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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. 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 27, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.132, revise the introductory text of paragraph (a) and revise the entry for ''Strawberry'' in the table in paragraph (a) to read as follows:

§ 180.132 Thiram; tolerances for residues.

(a) *General.* Tolerances for residues of the fungicide thiram (tetramethyl thiuram disulfide), including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified is to be determined by measuring only thiram.

Commodity	Parts per million	Expiration/ revocation date
* * * * *		
Strawberry	20	None.
* * * * *		

[FR Doc. 2014–03074 Filed 2–11–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0791; FRL–9905–22]

Linuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of linuron in or on multiple commodities which are identified and discussed later in this document. This regulation additionally removes a tolerance with regional registrations in or on parsley leaves, as it will be superseded by a tolerance without regional registrations. IR–4 requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 12, 2014. Objections and requests for hearings must be received on or before April 14, 2014, and must be filed in accordance with 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–2012–0791, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0791 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 14, 2014. 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–2012–0791, by one of the following methods:

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

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of November 7, 2012 (77 FR 66781) (FRL–9367–5), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8083) by IR–4, 500 College Road East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.184 be amended by establishing tolerances for residues of the herbicide linuron, 3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea), and its metabolites, in or on cilantro, dried leaves at 27 parts per million (ppm); cilantro, fresh leaves at 3 ppm; dillweed, dried leaves at 7.1 ppm; dillweed, fresh leaves at 1.5 ppm; dill oil at 4.8 ppm; dill seed at 0.3 ppm; horseradish at 0.050 ppm; parsley, dried leaves at 8.3 ppm; parsley leaves at 3 ppm; and pea, dry, seed at 0.08 ppm. The petition additionally requested to delete the regional tolerance in 40 CFR 180.184(c) for residues of linuron in or on parsley, leaves at 0.25 ppm upon approval of the requested tolerances for parsley leaves. That document referenced a summary of the petition prepared on behalf of IR–4 by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Subsequent to the publication of the November 7, 2012 **Federal Register** notice, the petitioner submitted a second petition, in which it requested again the same tolerances noticed in the November 7, 2012 **Federal Register** document and added a new request for a tolerance for residues of linuron and its metabolites in or on coriander seed at 0.01 ppm. So, in the **Federal Register** of July 19, 2013 (78 FR 43115) (FRL–9392–9), EPA issued another document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8083) by IR–4, seeking tolerances for commodities as noted in the November 7, 2012 document as well as a tolerance for coriander seed at 0.01 ppm. That document referenced a summary of the petition prepared on behalf of IR–4 by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the tolerances for several proposed commodities. The Agency has also determined that the tolerance expression should be revised for all commodities. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish 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. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), 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 linuron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with linuron follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its 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.

With repeated dosing in test animals, linuron produces two primary effects: (1) Changes in the hematopoetic system in rats, mice, and dogs and; (2) changes in the male reproductive system in developing rats. Lowest observed adverse effect levels (LOAELs) for hematological effects produced by linuron were substantially lower than LOAELs for reproductive effects. Dogs were shown to be most sensitive to the hematological effects, including hemolytic anemia characterized by slightly reduced hemoglobin, hematocrit, and erythrocyte counts accompanied by hemosiderin deposition in liver Kupffer cells. Secondary erythropogenic activity (erythroid hyperplasia of bone marrow) was also found. Systemic toxicity observed in mice included increased methemoglobin formation, vacuolation and hemosiderosis of the spleen, and decreased erythrocyte counts. In the chronic rat study, microscopic observations consistent with hemolysis (hemosiderin in Kupffer cells and increased hemosiderosis in bone marrow, spleen, and/or mesenteric lymph nodes) were found.

The rat developmental study showed increased post-implantation loss, fetal resorptions, decreased litter size, and decreased fetal body weight. In the rabbit developmental toxicity study, an increased incidence of fetuses with skeletal skull variations was found. In the 2-generation reproductive toxicity study, rats exposed to linuron during both development and adulthood had gross lesions of the testes (including reduction in size); abnormally soft and small epididymides, deformities of the epididymides, decreased pup survival, decreased weanling body weights, decreased liver and kidney weights; and increased incidence of offspring liver atrophy.

The developmental effects on the reproductive system seen in the guideline studies are consistent with those reported in the published literature, though it should be noted that most of the literature studies employed dose levels of 100 milligrams/kilogram (mg/kg) or greater. The available data indicate that linuron inhibits transcriptional activity of dihydrotestosterone (DHT), human androgen receptor (hAR) *in vitro,* and steroidogenic enzymes. Additional findings indicate that linuron exposure decreases anogenital distance; may increase retention of areole/nipples in male rat offspring following *in utero* exposure; increases luteinizing hormone (LH) levels in F0 and F1 male rats; reduces the size of androgen dependent tissues such as seminal vesicles, epididymis, and ventral prostate; and demonstrates a weak affinity for androgen receptors, which may decrease fetal testosterone synthesis (Refs 1, 2, 3, and 4). At this time, linuron has not been demonstrated to be an estrogen receptor antagonist (Ref 5). It should be emphasized that the toxicity endpoints based on the hematological effects for chronic exposures were derived from the chronic oral toxicity study in dogs. The point of departure (POD) for hematological effects was approximately 40X lower than the LOAEL that caused the testicular effects seen in the rat reproduction toxicity study.

In rat and mouse carcinogenicity studies, linuron induced interstitial cell adenomas in the testes of rats and hepatocellular adenomas in mice. In a special study with aged rats, linuron induced hyperplasia and adenomas of the testes within 6 to 12 months. However, EPA has concluded that quantification of cancer risk is not necessary because both interstitial cell adenomas and hepatocellular adenomas were benign and show no progression towards malignancy. In addition, linuron was not mutagenic in bacteria or in cultured mammalian cells. There was also no indication of a clastogenic effect up to toxic doses *in vivo.* Finally, the cRFD is a NOAEL of 0.77 mg/kg/day, which would be protective of any tumors caused by linuron in the rat and mouse carcinogenicity study at higher doses.

At the highest dose tested, the acute neurotoxicity study demonstrated that linuron produced changes in the parameters of the field observation battery (FOB). These changes included rats holding their heads low, crusty deposits on the nose, impaired mobility, ataxia, low arousal, decreased rearing, no reaction to tail pinch or startle, decreased righting reflex, reduced or no hindlimb extensor strength, decreased grip strength in both hindlimbs and forelimbs, reduced rotarod performance, decreased hindlimb footsplay, and increased catalepsy. At the lowest-observed-adverse-effect-level (LOAEL), linuron produced decreases in motor activity and rearing. No compound-related changes in neurohistopathology were observed at any of the tested dose levels. In addition, linuron did not show any signs of immunotoxicity in the submitted immunotoxicity study up to the highest dose tested.

Specific information on the studies received and the nature of the adverse effects caused by linuron as well as the no-observed-adverse-effect-level (NOAEL) and the LOAEL from the toxicity studies can be found at *http://www.regulations.gov* in document: ''Linuron: Section 3 Human Health Risk Assessment for Proposed Use on Coriander, Dill, Horseradish, Parsley, Celeriac, Rhubarb, and Pea (Dry).'' at pages 33–38 in docket ID number EPA–HQ–OPP–2012–0791. References for the published toxicity studies cited in this section may be found Unit VI.

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 *http://www.epa.gov/pesticides/factsheets/riskassess.htm.* A summary of the toxicological endpoints for linuron used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR LINURON FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age).	NOAEL = 12 mg/kg/day UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 0.12 mg/kg/day aPAD = 0.12 mg/kg/day	Rat Developmental Toxicity. LOAEL = 50 mg/kg/day based on increased post-implantation loss and fetal/litter resorptions.
Acute dietary (General population including infants and children).	NOAEL = 20 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Acute RfD = 0.2 mg/kg/day. aPAD = 0.2 mg/kg/day	Acute Neurotoxicity Study (Rat). LOAEL = 100 mg/kg based on decreases in rearing and in motor activity.
Chronic dietary (All populations)	NOAEL= 0.77 mg/kg/day. UF_A = 10X UF_H = 10X FQPA SF = 1X	Chronic RfD = 0.0077 mg/kg/day. cPAD = 0.0077 mg/kg/day	Chronic Oral Dog Study. LOAEL = 3.5 mg/kg/day based on hematological effects (increased met- and sulf-hemoglobin levels).

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR LINURON FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Cancer (Oral, dermal, inhalation)	Quantification of human cancer risk is not necessary for reasons stated in Unit III.A.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligrams/kilogram/day. 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_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to linuron, EPA considered exposure under the petitioned-for tolerances as well as all existing linuron tolerances in 40 CFR 180.184. EPA assessed dietary exposures from linuron in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for linuron. In estimating acute dietary exposure, EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 3.16, which uses food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, ''What We Eat in America'' (NHANES/WWEIA) from 2003 through 2008. As to residue levels in food, EPA utilized tolerance-level residues, DEEM (Ver. 7.81) default processing factors as necessary, and 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment. EPA used the food consumption data from the USDA's 2003–2008 NHANES/WWEIA. As to residue levels in food, EPA used tolerance-level residues for all commodities, and DEEM default processing factors. The Agency utilized average PCT estimates, when available, and 100 PCT for all other commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a cancer exposure assessment is not necessary.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the average PCT for existing uses for use in the chronic dietary assessment as follows:

Asparagus, 25%; carrots, 85%; celery, 25%; corn, 1.0%; cotton, 1.0%; potatoes, 5.0%; sorghum, 1.0%; soybeans, 1.0%; sweet corn, 1.0%; and wheat, 1.0%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6–7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which linuron may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for linuron in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of linuron. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of linuron for surface water are estimated to be 89.05 parts per billion (ppb) for acute exposures and 48.69 ppb for chronic exposures for non-cancer assessments. The EDWCs of linuron for groundwater are estimated to be 48.8 ppb for acute

and chronic exposures for non-cancer assessments.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 89.05 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 48.8 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Linuron is not registered for any specific use patterns that would result in residential exposure.

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 linuron to share a common mechanism of toxicity with any other substances, and linuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that linuron does 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 Web site at *http://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.

2. *Prenatal and postnatal sensitivity.* The following acceptable studies are available to assess the prenatal and postnatal sensitivity to linuron: rat and rabbit developmental toxicity studies, a 2-generation rat reproductive toxicity study, and a 3-generation rat reproductive toxicity study. There is no qualitative or quantitative evidence of increased susceptibility of rabbits in the developmental study; developmental effects were seen at a dose higher than those causing maternal toxicity. In the rat developmental study, increases in post-implantation losses and increases in fetal resorptions/litter were seen at a dose that caused decreases in maternal body weight and food consumption. Since increases in resorptions were marginal and there was no change in the number of live fetuses to corroborate the increases in post-implantation losses, these effects were not indicative of qualitative evidence of susceptibility.

There was no quantitative evidence of susceptibility in either the 2-generation or the 3-generation reproduction studies. In the 2-generation study, reduced body weight gains of pups were seen at the same dose that caused decreases in parental body weights. In the 3-generation study, offspring effects including deceased pup survival and pup body weight were seen a dose (44 mg/kg/day) higher than the dose that caused decreases in body weight gain in the parental animals (9 mg/kg/day). However, when reproductive effects were examined, testicular atrophy was seen at the same dose (45 mg/kg/day) in both studies. In both studies, while the F0 males were not affected, testicular lesions and reduced fertility were seen in the F1 males. This effect in the F1 males is an indication of qualitative evidence of susceptibility.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for linuron is complete.

ii. In an acute neurotoxicity study, FOB findings of impaired mobility, alterations in gait, lack of coordination, lowered body temperature, no reaction to stimuli, low arousal, and decreases in motor activity were seen at the time of peak effect (7 hours post dosing) on study day 0. These observations were mostly seen in the 500 mg/kg group and no pathological changes were found in nervous system tissues. A clear NOAEL (20 mg/kg/day) was established, and this NOAEL was approximately 2–26X greater than most PODs selected for risk assessment. The nervous system was not a target organ for linuron. The requirement of a subchronic neurotoxicity study was waived by the Agency because the target systems for linuron toxicity are the hematopoietic and endocrine systems and not the nervous system as shown by all available/required toxicity studies. There is no need for a developmental neurotoxicity study because linuron affects testes and hematological parameters but did not produce an increased susceptibility in young rats. Therefore, the concern for neurotoxicity is low, and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that linuron results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies. While increased qualitative susceptibility was identified from the reproductive findings in the 2-generation and 3-generation rat toxicity studies, clear NOAELs were established for the effects on the reproductive system. Furthermore, the point of departure (POD) selected for assessment of chronic effects, is approximately 40X lower than the LOAEL that caused the testicular effects seen in the rat reproduction toxicity study; therefore, EPA considers the PODs for risk assessment to be protective of the effects seen on the male reproductive system and an additional safety factor to account for this qualitative susceptibility is not necessary.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on tolerance-level residues, 100 PCT for the acute assessment and average PCT for available commodities in the chronic dietary assessment. EPA made conservative (protective) assumptions in the ground-water and surface water modeling used to assess exposure to linuron in drinking water. These assessments will not underestimate the exposure and risks posed by linuron.

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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to linuron will occupy 10% of the aPAD for all infants less than 1 year old, the most highly exposed U.S. population subgroup; and 5.7% of the aPAD for females 13–49 years old.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to linuron from food and water will utilize 60% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for linuron.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, linuron is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there are no short- or intermediate-term residential exposures and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- or intermediate-term risks), no further assessments of short- or intermediate-term risk are necessary, and EPA relies on the chronic dietary risk assessment for evaluating the short- and intermediate-term risks for linuron.

4. *Aggregate cancer risk for U.S. population.* Based on the discussion of carcinogenicity for linuron in Unit III.A., EPA has concluded that the cPAD is protective of possible cancer effects. Given the results of the chronic risk assessment, EPA has concluded that linuron does not pose a cancer risk.

5. *Determination of safety.* Based on these risk assessments, 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 linuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, Method ABC–68406–M, is available to enforce the tolerance expression. This method involves reflux of crop samples in strong base to hydrolyze residues of linuron and its metabolites to 3,4-DCA, which is analyzed using gas chromatography/mass spectrometry (GC/MS).

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

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). The Codex Alimentarius 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 linuron.

C. Response to Comments

EPA received one comment to the notice of filing from November 7, 2012 which opposed the use of linuron on any food. The commenter expressed a general opposition to the use of ''toxic chemicals'' on food and further noted that ''red blood cells are harmed in animals from this toxic chemical.'' The Agency understands the commenter's concerns and recognizes that some individuals believe that certain pesticide chemicals should not be permitted in our food. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when the pesticide meets the safety standard imposed by that statute. The Agency is required by Section 408 of the FFDCA to estimate the risk of the potential exposure to these residues. EPA has concluded, based on data submitted in support of the petition and other reliable data, that there is a reasonable certainty that no harm will result from aggregate human exposure to linuron residues from these uses. The points of departure selected for risk assessment are protective of any effects on the hematopoietic system, including red blood cells. Additionally, testing requirements for pesticide tolerances have been specified by rulemaking after allowing for notice and comment by the public and peer review by appropriate scientific bodies. See 40 CFR part 158 for further information.

D. Revisions to Petitioned-for Tolerances

Based on the data supporting the petition, EPA has revised the proposed tolerances for several commodities, as follows: Cilantro, dried leaves from 27 ppm to 10 ppm; dillweed, dried leaves from 7.1 ppm to 5.0 ppm; dill, seed from 0.3 ppm to 0.5 ppm; dill, oil from 4.8 ppm to 2.0 ppm; parsley, leaves from 3.0 ppm to 4.0 ppm; parsley, dried leaves from 8.3 ppm to 9.0 ppm; and pea, dry, seed from 0.08 ppm to 0.09 ppm. The Agency revised the cilantro, fresh leaves; dillweed, fresh leaves, and pea, dry seed tolerance levels based on analysis of the residue field trial data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures. Due to a limited number of field trials, EPA used the formula of 5X the mean in order to establish tolerance levels for coriander, seed; dill, seed; and parsley, leaves. Finally, for the dried herbs (cilantro, dillweed, and parsley) and dill oil, the formula of the highest average field trial (HAFT), multiplied by the concentration factor was used to calculate the recommended tolerance levels for these commodities. These concentration factors were derived from dividing the average dried or oil commodity residue by the average fresh commodity residue. Based on this calculation method, all four tolerance levels were decreased.

Finally, the Agency has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of linuron not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only residues of linuron convertible to 3,4-dichloroaniline.

V. Conclusion

Therefore, tolerances are established for residues of linuron, 3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea), and its metabolites, in or on cilantro, fresh leaves at 3.0 ppm; cilantro, dried leaves at 10 ppm; coriander, seed at 0.01 ppm; dillweed, fresh leaves at 1.5 ppm; dillweed, dried

leaves at 5.0 ppm; dill, seed at 0.5 ppm; dill, oil at 2.0 ppm; horseradish at 0.05 ppm; parsley, leaves at 4.0 ppm; parsley, dried leaves at 9.0 ppm; and pea, dry, seed at 0.09 ppm. The regulation additionally removes the tolerance in or on parsley, leaves at 0.25 ppm from 40 CFR 180.184(c).

VI. References

The following literature was referenced in the preamble of this document.

1. Gray, L; Wolf, C; Lambright, C; Mann, P; Price, M; Cooper, R; Ostby, J. 1999. Administration of potentially antiandrogenic pesticides (procymidone, linuron, iprodione, chlozolinate, p,p'-DDE, and ketoconazole) and toxic substances (dibutyl- and diethylhexyl phthalate, PCB 169, and ethane dimethane sulphonate) during sexual differentiation produces diverse profiles of reproductive malformations in the male rat. *Toxicol Ind Health,* 15 (1–2):94–118.
2. Hotchkiss, A; Parks-Saldutti, L; Ostby, J; Lambright, C; Furr, J; Vandenbergh, J; & Gray, L. 2004. A mixture of the ''antiandrogens'' linuron and butyl benzyl phthalate alters sexual differentiation of the male rats in a cumulative fashion. *Biol.of Reprod* 71:1852–1861.
3. Lambright, C; Ostby, J; Bobseine, K; Wilson, V; Hotchkiss, A; Mann, PC; Gray, L. 2000. Cellular and molecular mechanisms of action of linuron: an antiandrogenic herbicide that produces reproductive malformations in male rats. *Toxicol Sci.* 56(2):389–99.
4. McIntyre, B; Barlow, N; Wallace, D; Maness, S; Gaido, K; Foster, P. 2000. Effects of *in utero* exposure to linuron on androgen-dependent reproductive development in the male Crl:CD(SD)BR rat. *Toxicol Appl Pharmacol.* 167(2):87–9.
5. Vinggaard, A., Breinholt, V., and Larsen, J. 1999. Screening of selected pesticides for oestrogen receptor activation *in vitro.* Food Addit Contam. 16(12):533–542.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 tolerances 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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 24, 2014.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.184:

■ a. Revise the introductory text in paragraph (a).

■ b. Add ''Cilantro, dried leaves'', Cilantro, fresh leaves'', ''Coriander, seed'', ''Dill, oil'', ''Dill, seed'', ''Dillweed, dried leaves'', Dillweed, fresh leaves'', Horseradish'', ''Parsley, dried leaves'', ''Parsley, leaves'', and ''Pea, dry, seed'' to the table in paragraph (a).

■ c. Revise the introductory text in paragraph (b).

■ d. Revise the introductory text in paragraph (c).

■ e. Remove ''Parsley, leaves'' from the table in paragraph (c).

The amendments read as follows:

§ 180.184 Linuron; tolerance for residues.

(a) *General.* Tolerances are established for residues of the herbicide linuron (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea), including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only those linuron residues convertible to 3,4-dichloroaniline, calculated as the stoichiometric equivalent of linuron, in or on the commodity:

Commodity	Parts per million
* * * * *	
Cilantro, dried leaves	10
Cilantro, fresh leaves	3.0
Coriander, seed	0.01
* * * * *	
Dill, oil	2.0
Dill, seed	0.5
Dillweed, dried leaves	5.0
Dillweed, fresh leaves	1.5

Commodity	Parts per million
* * * * *	
Horseradish	0.05
* * * * *	
Parsley, dried leaves	9.0
Parsley, leaves	4.0
* * * * *	
Pea, dry, seed	0.09
* * * * *	

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the herbicide linuron [3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea], including its metabolites and degradates, in or on the commodities in the table below, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified below is to be determined by measuring only those linuron residues convertible to 3.4-dichloroaniline, calculated as the stoichiometric equivalent of linuron, in or on the commodity. The tolerance expires and is revoked on the date specified in the table.

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registrations, as defined in § 180.1(l), are established for residues of the herbicide linuron (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea), including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only those linuron residues convertible to 3,4-dichloroaniline, calculated as the stoichiometric equivalent of linuron, in or on the commodity.

* * * * *

[FR Doc. 2014–03077 Filed 2–11–14; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket No. 12–267; FCC 13–111]

Comprehensive Review of Licensing and Operating Rules for Satellite Services

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Federal Communications Commission (FCC) has adopted many changes in its rules, which governs licensing and operation of space stations and earth stations. Collectively, the changes adopted in this document will streamline the Commission's regulations, fostering more rapid deployment of services to the public, greater investment, and new innovations in satellite services.

DATES: The rules in this document contain information collection requirements that have not been approved by Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing such OMB approval, the effective date of all of the rule amendments adopted in the Report and Order, and the approval date of the incorporation by reference of a certain publication listed in the rule.

FOR FURTHER INFORMATION CONTACT: William Bell (202) 418–0741, Satellite Division, International Bureau, Federal Communications Commission, Washington, DC 20554. For additional information concerning the information collection(s) contained in this document, contact Leslie Smith at 202–418–0217, or via the Internet at *Leslie.Smith@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order in IB Docket No. 12–267, FCC 13–111, adopted and released on August 9, 2013. The full text of the Report and Order is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone 202–488–5300, facsimile 202–488–5563, or via email *FCC@BCPIWEB.com*. The full text may also be downloaded at *http://apps.fcc.gov/ecfs/document/view?id=7520937207 http://www.fcc.gov*. Alternative formats are available to person with disabilities by sending an email to *fcc504@fcc.gov* or calling the Consider & Governmental Affairs Bureau at 202–418–0530 (voice), or 202–418–0432 (tty).

Synopsis

1. In September 2012, the Commission issued a Notice of Proposed Rulemaking (NPRM), 77 FR 67172, November 8, 2012 proposing extensive changes in part 25 of its rules, which governs licensing and operation of space stations and earth stations for the provision of satellite communication services. Sixteen parties filed comments in response to the NPRM and 10 parties filed reply comments. In this Report and Order, we adopt most of the changes proposed previously and discuss recommendations for further changes. In all, we revise over 150 rule provisions in part 25 to better reflect evolving technology; eliminate unnecessary information filing requirements for licensees and applicants; eliminate unnecessary technical restrictions; reorganize existing requirements; eliminate redundancy and unnecessary verbiage; clarify vague, confusing, or ambiguous provisions; resolve inconsistencies; and codify existing policies to improve transparency. These changes will better enable the Commission to assess the interference potential of proposed operations; afford more operational flexibility for satellite licensees; enable applicants and licensees to conserve time, effort, and expense in preparing applications and reports; ease administrative burdens for the Commission; and make the rules easier to understand.

Paperwork Reduction Act

2. This document contains new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. It will be submitted to the Office of Management and Budget (OMB) for review under Section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the new or modified information collection requirements contained in this proceeding.

3. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), we previously sought specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees. We received no comments on this issue. We have assessed the effects of the revisions adopted that might impose information collection burdens on small business concerns, and find that the impact on businesses with fewer than 25 employees will be an overall reduction in burden. The amendments adopted in this Report and Order eliminate unnecessary information filing requirements for licensees and applicants; eliminate unnecessary technical restrictions and enable applicants and licensees to conserve time, effort, and expense in preparing applications and reports. Overall, these changes may have a greater positive