 40 CFR part 158 data tables, applicants will be required to satisfy those requirements, consistent with the requirements of subpart E. Conversely, where EPA determines that a requirement can be waived or that

alternative information to that listed in the data tables can serve to satisfy the data requirement, applicants will not be required to satisfy the requirements as set forth in the data tables. As noted in the preamble, given the flexibility of the data regulations, 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.

7. *Elimination of certification and documentation procedures for data gaps.* One commenter noted that, in the preamble to the proposed rule, the Agency states that a data submitter would no longer routinely receive requests from applicants to confirm a data gap, but that, under § 152.119 the Agency ''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.'' The commenter contended that this puts a burden upon data submitters to search for Agency actions that may be affected. Further, the commenter questioned how the Agency proposes to make such information available and whether the information will be available for all applications for new or amended registrations that rely upon the selective method or only for certain ones.

In response, EPA notes that while it is true that in the absence of receiving a data gap letter, the data submitter will not necessarily know at the time of application whether the applicant is claiming that a data gap exists, EPA believes there are numerous means to ensure protection of a data submitter's interest in compensable data should an applicant incorrectly assert that a data gap exists. First, as noted in the preamble to the proposed rule, with the completion of reregistration and the development of REDs for all pesticides that list by guideline the data received and reviewed by EPA, the Agency is now in a far better position to evaluate the legitimacy of data gap claims than it was when it issued the existing data compensation regulations in 1984. Second, data submitters will often have prior notice that an applicant is seeking registration when they receive offers to pay compensation for any data for which a data gap is not claimed. If they believe the offer to pay they receive should also extend to previously submitted studies not included in the offer, the data submitter can file a petition to deny the application under § 152.99. Finally, once a registration is issued, the data submitter may obtain a copy of any applicant's data compliance materials through the Freedom of Information Act, as provided in § 152.119 and consistent with EPA's information regulations at 40 CFR part 2. With that information, the data submitter can then file a petition to cancel under § 152.99 if the data submitter believes the Agency improperly accepted the applicant's data gap claim in lieu of citing data belonging to the data submitter.

III. The Final Rule

With the exception of the modifications discussed in the Unit II.B., EPA is finalizing the rule in essentially the same form as the proposed rule. The final rule does the following:

- Provides greater clarity when data compensation requirements do not apply by highlighting actions that do not require a scientific review of data and thus do not require satisfaction of data requirements;
- Updates the definition of an ''exclusive use study'' to incorporate the additional exclusive use criteria added by the FQPA;
- Conforms to the requirements of FIFRA section 33(f)(4), as most recently amended by PRIA II, by requiring applicants to submit data compensation materials at the time of application;
- Removes the outdated requirement that applicants use a Registration Standard for determining which data requirements need to be satisfied for a particular pesticide; instead, applicants will simply be directed to the data requirement listings in 40 CFR part 158; and
- Updates the regulations to be consistent with Agency practices since the regulations were first promulgated in 1984.

IV. FIFRA Review Requirements

In accordance with FIFRA sections 25(a) and (d), the Agency submitted a draft of this final rule to the appropriate Congressional Committees, the Secretary of Agriculture, and the FIFRA Scientific Advisory Panel (SAP). The SAP and the Secretary of Agriculture waived review of this rule.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

On May 5, 2011, the Office of Management and Budget (OMB) determined that this action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993), and is therefore not subject to review by OMB under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burdens that require additional review or approval by OMB under PRA, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are displayed in the **Federal Register** and are listed in 40 CFR part 9.

The information collection requirements contained in this rule are already approved by OMB under OMB control numbers 2070–0060 (EPA ICR No. 0277) and 2070–0174 (EPA ICR No. 2288.01). Since there is no new burden, it was not necessary to amend the Information Collection Requests (ICRs).

C. Regulatory Flexibility Act (RFA)

Pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.),* after considering the potential economic impacts of this 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. For purposes of assessing the impacts of this 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.

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

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 the final rule would not have any adverse impacts on affected small entities, because the revisions are of minimal impact and do not increase activities or related burden. The revisions change the timing, but do not alter the substance of the existing pesticide data submission or citation obligations. The revisions are expected to simplify the procedures for the satisfaction of data requirements. 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. EPA has therefore concluded that the final rule will not have any adverse impacts on affected small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of UMRA (2 U.S.C. 1531–1538). Therefore, this action is not subject to the requirements of UMRA.

E. Executive Order 13132: Federalism

This action does not have a 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 Executive Order 13132 (64 FR 43255, August 10, 1999). Since States or local governments are rarely pesticide applicants or registrants, this final rule may seldom affect a State or local government. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications because it does not have any effect on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000) do not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not an economically significant regulatory action as defined by Executive Order 12866, nor does it establish an environmental standard that is intended to mitigate health or safety risks, nor would it otherwise have a disproportionate effect on children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This final rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have any adverse effect on the energy supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This final rule does not impose any technical standards that would require Agency consideration of voluntary consensus standards provided in section 12(d) of the NTTAA, 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This rule only impacts entities that intend to register or currently hold registrations for pesticides. It does not involve special consideration of any environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

VI. Congressional Review Act (CRA)

Pursuant to the CRA, 5 U.S.C. 801 *et seq.,* EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 152

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

Dated: January 27, 2014.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR part 152, subpart E is amended as follows:

PART 152—PESTICIDE REGISTRATION AND CLASSIFICATION PROCEDURES

■ 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. Revise the heading of subpart E to read as follows:

Subpart E—Satisfaction of Data Requirements and Protection of Data Submitters' Rights

■ 3. Revise § 152.81 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 the Federal Insecticide, Fungicide, and Rodenticide Act (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 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 (EUP) 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, under 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.

§ 152.83 [Redesignated as § 152.82]

■ 4. Redesignate § 152.83 as § 152.82.

■ 5. Amend newly redesignated § 152.82 by revising the introductory text and removing the definition for ''Exclusive use study''.

The amendments read as follows:

§ 152.82 Definitions.

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

* * * * *

■ 6. Add § 152.83 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 a 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 the Federal Insecticide, Fungicide, and Rodenticide Act (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 period for the pesticide 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.

■ 7. Revise § 152.84 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.

■ 8. In § 152.86, revise paragraph (b)(2)(iv) to read as follows:

§ 152.86 The cite-all method.

* * * * *

(b) * * *

(2) * * *

(iv) The applicant's name, address, and contact information, including telephone number and email address.

* * * * *

■ 9. In § 152.90, revise the last sentence of the introductory text and paragraphs (a) and (b)(6) to read as follows:

§ 152.90 The selective method.

* * * Sections 152.91 through 152.96 contain specific procedures for citing or submitting a study or claiming a data gap.

(a) *List of data requirements.* (1) Each applicant must submit a list of the data requirements that would apply to his pesticide, its active ingredients, and its use patterns, if the product were being proposed for registration under the Federal Insecticide, Fungicide, and Rodenticide Act (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, 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 data gap. Refer to § 152.96.

■ 10. In § 152.91, revise paragraphs (a) and (c) to read as follows:

§ 152.91 Waiver of a data requirement.

* * * * *

(a) *Request for an extension of an existing waiver.* An applicant may claim that a waiver previously granted by the Agency also applies to a data requirement for the 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 Reregistration Eligibility Decision (RED) document or registration review decision document, and explain why that waiver should apply to the 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.

■ 11. In § 152.93, revise paragraph (b)(2)(v) to read as follows:

§ 152.93 Citation of a previously submitted valid study.

* * * * *

(b) * * *

(2) * * *

(v) The applicant's name, address, and contact information, including a telephone number and email address.

* * * * *

■ 12. In § 152.95, revise the introductory text and 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 email address.

* * * * *

■ 13. Revise § 152.96 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 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 obligation by claiming a data gap unless he 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 the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(7)(C).

(2) *Product not containing a new active ingredient.* An applicant for registration of a product under FIFRA sections 3(c)(7)(A) or (B) (a product not containing a new active ingredient) may not defer his 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 sections 3(c)(5) or (7).

■ 14. Revise § 152.97 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 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 Chemical Abstracts Service (CAS) number (if any) of the active ingredients(s), with respect to which he is an original data submitter.

(3) For each such active ingredient, the type(s) of study he has previously submitted (identified by reference to data/information requirements listed in part 158 of this chapter), 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 the submission of a relevant study whether he wishes to be included on the Data Submitters List for that pesticide.

■ 15. In § 152.99:

■ a. Remove paragraph (a)(2)(iv).

■ b. Redesignate paragraphs (a)(2)(v) and (a)(2)(vi) as paragraphs (a)(2)(iv) and (a)(2)(v).

■ c. Revise newly redesignated paragraph (a)(2)(iv) and paragraph (b)(2).

The amendments 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 application.

(b) * * *

(2) *Notice to affected registrant.* At the same time that the petitioner files his petition with the Agency, the petitioner shall send a copy to the affected applicant or registrant by certified mail or by any other method that provides evidence of delivery. The affected applicant or registrant shall have 60 days from the date of receipt of the petition to submit written comments to the Agency.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0668; FRL–9388–7]

Cyantraniliprole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyantraniliprole in or on multiple commodities that are identified and discussed later in this document. E.I. du Pont de Nemours & Company (DuPont) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 5, 2014. Objections and requests for hearings must be received on or before April 7, 2014, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0668, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION: