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 section 408(n)(4) of FFDCA. 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) (Pub. L. 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: March 24, 2011.

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. Section 180.448 is amended by alphabetically adding the following commodities to the table in paragraph (c), to read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

* * * * *

(c) * * *

Commodity	Parts per million
Bean, dried, seed (EPA Regions 7–12 only)	0.4
bean, succulent (EPA Regions 7–12 only)	0.3
* * * * * * *	
Corn, sweet, kernel plus cob with husks removed (EPA Regions 7–12 only)	0.1
Corn, sweet, forage (EPA Regions 7–12 only)	4.0
* * * * * * *	

* * * * *

[FR Doc. 2011–8182 Filed 4–5–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0636; FRL–8864–3]

Indaziflam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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

DATES: This regulation is effective April 6, 2011. Objections and requests for hearings must be received on or before June 6, 2011, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0636. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Bethany Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 347–8072; *e-mail address: benbow.bethany@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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.gpoaccess.gov/ecfr.*

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–2009–0636 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 June 6, 2011. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2009–0636, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of January 6, 2010 (75 FR 864) (FRL–8801–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of two pesticide petitions (PP 9F7589 and PP 9E7588) by Bayer CropScience LP, 2 T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by adding a section for the herbicide indaziflam and establishing tolerances therein for residues of indaziflam, *N*-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, in or on fruit, citrus, group 10; fruit, pome, group 11; fruit, stone, group 12; nut, tree, group 14; pistachio; grape; and olive; each at 0.01 parts per million (ppm) and almond, hulls at 0.20 ppm (PP 9F7589). Additionally, Bayer CropScience LP requested an import tolerance for sugarcane, sugar, refined at 0.01 ppm (PP 9E7588). That notice referenced a summary of the petitions prepared by Bayer CropScience LP, 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 petitions, EPA has modified the petitioner's request by lowering the proposed tolerance level for almond, hulls from 0.20 ppm to 0.15 ppm. EPA is also revising the proposed commodity term, "Sugarcane, sugar, refined" to read "Sugarcane, refined sugar." Additionally, EPA is revising the citrus and pome fruit crop group names and the requested tolerance expression. The reasons for these changes are explained in Unit IV.C.

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

The toxicology database for indaziflam is complete and adequate for selecting toxicity endpoints for risk assessment. The scientific quality of the data is relatively high, and the toxicity is well-characterized for all types of effects, including potential developmental, reproductive, immunologic and neurologic toxicity.

Indaziflam has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not irritating to the eye or skin and is not a dermal sensitizer.

The nervous system is a target for indaziflam in rats and dogs. In the dog degenerative neuropathology of the brain, spinal cord and sciatic nerve was reported in the dog following both subchronic and chronic oral exposure. Neuropathology in the dog was the most sensitive effect and was selected as the risk assessment endpoint for all

repeated exposure scenarios. In the rat, histopathology of the brain and pituitary *pars nervosa* was observed following chronic exposure. Clinical signs of neurotoxicity were observed in both species in several studies, including rat adult and developmental neurotoxicity studies. Decreased motor activity observed in the rat acute neurotoxicity study was selected as the appropriate endpoint for assessing acute oral exposures.

In addition to the neurological system, chronic exposure was associated with degenerative renal effects in the rat and mouse, hypertrophy (considered adaptive), increased macrovacuolation and multinucleated hepatocytes in the rat liver, increased follicular cell hypertrophy and colloid alteration in the rat thyroid, degeneration in rat reproductive tissues including atrophied seminal vesicles (males), and in female mice, blood-filled ovarian cysts/follicles (females) and gastric lesions. Thyroid and gastric effects were also observed following subchronic exposure of the rat. Decreased body weight gains were generally observed in the available subchronic and chronic studies. No systemic toxicity was observed in a 28-day dermal toxicity study in the rat.

Developmental effects in offspring were absent or limited to doses that also caused systemic toxicity in the adult. In the rat developmental toxicity study, decreased fetal weight was observed in the presence of maternal effects that included decreased body weight and clinical signs of toxicity. No developmental effects were observed in rabbits up to maternally toxic dose levels. Decreased pup weight and delays in sexual maturation (preputial separation in males and vaginal patency in females) were observed in the rat 2-generation reproductive toxicity study, along with clinical signs of toxicity, at a dose causing parental toxicity that included clinical signs and decreased weight gain. In the developmental neurotoxicity study, transiently decreased motor activity (PND 21 only) in male offspring was observed and was considered a potential neurotoxic effect. It was observed at a dose that also caused clinical signs of neurotoxicity along with decreased body weight in maternal animals.

There was no evidence of carcinogenicity observed in the 2-year dietary rat or mouse carcinogenicity bioassays and no evidence of genotoxicity in mutagenicity studies (reverse gene mutation in bacteria, forward gene mutation in mammalian cells) or *in vitro* and *in vivo* chromosomal aberration assays. Based on the lack of evidence of carcinogenicity or genotoxicity, the Agency classified indaziflam as "not likely to be carcinogenic to humans."

Specific information on the studies received and the nature of the adverse effects caused by indaziflam, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document "Indaziflam: Human health risk assessment for use in citrus, stone, and pome fruits; grapes; tree nuts; pistachios; olives; and sugar cane (imported refined sugar)," p. 41 in docket ID number EPA–HQ–OPP–2009–0636.

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 NOAEL are observed and the LOAEL which adverse effects of concern are identified. 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 indaziflam used for human risk assessment is shown in the table below of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR INDAZIFLAM 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 (General population including females 13–49 years of age and infants and children).	NOAEL = 50 mg/kg/day .... UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.5 mg/kg/day aPAD = 0.5 mg/kg/day	Acute oral neurotoxicity in the rat. LOAEL = 100 mg/kg/day based on decreased motor and locomotor activity in females.
Chronic dietary (All populations).	NOAEL = 2 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.02 mg/kg/day. cPAD = 0.02 mg/kg/day	Chronic oral (dietary) toxicity in the dog. LOAEL = 6/7 mg/kg/day M/F, based on nerve fiber degenerative lesions in the brain, spinal cord and sciatic nerve.
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL= 7.5 mg/kg/day .... UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic oral (gavage) in the dog. LOAEL = 15 mg/kg/day based on axonal degenerative microscopic findings in the brain, spinal cord and sciatic nerve.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR INDAZIFLAM 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
Dermal short-term ..... (1 to 30 days) and intermediate-term (1 to 6 months).	Dermal (or oral) study NOAEL = 7.5 mg/kg/day (dermal absorption rate = 7.3%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic oral (gavage) in the dog. LOAEL = 15 mg/kg/day based on axonal degenerative microscopic findings in the brain, spinal cord and sciatic nerve.
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months).[1]	Inhalation (or oral) study NOAEL= 7.5 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic oral (gavage) in the dog. LOAEL = 15 mg/kg/day based on axonal degenerative microscopic findings in the brain, spinal cord and sciatic nerve.
Cancer (Oral, dermal, inhalation).	Classification: "Not Likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in the two-year dietary rat and mouse bioassays.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

[1] EPA selected a point of departure from an oral study to assess short-term residential handler inhalation risks for indaziflam. While it is possible that extrapolation of an inhalation endpoint from an oral study may sometimes underestimate inhalation risk, in this case the Agency believes the risk assessment is protective of adult handlers. MOEs calculated for residential handlers ranged from 3,000 to 510,000, thus providing an ample margin of safety to account for any uncertainties in route-to-route extrapolation. Further, the contribution of residential inhalation exposure to aggregate risk is small.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to indaziflam, EPA considered exposure under the petitioned-for tolerances. There are no tolerances currently established for indaziflam. EPA assessed dietary exposures from indaziflam 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 indaziflam. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed that residues are present in all commodities at the tolerance level and that 100% of commodities are treated with indaziflam. DEEM–FCID, Version 2.03 default concentration factors were used to estimate residues of indaziflam in processed commodities with the exception of the empirically derived raisin processing factor of 2.8x.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed that residues are present in all commodities at the tolerance level and that 100% of commodities are treated with indaziflam. DEEM–FCID, Version 2.03 default concentration factors were used to estimate residues of indaziflam in processed commodities with the exception of the empirically derived raisin processing factor of 2.8x.

iii. *Cancer.* Based on the results of carcinogenicity studies in rats and mice, EPA classified indaziflam as "Not Likely to be Carcinogenic to Humans" therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for indaziflam. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The residues of concern in drinking water include indaziflam and its degradates: Triazine indanone, indaziflam-carboxylic acid, indaziflam-olefin, indaziflam-hydroxyethyl, fluoroethyl-diaminotriazine (FDAT), and dihydroaminotriazine (a degradate of FDAT). The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for indaziflam and its degradates in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of indaziflam and its degradates. 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 Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of indaziflam and its degradates for acute exposures are estimated to be 84 parts per billion (ppb) for surface water and 3.7 ppb for ground water. The chronic exposures for non-cancer assessments are estimated to be 26 ppb for surface water and 3.7 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 84 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 26 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). Indaziflam

is currently registered for the following uses that could result in residential exposures: Residential turfgrass and recreational areas. EPA assessed residential exposure using the following assumptions: There is a potential for short-term exposure of homeowners applying products containing indaziflam on home lawns. There is also a potential for short- and intermediate-term post-application exposure of adults and children entering lawn and recreation areas, including golf courses, which have been treated with indaziflam. Indaziflam post-application inhalation exposures are expected to be negligible due to its low vapor pressure, low application rates, and the types of application equipment used (i.e., hand-held equipment that is not likely to generate a vapor). Therefore, a quantitative post-application inhalation exposure assessment was not considered necessary. EPA assessed the following residential exposure scenarios:

i. Short-term dermal and inhalation exposures of residential handlers using various types of application equipment and formulation types on the proposed residential use sites;

ii. Short-term post-application dermal exposures of adults and children entering treated turf areas; and

iii. Short-term postapplication incidental oral exposures of children from contact with treated turfgrass.

Since the doses and endpoints selected to assess short- and intermediate-term exposures are the same, a separate quantitative intermediate-term assessment was not completed; the short-term risk assessments are protective of intermediate-term risks.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

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 indaziflam to share a common mechanism of toxicity with any other substances. Indaziflam and its metabolite fluoroethyldiaminotriazine (FDAT) contain a triazine moiety within their chemical structures. Several triazine herbicides were determined by EPA to have a common mechanism of toxicity based on their ability to disrupt the hypothalamic-pituitary-gonadal axis (U.S. EPA, 2002). The triazine common mechanism group (TCMG) includes atrazine, simazine, propazine, and the metabolites desethyl-s-atrazine (DEA), deisopropyl-s-atrazine (DIA), and diaminochlorotriazine (DACT). Indaziflam and its metabolite FDAT were considered for incorporation into the TCMG by EPA based on structure; indaziflam, FDAT, and the TCMG members contain a common triazine moiety. However, EPA determined that it would not be appropriate to include indaziflam and FDAT in the TCMG for the following reasons:

i. The structure of indaziflam and FDAT are unique in that they contain a fluoroethyl group at the 2-position of the triazine ring, whereas the TCMG members contain a chlorine substituent at the 2-position of the triazine ring and;

ii. Indaziflam and FDAT do not elicit the same toxicological responses shared by the TCMG members. The TCMG members cause an increase in mammary gland tumors in rats and multiple developmental effects such as attenuation of the luteinizing hormone surge, altered pregnancy outcome, and delayed preputial separation. Although delayed sexual maturation was observed in the rat reproductive toxicity study, the effects occurred only at the highest dose. None of the other effects associated with the TCMG members were observed in the carcinogenicity, developmental, or reproductive guideline studies for indaziflam. In a non-guideline study, FDAT delayed vaginal patency in a dose-dependent manner. However, none of the other characteristic developmental effects of the TCMG members were observed, and this effect only occurred at higher doses compared to DACT. Therefore, unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA found that neither indaziflam nor its metabolite FDAT have a common mechanism of toxicity with any other substances, and indaziflam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that indaziflam 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 pre- and post-natal toxicity database for indaziflam includes guideline rat and rabbit developmental toxicity studies, a 2-generation reproduction toxicity study in rats and a developmental neurotoxicity study in rats. As discussed in Unit III.A., there was no evidence of increased pre- or post-natal susceptibility of fetuses or offspring in any of these studies.

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 indaziflam is considered complete and includes acceptable developmental toxicity studies in rats and rabbits, a 2-generation reproductive toxicity study in rats, a developmental neurotoxicity in rats, acute and subchronic neurotoxicity screening studies in rats, and an immunotoxicity study.

ii. There is no evidence that indaziflam results in increased pre- or post-natal susceptibility of rats or rabbits in the prenatal developmental studies of rats in the 2-generation reproduction study, or of rats in the developmental neurotoxicity study.

iii. There are no significant residual uncertainties in the exposure databases. The final report on the stability of indaziflam in frozen storage and processing data for citrus oil were only recently submitted by the petitioner and are currently undergoing full review at the Agency; however, based on a preliminary screening of the data, EPA does not expect these studies to have a measurable impact on exposure estimates for indaziflam.

a. *Storage stability.* Preliminary information from the study indicates that indaziflam is stable in frozen

storage over a 25–26 month period, well beyond the 17-month period that samples from the residue field trials were stored frozen prior to analysis.

b. *Citrus oil processing data.* Although all citrus commodities from submitted field trials and a processing study have total residues below the method limit of quantitation (LOQ) at a 5× exaggerated application rate, data were required for the processed commodity citrus oil due to the extremely high theoretical concentration factor (1000x). Citrus oil was not analyzed during the originally submitted processing study. Data from the recently submitted study indicate that indaziflam residues concentrate in citrus oil at approximately 11.7x compared to those in citrus raw agricultural commodities (RACs). Based on this preliminary concentration factor, the total residues in citrus oil are still estimated to be less than the LOQ. Therefore, EPA believes that the tolerance of 0.01 ppm (the LOQ) for citrus fruit is adequate to cover residues in citrus oil, as no finite residues would be expected in citrus oil even at exaggerated rates.

The dietary food exposure assessments were performed assuming tolerance-level residues and 100 PCT for all commodities. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to indaziflam in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children including incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by indaziflam.

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. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to indaziflam will occupy 3% of the aPAD for infants, less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to indaziflam from food and water will utilize 10% of the cPAD for infants, less than 1 year old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of indaziflam is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Indaziflam is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to indaziflam.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 2,400 for adults and 1,300 for children. For adults, EPA aggregated short-term residential handler inhalation and dermal exposure with chronic dietary exposure from food and water. For children, EPA aggregated short-term dermal and incidental oral residential exposures plus chronic dietary exposure from food and water. Because EPA's level of concern for indaziflam is for MOEs below 100, these MOEs are 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). Since the doses and endpoints selected to assess short- and intermediate-term exposures to indaziflam are the same, a separate quantitative intermediate-term assessment was not completed; the short-term risk assessments are protective of both short- and intermediate-term risks.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, indaziflam is not expected to pose a cancer risk to humans.

6. *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 indaziflam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) Method DH–003–P07–02) is available to enforce the tolerance expression. The method is able to determine, separately, residues of indaziflam and FDAT. 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; *e-mail 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 U.N. 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 an MRL for indaziflam.

C. Revisions to Petitioned-For Tolerances

EPA is lowering the almond, hulls tolerance proposed at 0.20 ppm to 0.15 ppm based on analysis of the field trial data using the Agency's NAFTA-harmonized tolerance/MRL calculator in accordance with the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data.* EPA is also revising the proposed commodity term, "Sugarcane, sugar, refined" to read "Sugarcane, refined sugar" to agree with the Agency's Food and Feed Vocabulary. Additionally, EPA is revising the requested tolerance expression to clarify the chemical moieties that are covered by the tolerances and specify how compliance with the tolerances is to be measured. The revised tolerance expression makes clear that the

tolerances cover residues of the herbicide indaziflam, including its metabolites and degradates, but that compliance with the tolerance levels is to be determined by measuring only indaziflam, *N*-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, in or on the commodities.

EPA was petitioned for tolerances on citrus fruit group 10 and pome fruit group 11. In the **Federal Register** of December 8, 2010 (75 FR 76284) (FRL–8853–8), EPA issued a final rule that revised the crop grouping regulations. As part of this action, EPA expanded and revised the existing citrus fruit group 10 and pome fruit group 11. Changes to crop group 10 included adding the specialty commodities Australian desert lime, Australian finger lime, Australian round lime, Brown River finger lime, Japanese summer grapefruit, Mediterranean mandarin, Mount White lime, New Guinea wild lime, Russell River lime, sweet lime, Tachibana orange, Tahiti lime, tangelo, tangor, trifoliate orange, and uniq fruit; creating subgroups; revising the representative commodities; and naming the new crop group citrus fruit group 10–10. Changes to crop group 11 included adding the specialty commodities azarole, medlar, Asian pear, Chinese quince, Japanese quince, and tejocote; creating subgroups; revising the representative commodities; and naming the new crop group pome fruit group 11–10. EPA indicated in the December 8, 2010 final rule as well as the earlier January 6, 2010 proposed rule (75 FR 807) (FRL–8801–2) that, for existing petitions for which a Notice of Filing had been published, the Agency would attempt to conform these petitions to the rule. Therefore, consistent with this rule, EPA has assessed exposure to the herbicide, indaziflam, assuming use under the revised crop groups. Because revising the requested crop groups to the updated crop groups did not result in a risk of concern, EPA is proposing to establish tolerances for indaziflam residues on citrus fruit group 10–10 and pome fruit group 11–10.

V. Conclusion

Therefore, tolerances are established for residues of the herbicide indaziflam, including its metabolites and degradates, in or on fruit, citrus, group 10–10 at 0.01 ppm; fruit, pome, group 11–10 at 0.01 ppm; fruit, stone, group 12 at 0.01 ppm; nut, tree, group 14 at 0.01 ppm; pistachio at 0.01 ppm; almond, hulls at 0.15 ppm; grape at 0.01 ppm; olive at 0.01 ppm; and sugarcane, refined sugar at 0.01 ppm. Compliance with the tolerance levels is to be determined by measuring only indaziflam, *N*-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, in or on the commodities.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 section 408(d) of FFDCA, 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 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 section 408(n)(4) of FFDCA. 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) (Pub. L. 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: March 23, 2011.

Steven Bradbury,

Director, 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. Section 180.653 is added to read as follows:

§ 180.653 Indaziflam; tolerances for residues:

(a) *General.* Tolerances are established for residues of the herbicide indaziflam, *N*-[(1R,2S)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the table below is to be determined by

measuring only indaziflam, in or on the commodity.

Commodity	Parts per million
Almond, hulls	0.15
Fruit, citrus, group 10–10	0.01
Fruit, pome, group 11–10	0.01
Fruit, stone, group 12	0.01
Grape	0.01
Nut, tree, group 14	0.01
Olive	0.01
Pistachio	0.01
Sugarcane, refined sugar [1]	0.01

[1] Tolerance without a corresponding U.S. registration.

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2011–7774 Filed 4–5–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0307; FRL–8864–1]

Mancozeb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mancozeb in or on almonds, cabbage, lettuce, peppers, and broccoli. Dow AgroSciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 6, 2011. Objections and requests for hearings must be received on or before June 6, 2011, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0307. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 308–9367; *e-mail address: ertman.andrew@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

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

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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.gpoaccess.gov/ecfr.*

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–2005–0307 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 June 6, 2011. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2005–0307, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of November 30, 2005 (70 FR 71836) (FRL–7747–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 3E6536 for mandarin oranges/mandarins; PP 4F4324 for almond nuts and almond hulls; PP 4F4333 for broccoli, cabbage, lettuce, and peppers) by Dow AgroSceinces LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petitions requested that 40 CFR 180.176 be amended by establishing tolerances for residues of the fungicide mancozeb, zinc manganese ethylenebis dithiocarbamate, in or on mandarin