ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0364; FRL–9534–01–OCSPP]

Fatty Acids, Esters With Ethoxylated Triethanolamine; 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 fatty acids, tall-oil, esters with triethanolamine, ethoxylated (CAS Reg No. 68605–38–9) and fatty acids, $C_{8–18}$ and C_{18}-unsatd., esters with polyethylene glycol ether with triethanolamine (3:1) (CAS Reg No. 2464873–19–4) (herein referred to 20ETO and 10ETO, respectively) when used as inert ingredients (surfactant) in pesticide formulations applied to growing crops pre- and post-harvest, not to exceed 10% in the final pesticide formulation. Exponent, Inc. on behalf of Lamberti USA, Incorporated 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 20ETO and 10ETO.

DATES: This regulation is effective February 28, 2022. Objections and requests for hearings must be received on or before April 29, 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–2021–0364, 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 is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, 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.*

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 the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40.*

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–2021–0364 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 29, 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–2021–0364, 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 August 3, 2021 (86 FR 41809) (FRL–8792–01), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11506) by Exponent, Inc. (1150 Connecticut Ave., Suite 1100, Washington, DC 20036) on behalf of Lamberti USA, Incorporated (P.O. Box 1000, Hungerford, TX 77448). The petition requested that the 40 CFR be amended by establishing an exemption from the requirement of a tolerance for residues of 20ETO (CAS Reg No. 68605–38–9) and 10ETO (CAS Reg No. 2464873–19–4) when used as inert ingredients (surfactant) in pesticide formulations applied to growing crops pre- and post-harvest under 40 CFR 180.910. That document referenced a summary of the petition prepared by Exponent, Inc. on behalf of Lamberti USA, Incorporated, the petitioner, which is available in the docket, *https://www.regulations.gov.* No comments were received on the notice of filing.

Based upon review of the data supporting the petition, EPA has limited the maximum concentration of 20ETO or 10ETO to not more than 10% in pesticide formulations for use under 40 CFR 180.910. This limitation is based on the Agency's risk assessment which can be found at *https://www.regulations.gov* in the document titled ''Fatty acids, Tall-Oil, Esters with Triethanolamine, Ethoxylated (20ETO) and Fatty Acids, $C_{8–18}$ or C_{18}-Unsatd., Esters with

Polyethylene Glycol Ether with Triethanolamine (3:1) (10ETO); Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations'' in docket ID number EPA–HQ–OPP–2021–0364.

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 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(b)(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. 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 . . . .''

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 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 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. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 20ETO and 10ETO including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 20ETO and 10ETO 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 20ETO and 10ETO as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

EPA considered studies on either substance to evaluate the toxicity of both substances. Based on the available data, the acute oral toxicity is expected to be low for 20ETO and 10ETO because the oral LD_{50} (lethal dose) for 20ETO is greater than 2,000 milligrams/kilogram (mg/kg). Both substances are also not expected to be acutely toxic via dermal exposure, as the LD_{50} for 20ETO is greater than 2,000 mg/kg in rats. The substances are also not expected to be irritating to the skin in the rat and rabbit nor sensitizing to the guinea pig. However, the substances are expected to be minimally irritating to the rabbit eye.

No repeated-dose toxicity studies are available for 10ETO or 20ETO. Therefore, data for triethanolamine (TEA) and fatty acids, tall oil were used, based on the predicted degradation pathways of 20ETO and 10ETO. Subchronic oral toxicity studies in guinea pigs via gavage (TEA) and rats (fatty acids, tall oil) via the diet resulted in hepatocellular cloudy swelling and fatty change in the liver and cloudy swelling of the convoluted tubules and Henle's loop in the kidney at 400 and 450 mg/kg/day, respectively, following 60- and 120-day exposures. The no observed adverse effect level (NOAEL) in these studies is 200 and 225 mg/kg/day for the guinea pig and rat, respectively. Increased liver and kidney weights and histological lesions are observed at 730 mg/kg/day in a 90-day oral toxicity study in rats. The NOAEL in this study is 170 mg/kg/day. Chronic exposure via drinking water (TEA) resulted in an increased incidence and severity of chronic nephropathy at 455 mg/kg/day in rats. No LOAEL was established in this study. In mice, decreased body weight was observed at 1,688 mg/kg/day following chronic exposure via drinking water (TEA).

In subchronic dermal toxicity studies, no systemic toxicity was observed up to 1,000 mg/kg/day, the limit dose, in rats. However, in the same study, an increased incidence of hypertrophy of the pituitary gland pars intermedia was observed at 2,000 mg/kg/day and dermal effects manifested as increased incidence and severity of acanthosis and inflammation at 500 mg/kg/day. In mice, no systemic toxicity was observed up to 4,000 mg/kg/day following 13 weeks of exposure. Mild dermal hyperplasia was observed at 140 mg/kg/day and an increased incidence and severity of acanthosis was seen at 250 mg/kg/day.

Following chronic dermal exposure in rats, an increased incidence of acanthosis and inflammation along with ulcers and dermal erosion was observed at 63 mg/kg/day.

A developmental toxicity study showed no maternal or developmental toxicity up to 1,125 mg/kg/day in mice. Another developmental toxicity study via the dermal exposure showed no toxicity up to 30 mg/kg/day, which was the highest dose tested in rats. Further, no parental, offspring, or reproduction toxicity was observed in a 2-generation reproduction toxicity study in rats (fatty acid, tall oil) up to 5,000 mg/kg/day. In a combined reproduction/developmental toxicity test, a decrease in the number of implantation sites and litter size, and an increase in the number of post-implantation loss were observed at 1,000 mg/kg/day. The NOAEL is 300 mg/kg/day. However,

there is no concern for fetal susceptibility or reproduction toxicity since the cRfD (0.455 mg/kg/day) is protective of effects seen at 1,000 mg/kg/day.

Several mutagenicity studies with TEA and fatty acids, tall oil (*e.g.,* Ames, chromosome aberration, micronucleus assay, sister chromatid exchange, and cell dominant lethal assay) were reviewed and the results for these studies are negative.

Two chronic/carcinogenicity studies in which the test substance was administered via drinking water were also reviewed. In mice, decreased bodyweight was observed at 1,688 mg/kg/day. The NOAEL is 673 mg/kg/day. No evidence of an increased incidence of tumors was seen in this study. In rats, chronic nephropathy is observed in female rats at 455 mg/kg/day. A NOAEL was not established in this study. An increased incidence of hepatocellular adenomas was observed at doses greater than 1,000 mg/kg/day. The chronic reference dose (cRfD) is based on this study.

Neurotoxicity and immunotoxicity studies are not available for review. However, evidence of neurotoxicity and immunotoxicity was not observed in the submitted 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 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.*

A summary of the toxicological endpoints for 20ETO and 10ETO used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR 20ETO AND 10ETO FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13 to 50 years of age, General population including infants and children).	An acute effect was not found in the database therefore an acute dietary assessment is not necessary.		
Chronic dietary (All populations)	LOAEL= 455 mg/kg/day UF_A = 10x UF_H = 10x UF_L = 10x FQPA SF = 1x	Chronic RfD = 0.455 mg/kg/day. cPAD = 0.455 mg/kg/day.	Chronic/Carcinogenicity Study (TEA). LOAEL = 455 mg/kg/day based on chronic nephropathy in female rats.
Incidental oral intermediate-term (1 to 6 months).	NOAEL= 300 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Combined Reproduction/Developmental (TEA). LOAEL = 1,000 mg/kg/day based on decreased number of implantation sites and litter size, and an increased number of post-implantation loss.
Inhalation short-term (1 to 30 days) ..	Inhalation study NOAEL = 43.39 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	16-Day Inhalation Toxicity Study (TEA). LOAEL = 86.77 mg/kg/day based on laryngeal inflammation.
Inhalation intermediate-term (1 to 6 months).	Inhalation study NOAEL = 43.39 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x UFs = 10x FQPA SF = 1x	LOC for MOE = 1000 ...	16-Day Inhalation Toxicity Study (TEA) LOAEL = 86.77 mg/kg/day based on laryngeal inflammation.
Cancer (Oral, dermal, inhalation)	There is no evidence of carcinogenicity in the available database. The RfD approach is protective of any potential carcinogenic effects.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 20ETO and 10ETO, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 20ETO and 10ETO in food as follows:

In conducting the chronic dietary exposure assessment using the Dietary

Exposure Evaluation Model DEEM–FCIDTM, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's (USDA's) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for 10ETO and 20ETO. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts,'' (D361707, S. Piper, 2/25/09) and can be found at *https://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

Generally, in the dietary exposure assessments for inert ingredients, the Agency assumes that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest levels of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50 percent of the product and often can be much higher. However, in assessing this petition request, the Agency assumed that a product consisted of 10% percent 10ETO and 20ETO. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity.

Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, this conservative assumption will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for 10ETO and 20ETO, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *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, for lawn and garden pest control, indoor pest control, termiticides, flea and tick control on pets, and hard surface disinfection on walls, floors, tables).

20ETO and 10ETO may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. For residential handlers, the Agency assumed handlers may receive short-term dermal and inhalation exposure to 20ETO and 10ETO from formulations containing the inert ingredient in outdoor and indoor scenarios. Short- and intermediate-term dermal exposures were not quantitated since no systemic toxicity is observed in dermal toxicity studies. Also, intermediate- and long-term inhalation exposures are not expected because applications are not expected to occur daily or for more than 30 days. Therefore, only short-term inhalation exposures were estimated and were based on the NOAEL of 43.39 mg/kg/day and a LOC for an MOE of 100. The short-term residential handler MOE is 36000, which is not a risk of concern because EPA considers MOEs of 100 or less to be of concern. The Agency also considered intermediate-term incidental oral exposures to children due to residential exposure associated with contact with treated surfaces (dermal and hand-to-mouth exposures). The MOE is 1964 for children, which is not a risk of concern because EPA considers MOEs of 100 or less to be of concern.

As introduced above, 10ETO and 20ETO are expected to biodegrade into TEA and fatty acids, tall oil. Residential exposure to TEA may occur from existing pesticide uses as well as from non-pesticide products that may be used in and around the home, such as cosmetics. Dermal contact is the primary route of exposure to TEA in cosmetics. However, a dermal endpoint of concern was not identified, and therefore a quantitative dermal exposure assessment is not necessary. TEA can be used in products that may be sprayed, however, so there is the potential for inhalation exposure. The Cosmetic Ingredient Review (CIR) Expert Panel has noted that 95% to 99% of TEA particles produced in cosmetic aerosols are not respirable. This assumption, coupled with the small actual exposure in the breathing zone and the concentrations at which TEA is used, suggests that inhalation would not be a significant route of exposure that might lead to local respiratory or systemic toxic effects (Fiume et. al., 2013). Small amounts of TEA may also be ingested (oral exposure) from lipsticks as they are reported to potentially contain up to 1% TEA. However, any contribution to the estimated oral pesticide exposure resulting from cosmetic uses is likely to

be insignificant in comparison to the estimates for exposure from the pesticide use.

4. *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.''

EPA has not found 20ETO and 10ETO to share a common mechanism of toxicity with any other substances, and 20ETO and 10ETO do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 20ETO and 10ETO do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *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 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.

The Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1X for the chronic dietary assessment for the following reasons. The toxicity database for 20ETO and 10ETO contains developmental, 2-generation reproduction, combined reproduction/developmental toxicity and mutagenicity studies. There is no indication of immunotoxicity or neurotoxicity in the available studies; therefore, there is no need to require an immunotoxicity or neurotoxicity study. Additionally, no fetal susceptibility or reproduction toxicity was observed in the available studies. Based on the adequacy of the toxicity database, the conservative nature of the exposure assessment and the lack of concern for prenatal and postnatal sensitivity, the Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1X.

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 chronic PAD (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 risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, 20ETO and 10ETO is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to 20ETO and 10ETO from food and water will utilize 32.6% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure generally takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

20ETO and 10ETO may be used as inert ingredients in pesticide products that could result in short-term residential exposure. The Agency has determined that it is not appropriate to aggregate chronic exposure through food and water with short-term residential exposures to 20ETO and 10ETO since toxicological effects were different depending on the route of exposure.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term residential exposures result in aggregate MOEs of 36000 for adult males and females. Because EPA's level of concern for 20ETO and 10ETO is an MOE of 100 or below, this MOE is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

20ETO and 10ETO may be used as inert ingredients in pesticide products that could result in intermediate-term residential exposure, and the Agency has determined that it is not appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to 20ETO and 10ETO since toxicological effects were different depending on the route of exposure.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 1964 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). Because EPA's level of concern for children's residential exposure (incidental oral exposure) to 20ETO and 10ETO is an MOE of 100 or below, this MOE is not of concern.

5. *Long-term risk.* Long-term aggregate exposure takes into account long-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Long-term residential exposures are not expected from the use of 20ETO and 10ETO in pesticides used in and around the home. Therefore, long-term aggregate exposure considers chronic food and water. The MOE is 10833 based on the cPAD of 0.455 mg/kg/day. As the level of concern is for an MOE that is lower than 1000, this MOE is not of concern.

TEA, a metabolite of 10ETO and 20ETO, may be used as inert ingredients in non-pesticide products that could result in long-term residential exposure. Based on the exposure assumptions described in unit IV. C. 3, the Agency anticipates that the contribution to the estimated oral non-pesticide exposure due to its use in cosmetics is likely to be insignificant in comparison to the estimates for exposure from the pesticide use. Therefore, the Agency believes the assessments of aggregate exposures due to pesticide uses more than adequately protect for exposure from uses in cosmetics products.

6. *Aggregate cancer risk for U.S. population.* Based on the lack of tumors in the carcinogenicity studies in rats and mice and the lack of mutagenicity, 20ETO and 10ETO are not expected to pose a cancer risk to humans.

7. *Determination of safety.* Taking into consideration all available

information on 20ETO and 10ETO, EPA concludes that there is a reasonable certainty that no harm will result to the general population, including infants and children, from aggregate exposure to 20ETO and 10ETO residues.

V. Other Considerations

Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of 20ETO and 10ETO in or on any food commodities. EPA is establishing a limitation on the amount of 20ETO and 10ETO that may be used in pesticide formulations. 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 10% in the final pesticide formulations for indoor and outdoor residential use.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of 20ETO (CAS Reg No. 68605–38–9) and 10ETO (CAS Reg No. 2464873–19–4) when used as inert ingredients (surfactant) in pesticide formulations applied to growing crops pre- and post-harvest under 40 CFR 180.910.

VII. Statutory and Executive Order Reviews

This action establishes a tolerance exemption 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), EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. As such, to the extent that information is publicly available or was submitted in comments to EPA, the Agency considered whether groups or segments of the population, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance 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).

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: February 22, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR part 180 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 § 180.910, amend Table 1 to 180.910 by adding in alphabetical order the inert ingredients ''Fatty acids, tall-oil, esters with triethanolamine, ethoxylated'' and ''Fatty acids, $C_{8–18}$ and C_{18}-unsatd., esters with polyethylene glycol ether with triethanolamine (3:1)'' to reads as follows:

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

* * * * *

TABLE 1 TO 180.910

Inert ingredients	Limits (%)	Uses
* * * * * * *		
Fatty acids, tall-oil, esters with triethanolamine, ethoxylated (CAS Reg. No. 68605–38–9)	10	Surfactant.
Fatty acids, $C_{8–18}$ and C_{18}-unsatd., esters with polyethylene glycol ether with triethanolamine (3:1) (CAS Reg. No. 2464873–19–4).	10	Surfactant.
* * * * * * *		

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 206

[Docket DARS–2019–0051]

RIN 0750–AK67

Defense Federal Acquisition Regulation Supplement: Exception to Competition for Certain Follow-On Production Contracts (DFARS Case 2019–D031)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2016 that modifies the criteria required to exempt from competition certain follow-on production contracts.

DATES: Effective February 28, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly R. Ziegler, telephone 571–372–6095.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 84 FR 50811 on September 26, 2019, to amend DFARS 206.001 to implement section 815 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016 (Pub. L. 114–92). Section 815 repeals and replaces section 845 of the NDAA for FY 1994 (Pub. L. 103–160; 10 U.S.C. 2371 note) with 10 U.S.C. 2371b, which modifies the authority of DoD to carry out other transaction (OT) agreements for prototype projects, as well as the criteria required to award an associated follow-on production contract to the participants in the other transaction agreement without the use of competitive procedures. One respondent submitted comments on the proposed rule.

II. Discussion and Analysis

A. Summary of Significant Changes

The purpose of this rule is to provide contracting officers with updated internal guidance when awarding a follow-on production contract that is exempt from the competitive procedures of Federal Acquisition Regulation part 6, as set forth in 10 U.S.C. 2371b. The rule is not intended to implement policy, regulation, or guidance on DoD's authority to enter into OT prototype agreements at 10 U.S.C. 2371b. As such, this final rule changes the rule text to specify that the agreements officer for the OT agreement for the prototype project is responsible for providing to the contracting officer information that confirms the requirements to award a noncompetitive follow-on production contract, as specified in 10 U.S.C. 2371b and DoD OT agreement policy, have been met.

B. Analysis of Public Comments

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided, as follows:

Comment: The respondent advised that DoD should provide clear guidance on what constitutes ''successful completion'' of a prototype transaction; the rule text should be clarified to explain what it means to award a follow-on production contract to ''the participants in the transaction,'' as contracts are usually made between the Government and a single entity; the rule should clarify what a ''participant'' is, given that not all parties to a transaction necessarily participate in the project.

The respondent also advised that the rule should be revised to clarify the prerequisites for awarding the OT for the prototype project and the prerequisites for awarding a follow-on production contract. Specifically, one of the criteria for awarding a follow-on production contract is that the OT for the prototype project is based on specific determinations made by certain acquisition officials according to different threshold values. The proposed rule, however, applies these determination requirements only to the follow-on production contract, when they should instead apply only to the initial OT agreement.

Response: This rule is not intended to implement policy, regulation, or guidance on DoD's authority to enter into OT prototype agreements at 10 U.S.C. 2371b. Instead, the Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)) is the organization responsible for promulgation of policy for OT agreements, which can be viewed at *https://aaf.dau.edu/aaf/ot-guide/.* As a result, this rule is modified to clarify that the contracting officer does not make the determination that the prototype project was successfully completed and, instead, should receive that information from the agreements officer for the OT agreement.

Comment: The respondent advised that 32 CFR part 3 should be updated to reflect the current authority at 10 U.S.C. 2371b.

Response: This comment is outside the scope of this rule, which amends 48 CFR chapter 2.

C. Other Changes

The proposed numbering of the DFARS text is redesignated as DFARS 206.001–70 from 206.001(S–70) to align with FAR system drafting conventions.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold, for Commercial Products Including Commercially Available Off-the-Shelf Items, and for Commercial Services

This rule only impacts the internal operating procedures of the agency. The rule does not impose any new requirements on contracts at or below