date of this AD, perform a UI of affected HPT stage 1 and stage 2 disks using the Accomplishment Instructions, paragraph 3.A.(2), of GE SB 72–1562.


(3) If any disk fails the inspection required by paragraph (g)(1) or (2) of this AD, replace the disk with a part eligible for installation before further flight.

(h) No Reporting Requirements

The reporting requirements specified in the Accomplishment Instructions, paragraphs 3.A.(2)(c) and 3.A.(2)(f), of GE SB 72–1562, and paragraph 3.A.(3), of GE SB 72–0869, are not required by this AD.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k) of this AD. Information may be emailed to: ANE-AMOC@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.

(k) Related Information

For more information about this AD, contact Sungmo Cho, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7241; fax: (781) 238–7199; email: Sungmo.D.Cho@faa.gov.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.


(3) If any disk fails the inspection required by paragraph (g)(1) or (2) of this AD, replace the disk with a part eligible for installation before further flight.

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(l) Material Incorporated by Reference

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(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.
B. How can I get electronic access to other related information?


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–2017–0541 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 April 8, 2022. 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–2017–0541, by one of the following methods:

- Federal eRulemaking Portal: https://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.
- Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at https://www.epa.gov/dockets/contacts.html.

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

II. Petition for Exemption

In the Federal Register of December 15, 2017 (82 FR 59604) (FRL–9970–50), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11066) by SciReg Inc., 12733 Director’s Loop, Woodbridge, VA, 22192 on behalf of Solvay USA Inc., 504 Carnegie Center, Princeton, NJ, 08540. The petition requested that 40 CFR 180.910 and 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol (CAS Reg. No. 5660–53–7) when used as an inert ingredient (solvent/co-solvent) in pesticide formulations applied to growing crops or raw agricultural commodities after harvest under 40 CFR 180.910 and when used in antimicrobial formulations (food-contact surface sanitizing solutions) applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(a). That document referenced a summary of the petition prepared by SciReg Inc., on behalf of Solvay USA Inc., the petitioner, which is available in the docket. https://www.regulations.gov. There were no relevant comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own):

- Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted endorsed inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. When making a safety determination for an exemption for the requirement of a tolerance FFDCA section 408(c)(2)(B) directs EPA to consider the considerations in section 408(b)(2)(C) and (D). Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...” Section 408(b)(2)(D) lists other factors for EPA consideration making safety determinations, e.g., the validity, completeness, and reliability of available data, nature of toxic effects, available information concerning the cumulative effects of the pesticide chemical and other substances with a common mechanism of toxicity, and available information concerning aggregate exposure levels to the pesticide chemical and other related substances, among others.

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to the pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 2-isobutyl-2-
methyl-1,3-dioxolane-4-methanol including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol as well as the observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies

The toxicological database of 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol is supported by data regarding 2,2-dimethyl-1,3-dioxolane-4-methanol. EPA has determined that it is appropriate to bridge 2,2-dimethyl-1,3-dioxolane-4-methanol data to similarities in the manufacturing processes, functional groups/structure, composition, and physical/chemical properties, and among the available human health toxicity and ecological toxicity data of the two substances.

2-Isobutyl-2-methyl-1,3-dioxolane-4-methanol exhibits low levels of acute toxicity via the oral, dermal, and inhalation routes of exposure. In the rat, the oral LD<sub>50</sub> 7,000 mg/kg, the dermal LD<sub>50</sub> > 2,000 mg/kg, and the inhalation LC<sub>50</sub> is > 5.11 mg/L. It is not irritant to the rabbit skin. It is irritating to the rabbit eye. It is not a dermal sensitizer, it is negative for mutagenicity and the DEREK analysis indicates it is unlikely to pose a carcinogenic risk to humans. In a 6-week, repeat-dose toxicity study with reproduction/developmental screening, the maternal, offspring and reproduction NOAELs were 1,000 mg/kg/day.

There were no studies/data directly related to the possible neurotoxicity of 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol. However, evidence of potential neurotoxicity was not observed in functional observation battery (FOB) performed in the developmental study in the rat. Therefore, 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol is not expected to be neurotoxic.

There were no studies/data directly related the immunotoxic potential of 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol. There were no indications of possible immunotoxicity from the data that are available.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see https://www.epa.gov/pesticides/factsheets/riskassess.html.

The hazard profile of 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol is adequately defined. Overall, 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol is of low acute, subchronic, and developmental toxicity. No systemic toxicity is observed up to 1,000 mg/kg/day. Since signs of toxicity were not observed, no endpoint of concern was identified. Therefore, a qualitative risk assessment for 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol was conducted.

C. Exposure Assessment

1. Dietary exposure from food and feed uses.

In evaluating dietary exposure to 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol in food as follows:

Dietary exposure (food and drinking water) to 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol may occur following ingestion of foods with residues from their use in accordance with this exemption. However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

2. From non-dietary exposure. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tablets).

2-Isobutyl-2-methyl-1,3-dioxolane-4-methanol may be used in pesticide products and non-pesticide products that may be used in and around the home. Based on the discussion above regarding the low toxicity of the 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol, a quantitative residential exposure assessment was not conducted.

3. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

Based on the lack of toxicity in the available data, 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol and its metabolites are not expected to share a common mechanism of toxicity with other chemicals; therefore, section 408(b)(2)(D)(v) does not apply.

D. Safety Factor for Infants and Children

In general, Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Because there are no threshold effects associated with 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol, EPA conducted a quantitative assessment as part of that assessment, the Agency did not use safety factors for assessing risk, and no
additional safety factor is needed for assessing risk to infants and children. Based on an assessment of 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol residues.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance is established for residues of 2-isobutyl-2-methyl-1,3-dioxolane-4-methanol (CAS Reg. No. 5660–53–7) when used as an inert ingredient (solvent/co-solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 and when used in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils under 40 CFR 180.940(a).

VII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulations that Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it require any special considerations under Executive Order 12866, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, in the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (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 180

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

Dated: January 20, 2022.

Marietta Echeverria,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:


2. In § 180.910, amend Table 1 to 180.910 by adding, in alphabetical order, an entry for “2-Isobutyl-2-methyl-1,3-dioxolane-4-methanol (CAS Reg. No. 5660–53–7)” to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

<table>
<thead>
<tr>
<th>TABLE 1 TO 180.910</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inert ingredients</td>
</tr>
<tr>
<td>---------------------</td>
</tr>
</tbody>
</table>
3. In § 180.940, amend Table 1 to Paragraph (a) by adding, in alphabetical order, an entry for “2-Isobutyl-2-methyl-1,3-dioxolane-4-methanol” to read as follows:

<table>
<thead>
<tr>
<th>Inert ingredients</th>
<th>CAS Reg. No.</th>
<th>Limits</th>
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<td>2-Isobutyl-2-methyl-1,3-dioxolane-4-methanol</td>
<td>5660–53–7</td>
<td></td>
</tr>
</tbody>
</table>

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 659

[Docket No. FTA–2022–0003]
RIN 2132–AB39

Rail Fixed Guideway Systems; State Safety Oversight; Recission

AGENCY: Federal Transit Administration (FTA), Department of Transportation.

ACTION: Final rule.

SUMMARY: This rulemaking rescinds an FTA regulation for State Safety Oversight requirements. The statutory basis for this regulation was rescinded by legislation in 2012.

DATES: This final rule is effective on February 7, 2022.

FOR FURTHER INFORMATION CONTACT: Emily Jessup, Office of Chief Counsel, (202) 366–8907 or Emily.Jessup@dot.gov. Office hours are from 9 a.m. to 5:30 p.m., ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing


Background

Part 659 in title 49 of the Code of Federal Regulations contains State Safety Oversight (SSO) requirements for rail fixed guideway systems. These regulations were authorized by 49 U.S.C. 5330, State Safety Oversight, which was repealed by Section 20030(e) of the Moving Ahead for Progress in the 21st Century Act (MAP–21) (Pub. L. 112–141). In 2016, FTA replaced 49 CFR part 659 with a new SSO final rule, codified at 49 CFR part 674 (81 FR 14230). 49 CFR 674.9(b) provides that FTA will rescind the regulations codified at Part 659 no later than April 15, 2019.

Discussion of the Changes

This action rescinds 49 CFR part 659, State Safety Oversight (SSO) requirements for rail fixed guideway systems, because the statutory basis for these regulations was repealed by MAP–21. These regulations were replaced with a new SSO final rule, codified at 49 CFR part 674. The regulations at part 674 are intended to carry out several explicit statutory mandates to strengthen the States’ oversight of the safety of their Rail Transit Agencies (RTAs) enacted through Section 20021 of MAP–21 and codified at 49 U.S.C. 5329. 49 CFR 674.9(b) provides that FTA will rescind the regulations codified at part 659 no later than April 15, 2019, three years following the effective date of Part 674. The three-year delayed rescission permitted RTAs to have a part 659 System Safety Program Plan in place until the Public Transportation Agency Safety Plan (PTASP) regulation deadline (See 49 CFR 679.11(e)). FTA delayed the rescission, in part due to the deferred enforcement of the PTASP regulation deadline. FTA’s most recent PTASP notice of enforcement discretion expired on July 28, 2021 and all applicable RTAs have certified their compliance with the PTASP regulation. Therefore, it is now timely to rescind the part 659 regulations.

Good Cause for Dispensing With Notice and Comment and Delayed Effective Date

Under the Administrative Procedure Act (APA) (5 U.S.C. 553(b)), an agency may waive the normal notice and comment procedure if it finds, for good cause, that it is impracticable, unnecessary, or contrary to the public interest. Additionally, 5 U.S.C. 553(d) provides that an agency may waive the 30-day delayed effective date upon finding of good cause.

FTA finds good cause that notice and comment for this rule is unnecessary due to the nature of the revisions (i.e., the rule simply carries out the statutory repeal included in MAP–21). The statutory language does not require regulatory interpretation to carry out its intent, and comments cannot alter the regulation given that the statute abrogated its purpose. Further, the delayed effective date is unnecessary because the removal of these safety regulations was already made effective by MAP–21 and the publication of new safety regulations at 49 CFR part 674. Accordingly, FTA finds good cause under 5 U.S.C. 553(b)(3)(B) and (d)(3) to waive notice and opportunity for comment and the delayed effective date.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and Department of Transportation (DOT) Regulatory Policies and Procedures

FTA has determined that this rulemaking is not a significant regulatory action within the meaning of Executive Order 12866, and within the meaning of DOT regulatory policies and procedures. This action complies with Executive Orders 12866 and 13563 to improve regulation.