

establishing the project partnership, entities, including the project coordinator, evaluator, and service provider, but excluding investors, must be procured following procurement standards set forth in 2 CFR 200.317 through 200.326.

\* \* \* \* \*

[FR Doc. 2020-11915 Filed 6-23-20; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 81

[EPA-R09-OAR-2020-0151; FRL-10010-56-Region 9]

### Finding of Failure To Attain the 1987 24-Hour PM<sub>10</sub> Standard; Reclassification as Serious Nonattainment; Pinal County, Arizona

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking final action to determine that the West Pinal County, Arizona nonattainment area did not attain the 1987 24-hour national ambient air quality standards (NAAQS or “standard”) for particulate matter with a diameter of ten micrometers or smaller (PM<sub>10</sub>) by December 31, 2018, the statutory attainment date for the nonattainment area. This action is based on the EPA’s calculation of the PM<sub>10</sub> design value for the nonattainment area over the 2016–2018 period, using complete, quality-assured, and certified PM<sub>10</sub> monitoring data. With this final determination that West Pinal County has failed to attain the PM<sub>10</sub> NAAQS by its attainment date, the Clean Air Act (CAA) section 188(b)(2) requires that the nonattainment area be reclassified to Serious by operation of law. Within 18 months from the effective date of this reclassification to Serious, the State must submit State Implementation Plan (SIP) revisions that comply with the statutory and regulatory requirements for Serious PM<sub>10</sub> nonattainment areas.

**DATES:** This rule will be effective on July 24, 2020.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA-R09-OAR-2020-0151. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

**FOR FURTHER INFORMATION CONTACT:** Jerry Wamsley, EPA Region IX, (415) 947-4111, [wamsley.jerry@epa.gov](mailto:wamsley.jerry@epa.gov).

**SUPPLEMENTARY INFORMATION:** Throughout this document, “we”, “us”, and “our” refer to the EPA.

### Table of Contents

- I. Summary of the Proposed Action
- II. Public Comments and EPA Responses
- III. Final Action
- IV. Statutory and Executive Order Reviews

#### I. Summary of the Proposed Action

On April 7, 2020, the EPA proposed to determine that the West Pinal County nonattainment area failed to attain the 1987 24-hour PM<sub>10</sub> NAAQS by December 31, 2018, the statutory attainment date for the area.<sup>1</sup> For a PM<sub>10</sub> nonattainment area classified as Moderate under the CAA, such as the West Pinal County area, section 188(c) of the CAA states that the area’s attainment date is “as expeditiously as practicable, but no later than the end of the sixth calendar year after the area’s designation as nonattainment.” Consequently, the applicable attainment date for West Pinal County, designated nonattainment in 2012, was December 31, 2018. CAA section 188(b)(2) requires the EPA to determine whether any PM<sub>10</sub> nonattainment area classified as Moderate attained the 24-hour PM<sub>10</sub> NAAQS by the area’s attainment date and requires the EPA to make such a determination within six months after that date.

Our proposed determination that the West Pinal County area failed to attain the PM<sub>10</sub> NAAQS was based on complete, quality-assured, and certified PM<sub>10</sub> monitoring data for the appropriate three-year period, 2016–2018. As discussed in our proposal, an area attains the 24-hour PM<sub>10</sub> standard of 150 micrograms per cubic meter (µg/m<sup>3</sup>) when the expected number of days per calendar year with a 24-hour concentration exceeding the standard, referred to as an “exceedance”, averaged over a three-year period is equal to or less than one.

In our proposal, the EPA’s evaluation of whether the West Pinal County nonattainment area has met the 1987 24-

hour PM<sub>10</sub> NAAQS was based on our review of the monitoring data, the adequacy of the PM<sub>10</sub> monitoring network in the nonattainment area, and the reliability of the data collected by that network. The PM<sub>10</sub> standard is attained when the expected number of exceedances, averaged over a three-year period, is less than or equal to one. The expected number of exceedances averaged over a three-year period at any given monitor is known as the PM<sub>10</sub> design value for that site. The PM<sub>10</sub> design value for the nonattainment area is the highest design value from a monitor within that area. Three consecutive years of air quality data are required to show attainment of the PM<sub>10</sub> standard.

We reviewed the 2018 PM<sub>10</sub> design values for all regulatory monitoring sites measuring PM<sub>10</sub> within the West Pinal County nonattainment area, expressed as a single value representing the average expected exceedances over the three-year period, 2016–2018.<sup>2</sup> The PM<sub>10</sub> data showed that the design values at multiple monitoring sites are greater than 1.0 estimated annual average exceedances of the 1987 24-hour PM<sub>10</sub> NAAQS. Consequently, the EPA proposed to determine, based upon three years of complete, quality-assured and certified data from 2016–2018, that the West Pinal County nonattainment area did not attain the 1987 24-hour PM<sub>10</sub> NAAQS by the applicable attainment date of December 31, 2018.

In our proposal to determine that the West Pinal County area did not attain the NAAQS by the relevant attainment date, the EPA noted that the consequence of our determination is that the West Pinal County area will be reclassified as a Serious PM<sub>10</sub> nonattainment area by operation of law and will be subject to all applicable Serious area attainment planning and nonattainment New Source Review requirements. This includes the requirement to submit a Serious area air quality plan within 18 months of the effective date of our final rule, per section 189(b)(2) of the CAA. This Serious area air quality plan must demonstrate attainment of the 24-hour PM<sub>10</sub> NAAQS by December 31, 2022, ten years after the area’s designation to nonattainment, per section 188(c)(2) of the CAA.

<sup>2</sup> A design value is calculated using a specific methodology from monitored air quality data and is used to compare an area’s air quality to a NAAQS. The methodologies for calculating expected exceedances for the 24-hour PM<sub>10</sub> NAAQS are found in 40 CFR part 50, Appendix K, Section 2.1(a).

<sup>1</sup> 85 FR 19408 (April 7, 2020).

## II. Public Comments and EPA Responses

The public comment period on the proposed rule opened on April 7, 2020, the date of its publication in the **Federal Register**, and closed on May 7, 2020. During this period, the EPA received one comment letter submitted by the Sierra Club and The Arizona Center for Law in the Public Interest (ACLIPI). The Sierra Club and ACLIPI comment letter expressed support for our proposal and suggested that the EPA take our final action without delay. A copy of this comment letter is included in the docket for this final action.

## III. Final Action

In accordance with section 188(b)(2) of the CAA, the EPA is taking final action to determine that the West Pinal County Moderate nonattainment area did not attain the 1987 24-hour PM<sub>10</sub> NAAQS by its applicable attainment date of December 31, 2018. Our determination that West Pinal County failed to attain the PM<sub>10</sub> NAAQS is based on complete, quality-assured, and certified PM<sub>10</sub> monitoring data for the appropriate three-year period, 2016–2018.

As a result of our determination of failure to attain the 1987 24-hour PM<sub>10</sub> NAAQS by its applicable attainment date, West Pinal County is reclassified as a Serious PM<sub>10</sub> nonattainment area by operation of law and is subject to all applicable Serious area attainment planning and nonattainment New Source Review requirements, in accordance with section 188(b)(2) of the CAA. This includes the requirement to submit a Serious area air quality plan within 18 months of the effective date of our final rule, per section 189(b)(2) of the CAA. This Serious area air quality plan must demonstrate attainment of the 24-hour PM<sub>10</sub> NAAQS by December 31, 2022, ten years after the area's designation to nonattainment, per section 188(c)(2) of the CAA.

## IV. Statutory and Executive Order Reviews

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

This action is not a significant regulatory action under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011), and therefore was not submitted to the Office of Management and Budget (OMB) for review.

### B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because it is not a significant regulatory action under Executive Order 12866.

### C. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501–3521) because it does not contain any information collection activities.

### D. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612. This action will not impose any requirements on small entities. This action requires the state to adopt and submit SIP revisions to satisfy the statutory requirements that apply to Serious areas and would not itself directly regulate any small entities. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

### E. Unfunded Mandates Reform Act

This action does not contain any unfunded mandate of \$100 million or more and does not significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531–1538). This action itself imposes no enforceable duty on any state, local, or tribal governments, or the private sector. This action determines that the West Pinal County nonattainment area failed to attain the 1987 24-hour PM<sub>10</sub> NAAQS by its applicable attainment date, triggering reclassification as a Serious nonattainment area and existing statutory timeframes for the state to submit SIP revisions. Such a reclassification in and of itself does not impose any federal intergovernmental mandate.

### F. Executive Order 13132: Federalism

This action does not have federalism implications. 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 Executive Order 13132 (64 FR 43255, August 10, 1999). The requirement to submit SIP revisions to meet the 1987 24-hour PM<sub>10</sub> NAAQS is imposed by the

CAA. This final rule does not alter the distribution of power and responsibilities established in the CAA. Thus, Executive Order 13132 does not apply to this action. In the spirit of Executive Order 13132 and consistent with EPA policy to promote communications between the EPA and state and local governments, the EPA specifically solicited comments on our prior proposed action from state and local officials.

### G. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. No areas of Indian country are located within the West Pinal County PM<sub>10</sub> nonattainment area. Therefore, no tribal areas are implicated in the area that the EPA has determined to have failed to attain the 1987 24-hour PM<sub>10</sub> NAAQS by the applicable attainment date. The CAA and the Tribal Authority Rule establish the relationship of the federal government and tribes in developing plans to attain the NAAQS, and this rule does nothing to modify that relationship. Thus, Executive Order 13175 does not apply to this action.

### H. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because the effect of this action is to reclassify the West Pinal County nonattainment area as Serious nonattainment for the 1987 24-hour PM<sub>10</sub> NAAQS triggering additional Serious area planning requirements under the CAA. This action does not establish an environmental standard intended to mitigate health or safety risks.

### I. Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use

This final rule is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) because it is not a significant

regulatory action under Executive Order 12866.

*J. National Technology Transfer and Advancement Act*

This action is not subject to the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because it does not involve technical standards.

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

Executive Order 12898 (59 FR 7629, Feb. 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. The EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. The effect of this final action is to reclassify

the West Pinal County nonattainment area as Serious nonattainment for the 1987 24-hour PM<sub>10</sub> NAAQS triggering additional Serious area planning requirements under the CAA.

*L. Congressional Review Act (CRA)*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

*M. Petitions for Judicial Review*

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 24, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for

the purposes of judicial review, does not extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

**List of Subjects in 40 CFR Part 81**

Environmental protection, Air pollution control, Intergovernmental relations, National parks, Particulate matter, Wilderness areas.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: June 8, 2020.

**John Busterud,**  
*Regional Administrator, Region IX.*

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

**PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES**

■ 1. The authority citation for part 81 continues to read as follows:

**Authority:** 42 U.S.C. 7401, *et seq.*

■ 2. In § 81.303 amend in the table “Arizona–PM–10” by revising the entry under Pinal County (part) for “West Pinal” to read as follows:

**§ 81.303 Arizona.**

\* \* \* \* \*

**ARIZONA—PM–10**

Designated area	Designation		Classification	
	Date	Type	Date	Type
* * * * *				
Pinal County (part):				
West Pinal .....	7/2/12	Nonattainment	7/24/20	Serious.
1. Commencing at a point which is the intersection of the western line of Range 2 East, Gila and Salt River Baseline and Meridian, and the northern line of Township 4 South, which is the point of beginning;				
2. Thence, proceed easterly along the northern line of Township 4 South to a point where the northern line of Township 4 South intersects the western line of Range 7 East;				
3. Thence, northerly along the western line of Range 7 East to a point where the western line of Range 7 East intersects the northern line of Township 3 South;				
4. Thence, easterly along the northern line of Township 3 South to a point where the northern line of Township 3 South intersects the western line of Range 8 East;				
5. Thence, northerly along the western line of Range 8 East to a point where the western line of Range 8 East intersects the northern line of Township 1 South;				
6. Thence, easterly along the northern line of Township 1 South to a point where the northern line of Township 1 South intersects the eastern line of Range 8 East;				
7. Thence southerly along the eastern line of Range 8 East to a point where the eastern line of Range 8 East intersects the Northern line of Township 3 South;				

## ARIZONA—PM—10—Continued

Designated area	Designation		Classification	
	Date	Type	Date	Type
8. Thence easterly along the northern line of Township 3 South to a point where the northern line of Township 3 South intersects the eastern line of Range 9 East;				
9. Thence southerly along the eastern line of Range 9 east to a point where the eastern line of Range 9 East intersects the northern line of Township 4 South;				
10. Thence easterly along the northern line of Township 4 South to a point where the northern line of Township 4 South intersects the eastern line of Range 10 East;				
11. Thence southerly along the eastern line of Range 10 East to a point where the eastern line of Range 10 East intersects the southern line of Township 5 South;				
12. Thence westerly along the southern line of Township 5 South to a point where the southern line of Township 5 South intersects the eastern line of Range 8 East;				
13. Thence southerly along the eastern line of Range 8 East to a point where the eastern line of Range 8 East intersects the northern line of Township 8 South;				
14. Thence easterly along the northern line of Township 8 South to a point where the northern line of Township 8 South intersects the eastern line of Range 9 East;				
15. Thence southerly along the eastern line of Range 9 east to a point where the eastern line of Range 9 East intersects the northern line of Township 9 South;				
16. Thence easterly along the northern line of Township 9 South to a point where the northern line of Township 9 South intersects the eastern line of Range 10 East;				
17. Thence southerly along the eastern line of Range 10 East to a point where the eastern line of Range 10 East intersects the southern line of Township 9 South;				
18. Thence westerly along the southern line of Township 9 South to a point where the southern line of Township 9 South intersects the western line of Range 7 East;				
19. Thence northerly along the western line of Range 7 East to a point where the western line of Range 7 East intersects the southern line of Township 8 South;				
20. Thence westerly along the southern line of Township 8 South to a point where the southern line of Township 8 South intersects the western line of Range 6 East;				
21. Thence northerly along the western line of Range 6 East to a point where the western line of Range 6 East intersects the southern line of Township 7 South;				
22. Thence, westerly along the southern line of Township 7 South to a point where the southern line of Township 7 South intersects the quarter section line common to the southwestern southwest quarter section and the southeastern southwest quarter section of section 34, Range 3 East and Township 7 South;				
23. Thence, northerly along the along the quarter section line common to the southwestern southwest quarter section and the southeastern southwest quarter section of sections 34, 27, 22, and 15, Range 3 East and Township 7 South, to a point where the quarter section line common to the southwestern southwest quarter section and the southeastern southwest quarter section of sections 34, 27, 22, and 15, Range 3 East and Township 7 South, intersects the northern line of section 15, Range 3 East and Township 7 South;				
24. Thence, westerly along the northern line of sections 15, 16, 17, and 18, Range 3 East and Township 7 South, and the northern line of sections 13, 14, 15, 16, 17, and 18, Range 2 East and Township 7 South, to a point where the northern line of sections 15, 16, 17, and 18, Range 3 East and Township 7 South, and the northern line of sections 13, 14, 15, 16, 17, and 18, Range 2 East and Township 7 South, intersect the western line of Range 2 East, which is the common boundary between Maricopa and Pinal Counties, as described in Arizona Revised Statutes sections 11–109 and 11–113;				
25. Thence, northerly along the western line of Range 2 East to the point of beginning which is the point where the western line of Range 2 East intersects the northern line of Township 4 South;				

ARIZONA—PM—10—Continued

Designated area	Designation		Classification	
	Date	Type	Date	Type
26. Except that portion of the area defined by paragraphs 1 through 25 above that lies within the Ak-Chin Indian Reservation, Gila River Indian Reservation, and the Tohono O’odham Nation’s Florence Village and San Lucy Farms.				
*	*	*	*	*

\* \* \* \* \*  
 [FR Doc. 2020–12827 Filed 6–23–20; 8:45 am]  
 BILLING CODE 6560–50–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2020–0045; FRL–10008–92]

**Indaziflam; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of indaziflam in or on multiple commodities which are identified and discussed later in this document. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective June 24, 2020. Objections and requests for hearings must be received on or before August 24, 2020, 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–2020–0045, 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 note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service

via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

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

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. 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:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Publishing Office’s e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation

in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2020–0045 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 24, 2020. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2020–0045, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of April 15, 2020 (85 FR 20910) (FRL–10006–54), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a