Commenced Construction On or Before December 9, 2004, adopted April 28, 2009.

(ii) [Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0090; FRL–9763–01–OCSPP]

Trans-Anethole; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *trans*-anethole (CAS No. 4180–23–8) when used as a fragrance inert ingredient in pesticide formulations at a concentration of 3% of the formulation in pre-harvest applications to crops. Landis International, Inc., on behalf of Morse Enterprises Limited, Inc. d/b/a KeyPlex submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *trans*-anethole (CAS No. 4180–23–8) on food or feed commodities when used in accordance with this exemption.

DATES: This regulation is effective May 5, 2022. Objections and requests for hearings must be received on or before July 5, 2022, 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–2018–0090, is available at *https://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 and OPP Docket is (202) 566–1744.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *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 40 CFR part 180 through the Office of **Federal Register**'s e-CFR site at *https://www.ecfr.gov/current/title-40.*

C. Can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), 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–2018–0090 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 July 5, 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–2018–0090, 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.
- *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 *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 April 11, 2018 (83 FR 15528) (FRL–9975–57), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP IN–11093) filed by Landis International, Inc., on behalf of Morse Enterprises Limited, Inc. d/b/a KeyPlex (P.O. Box 2515, Winter Park, FL 32790). The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of *trans*-anethole (CAS No. 4180–23–8) when used as a fragrance inert ingredient in pesticide formulations at a concentration of 3% of the formulation when applied pre-harvest to crops. That document included a summary of the petition prepared by the petitioner and solicited comments on the petitioner's request. The Agency did not receive any public comments.

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 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 the 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 exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that EPA has determined 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 it does not include occupational exposure. 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 an exemption 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.''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm 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 tolerance is not necessary to ensure that there is 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 and considered its validity, completeness and reliability and the relationship of this information 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. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure to *trans*-anethole, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with *trans*-anethole follows.

A. Toxicological Profile

Trans-anethole has low acute toxicity via the oral, dermal, and inhalation routes, and it is not an eye or dermal irritant, nor a skin sensitizer. In repeated-dose toxicity studies, the liver was the major target organ, with non-specific effects such as changes in body weight and food consumption also observed in multiple studies. There is no evidence of offspring susceptibility in the available developmental toxicity study or in the 2-generation reproductive toxicity study. The offspring effects observed in the developmental toxicity study occurred at doses higher than those in which maternal toxicity was observed. The uterine findings described in the 90-day oral study occurred only at the highest dose tested and have a clear no observed adverse effect level (NOAEL). No effects on reproductive parameters were observed in the 2-generation reproductive toxicity study. Concern for carcinogenicity is low, based on negative results in mutagenicity and genotoxicity studies and lack of biological significance of the neoplastic effects observed in females only at the highest dose tested in the chronic/carcinogenicity study. There is no evidence of neurotoxicity or immunotoxicity in the available studies.

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 (LOCs) 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.htm.*

An acute dietary endpoint was not selected because no effect attributable to a single dose was identified in the database. The chronic dietary, incidental oral, dermal and inhalation endpoints are all selected from the developmental toxicity study in rats, with a NOAEL of 35 mg/kg/day and a LOAEL of 175 mg/kg/day, based on decreases in maternal body weight and food consumption.

C. Exposure Assessment

1. Dietary exposure. Dietary exposure (food and drinking water) may occur from the existing (non-food) and proposed uses of *trans*-anethole (*e.g.,* eating foods treated with pesticide formulations containing *trans*-anethole, and drinking water exposures). There is also potential for non-pesticide dietary exposure since *trans*-anethole is a natural constituent of several food commodities (anise, fennel, thyme, cinnamon, clove bud, nutmeg, pepper, coriander seed, and dill seed) and is also used as a food additive (flavoring agent). An acute dietary assessment was not performed due to the lack of adverse effects attributed to a single dietary exposure. The chronic dietary exposure for food and drinking water utilized 14.6% of the chronic PAD (cPAD) for the U.S. population and 43.4% of the cPAD for children 1 to 2 years old, the most highly exposed population. Therefore, chronic dietary risks are not of concern, because they are less than 100% of the cPAD.

2. Residential exposure. The proposed pre-harvest use of *trans*-anethole in crops is not anticipated to result in residential exposure. Residential exposure to *trans*-anethole may occur from existing non-food pesticide uses as

well as from non-pesticide products that may be used in and around the home, such as toiletries. For residential handler short-term exposure scenarios, MOEs ranged from 540 to 4,900,000, which are greater than the LOC of 100 and therefore are not of concern. Residential handler intermediate-term and long-term exposures are not expected because applications are not expected to occur daily or for more than 30 days. For residential post-application exposure scenarios (short- and intermediate-term), MOEs ranged from 1,100 to 16,000,000, which are greater than the LOC of 100 and therefore are not of concern.

3. Cumulative effects from substances with a common mechanism of toxicity. Unlike pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to *trans*-anethole and any other substances, and *trans*-anethole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has assumed that *trans*-anethole does not have a common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold 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 unless EPA concludes that a different margin of safety will be safe for infants and children. Based on the evaluation of available toxicity studies, there is low concern for pre- and postnatal susceptibility for infants and children from exposure to *trans*-anethole. The FQPA safety factor has been reduced to 1X because: (1) The toxicity database is adequate to characterize potential pre- and postnatal risk for infants and children; (2) no effects on reproductive organs or reproductive parameters were observed in the available reproduction toxicity study; (3) the developmental effects observed occurred at doses above which maternal effects were seen, with clear NOAELs; (4) no evidence of neurotoxicity was observed in the database; and (5) the assumptions for the exposure assessment are unlikely to underestimate risk.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute aggregate risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. However, there was no hazard attributable to a single exposure seen in the toxicity database for *trans*-anethole. Therefore, *trans*-anethole is not expected to pose an acute aggregate risk.

2. *Short-term aggregate risk.* Short-term aggregate exposure takes into account short-term residential (dermal and inhalation) exposure plus chronic dietary exposure (food and drinking water). The short-term aggregate MOE is 490 for adults and 190 for children, which are greater than the LOC of 100 and therefore are not of concern.

3. *Intermediate-term aggregate risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential (dermal and inhalation) exposure plus chronic dietary exposure (food and drinking water). The intermediate-term aggregate MOE is 710 for adults and 190 for children, which are greater than the LOC of 100 and therefore are not of concern.

4. *Chronic aggregate risk.* A chronic aggregate risk assessment takes into account exposure estimates from chronic dietary consumption of food and drinking water. The chronic aggregate risk is equal to the chronic dietary risk and is not of concern.

5. *Aggregate cancer risk for U.S. population.* EPA has not identified any concerns for carcinogenicity relating to *trans*-anethole. Therefore, a cancer aggregate assessment was not conducted.

6. *Determination of safety.* Taking into consideration all available information on *trans*-anethole, EPA has determined that there is a reasonable certainty that no harm to the general population or any population subgroup, including infants and children, will result from aggregate exposure to *trans*-anethole residues. Therefore, the establishment of an exemption from the requirement of a tolerance under 40 CFR 180.920 for residues of *trans*-anethole when used as a fragrance inert ingredient in pesticide formulations applied pre-harvest to crops at a concentration of 3% of the formulation can be considered assessed as safe under section 408 of the FFDCA.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of *trans*-anethole in or on any food commodities. EPA is establishing a limitation on the amount of *trans*-anethole that may be used in pesticide formulations applied pre-harvest. This limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for food use that exceeds 3% *trans*-anethole in the final pesticide formulation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). Codex is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for *trans*-anethole.

VIII. Conclusion

Taking into consideration all available information on *trans*-anethole, EPA has determined that there is a reasonable certainty that no harm to the general population or any population subgroup, including infants and children, will result from aggregate exposure to *trans*-anethole residues. Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for *trans*-anethole when used as an inert ingredient at no more than 3% of the total pesticide formulation.

IX. Statutory and Executive Order Reviews

This action establishes an exemption 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 ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) 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 12898, 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 tolerance exemption 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, on 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).

X. 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: April 29, 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:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.920, amend Table 1 to 180.920 by adding in alphabetical order an entry for ''*Trans*-anethole (CAS Reg. No. 4180–23–8)'' to read as follows:

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

* * * * *

TABLE 1 TO 180.920

Inert ingredients	Limits	Uses
* * *	* * *	*
Trans-anethole (CAS Reg. No. 4180–23–8)	Not to exceed 3% in pesticide formulations	Fragrance.
* * *	* * *	*

[FR Doc. 2022–09621 Filed 5–4–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0204; FRL–9556–01–OCSPP]

Hydrolyzed Vegetable Proteins From Soy; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of hydrolyzed vegetable proteins from soy when used as an inert ingredient (pH adjusting agent, surfactant, or adhesive) in pesticide products applied to growing crops pre-harvest, limited to 25% in the pesticide formulation. SciReg, Inc. on behalf of Italpollina USA, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of hydrolyzed vegetable proteins from soy when used in accordance with this exemption.

DATES: This regulation is effective May 5, 2022. Objections and requests for hearings must be received on or before July 5, 2022, 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–2018–0204, is