G. Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). In this action, EPA is not addressing any tribal implementation plans. This action is limited to states that do not meet their existing obligation for PSD SIP submittal. Thus, Executive Order 13175 does not apply to this action.

Although Executive Order 13175 does not apply to this final rule, EPA specifically solicited additional comment on the proposal for this action from tribal officials and we received one comment from a tribal agency. Additionally, EPA participated in a conference call on July 29, 2010, with the National Tribal Air Association (NTAA).

H. Executive Order 13045—Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets E.O. 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the E.O. has the potential to influence the regulation. This action is not subject to E.O. 13045 because it merely prescribes EPA's action for states that do not meet their existing obligation for PSD SIP submittal.

I. Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866. This action merely prescribes EPA's action for states that do not meet their existing obligation for PSD SIP submittal.

J. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

K. Executive Order 12898—Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the U.S.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This rule merely prescribes EPA's action for states that do not meet their existing obligation for PSD SIP submittal.

L. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules: (1) Rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S. 804(3). EPA is not required to submit a rule report regarding this action under section 801 because this is a rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties.

V. Judicial Review

Under section 307(b)(1) of the Act, judicial review of this final action is available by filing of a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by February 28, 2011. Any such judicial review is limited to only those objections that are raised with reasonable specificity in timely comments. Under section 307(b)(2) of the Act, the requirements of this final action may not be challenged later in civil or criminal proceedings brought by us to enforce these requirements.

VI. Statutory Authority

The statutory authority for this action is provided by sections 101, 111, 114, 116, and 301 of the CAA as amended (42 U.S.C. 7401, 7411, 7414, 7416, and 7601).

List of Subjects in 40 CFR Part 52

Air pollution control, Carbon dioxide, Carbon dioxide equivalents, Carbon monoxide, Environmental protection, Greenhouse gases, Hydrofluorocarbons, Incorporation by reference, Intergovernmental relations, Lead, Methane, Nitrogen dioxide, Nitrous oxide, Ozone, Particulate matter, Perfluorocarbons, Reporting and recordkeeping requirements, Sulfur hexafluoride, Sulfur oxides, Volatile organic compounds.

Dated: December 23, 2010.

Gina McCarthy,

Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2010–32762 Filed 12–28–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0205; FRL–8857–4]

Imazosulfuron; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of imazosulfuron in or on pepper, bell; pepper, non-bell; rice, grain; and tomato. Valent USA Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 29, 2010. Objections and requests for hearings must be received on or before February 28, 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–2009–0205. 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@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.* To access the harmonized test guidelines referenced in this document electronically, please go *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

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–2009–0205 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 February 28, 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–2009–0205, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online 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 May 6, 2009 (74 FR 20947) (FRL–8412–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7535) by Valent USA Corporation, 1600 Riviera Ave., Suite 200, Walnut Creek, CA 94596. The petition requested that 40 CFR part 180 be amended by adding a section for the herbicide imazosulfuron and establishing tolerances therein for residues of imazosulfuron, 2-chloro-*N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl] imidazo-[1,2-a]pyridine-3-sulfonamide, in or on pepper, bell, fruit; pepper, non-bell, fruit; rice, grain; and tomato, fruit; each at 0.02 parts per million (ppm). That notice referenced a summary of the petition prepared by Valent USA Corporation, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

EPA has modified the proposed commodity terms for pepper and tomato commodities and revised the requested tolerance expression in accordance with current policy. 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 imazosulfuron including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with imazosulfuron 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 data for imazosulfuron suggest that this herbicide possesses relatively low toxicity. Many of the effects of single or repeated dosing were observed near or beyond the respective limit doses.

Imazosulfuron is of low acute toxicity by the oral, dermal, and inhalation routes of exposure; it is not a skin or eye irritant or a dermal sensitizer. The primary target organ of imazosulfuron in repeated-dose studies was the liver in all species tested. Mild to moderate thyroid effects were apparent only in the chronic toxicity study in dogs. Dramatic eye effects (retinal degeneration, lens vascularization, cataracts and corneal scarring) were observed in rats fed > 1,000 mg/kg/day beginning at 3 months in the chronic toxicity/carcinogenicity study. Ocular effects (increased incidence of eye opacity, corneal edema, inflammation and neovascularization) were also observed in the high-dose males (4,577 mg/kg/day) in the 90-day feeding toxicity study in rats. Decreased body weight and body weight gain compared to control were frequent findings throughout the toxicology database for imazosulfuron.

Clinical signs (decreased motor activity, abnormal gait, upward curvature of the spine and piloerection) were observed in males at the limit dose of the acute neurotoxicity study; however, these effects can be attributed to generalized toxicity and were resolved by Day 2 of the study. No neurotoxic effects were observed during the subchronic screening battery or noted as clinical signs in any other repeated-dose study.

No developmental effects were observed at the highest dose tested (HDT) (125 mg/kg/day) in the rabbit developmental toxicity study. No developmental or reproductive toxicity was observed in the 1-generation rat study. Decreased pup viability was observed in the rat 2-generation reproduction study at a dose approaching the limit dose (LOAEL = 892 mg/kg/day) in both the F1 and F2 offspring generations. Mortality was also observed in the parental generation at this dose. No increased qualitative or quantitative offspring susceptibility was apparent in any of the submitted studies for imazosulfuron.

There was no evidence of carcinogenicity in rats and mice up to the limit dose at 24 and 18 months, respectively. Imazosulfuron was determined to be non-mutagenic in bacteria and negative in an *in vivo* mammalian cytogenetics assay. Overall, there was no evidence that imazosulfuron was either mutagenic or clastogenic in either *in vivo* or *in vitro* assays. The cancer classification is "not likely to be carcinogenic to humans," based on the absence of significant tumor increases in the carcinogenicity studies.

Specific information on the studies received and the nature of the adverse effects caused by imazosulfuron 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 the document "Imazosulfuron: Human Health Risk Assessment for Proposed Uses on Rice, Peppers and Tomatoes," p. 45 in docket ID number EPA–HQ–OPP–2009–0205.

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 imazosulfuron used for human risk assessment is shown in the Table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR IMAZOSULFURON 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).	An acute reference dose specific to females age 13–49 was not identified, because there was no prenatal or fetal toxicity observed in developmental or reproductive animal studies following a single oral dose.		
Acute dietary (General population including females 13–49 years of age and infants and children).	NOAEL = 400 mg/kg/day UF_A = 10x.	Acute RfD = 4 mg/kg/day.	Acute neurotoxicity screening battery. LOAEL = 2,000 mg/kg/day based on the following clinical signs: Abnormal gait, decreased activity, piloerection and upward curvature of the spine; and incidents of irregular breathing, reduced righting reflex, tremors, decreased visual placement response in males and increased response to sound in one female.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR IMAZOSULFURON 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
Chronic dietary (All populations)	UF_H = 10x FQPA SF = 1x NOAEL= 75 mg/kg/day UF_A = 10x.	aPAD = 4 mg/kg/day Chronic RfD = 0.75 mg/kg/day.	Chronic toxicity in the dog. LOAEL = 150 mg/kg/day based on moderate thyroid hypertrophy (males at mid- and high-dose; mild hypertrophy in females at high-dose).
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	UF_H = 10x FQPA SF = 1x NOAEL= 235 mg/kg/day UF_A = 10x.	cPAD = 0.75 mg/kg/day. LOC for MOE = 100	Reproduction, 2-generation (rat). LOAEL = 892 mg/kg/day based on mortality, clinical signs, decreased body weights, body weight gains and food consumption in parents. 90-day oral toxicity (rat). LOAEL = 956 mg/kg/day based on decreased body weight gains and food efficiency.
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months).	UF_H = 10x. FQPA SF = 1x. No systemic toxicity occurred at the limit dose and the primary toxic effects of concern (liver, eye) were adequately assessed in a 21-day dermal toxicity study. It is concluded that this compound is not or is poorly absorbed through the skin and, therefore, a quantitative risk assessment for this route and duration of exposure is not necessary.		
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months).	Inhalation (or oral) study NOAEL = 235 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x. UF_H = 10x. FQPA SF = 1x	LOC for MOE = 100	Reproduction, 2-generation (rat). LOAEL = 892 mg/kg/day based on mortality, clinical signs, decreased body weights, body weight gains and food consumption in parents. 90-day oral toxicity (rat). LOAEL = 956 mg/kg/day based on decreased body weight gains and food efficiency.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. $UF_{S\ =}$ use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. 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.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to imazosulfuron, EPA considered exposure under the petitioned-for tolerances. There are no tolerances currently established for imazosulfuron. EPA assessed dietary exposures from imazosulfuron 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 imazosulfuron. 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 Intakes 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 imazosulfuron. DEEM™ 7.81 default concentration factors were used to estimate residues of imazosulfuron in processed commodities.

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 imazosulfuron. DEEM™ 7.81 default concentration factors were used to estimate residues of imazosulfuron in processed commodities.

iii. *Cancer.* Based on the results of carcinogenicity studies in rats and mice, EPA classified imazosulfuron 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 imazosulfuron. 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 imazosulfuron and its degradates HMS, IPSN, UDPM, ADPM, and SDPM. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for imazosulfuron and its degradates in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of imazosulfuron 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 First Index Reservoir Screening Tool (FIRST), Tier 1 Rice Model, and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of imazosulfuron and its degradates for both acute exposures and chronic exposures for non-cancer assessments are estimated to be 278.9 parts per billion (ppb) for surface water (based on the Tier 1 Rice Model results) and 4.8 ppb for ground water (based on the SCI–GROW model results).

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic dietary risk assessment, the water concentration value of 278.9 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). Imazosulfuron 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 exposure of homeowners applying products containing imazosulfuron on home lawns. There is also a potential for post-application exposure of adults and children entering turf areas that have been treated with imazosulfuron and for bystander exposure of adults and children in areas adjacent to pesticide applications.

Residential handlers may receive short-term dermal and inhalation exposure to imazosulfuron when mixing, loading and applying the pesticide on home lawns. Since a dermal endpoint of concern was not identified for imazosulfuron, only short-term inhalation exposure of residential handlers was assessed.

Adults and children may receive short-term inhalation and dermal exposures from entering turf areas treated with imazosulfuron. Volatilization of imazosulfuron may also be a source of short-term post-application inhalation exposure of bystanders nearby application sites. Finally, children may receive short-term incidental oral exposure (*i.e.,* hand-to-mouth, object-to-mouth and soil ingestion exposure) during post-application activities on treated turf. EPA did not identify any dermal endpoints of concern for imazosulfuron; and a quantitative post-application inhalation exposure assessment was not performed for imazosulfuron due to its low acute inhalation toxicity, low vapor pressure ($< 3.5 \times 10^{-6}$ Pa), low proposed use rate (0.3 lb ai/A), and the soil-directed application method (*i.e.,* it is not applied using equipment, such as air blast sprayers, that would result in higher post-application inhalation exposures). Therefore, EPA assessed only short-term post-application incidental oral exposure of children (toddlers).

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 imazosulfuron to share a common mechanism of toxicity with any other substances, and imazosulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that imazosulfuron 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 postnatal toxicity database for imazosulfuron includes guideline rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats. No developmental effects were observed at the HDT in the rabbit developmental toxicity study, and no developmental or reproductive toxicity was observed in the developmental (1-generation) rat study. In the 2-generation rat reproduction study, both decreased pup viability and parental mortality were observed, but only at a dose approaching the limit dose.

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 imazosulfuron is largely complete, lacking only an immunotoxicity study. EPA has evaluated the available toxicity data for imazosulfuron and determined that an additional database uncertainty factor is not needed to account for potential immunotoxicity. The most sensitive endpoint in the database is moderate thyroid hypertrophy. Liver toxicity accompanied by body weight and food consumption effects is seen throughout the toxicology database. No treatment-related changes indicative of potential immunotoxicity were seen in hematology parameters, organ weights (thymus, spleen), gross necropsy (enlarged lymph nodes) or histopathology (spleen, thymus, lymph nodes) when tested up to the limit dose in mice and rats. Therefore, EPA does not believe that conducting a special series 870.7800 immunotoxicity study will result in a NOAEL less than 75 mg/kg/day, which is presently used as the point of departure for chronic risk assessment.

ii. No neurotoxic effects were observed during the subchronic screening battery or noted as clinical signs in any other repeated-dose study. Although untoward clinical signs were observed in the acute neurotoxicity study, these effects can be attributed to generalized toxicity and were resolved by Day 2 of the study. Based on these considerations, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that imazosulfuron results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no significant residual uncertainties in the exposure databases. Data have been requested to confirm the stability of imazosulfuron during frozen storage and the metabolic profile of pyrimidine-labeled imazosulfuron in rice grain in the confined rotational crop trial. A field rotational crop study is also required for grain (wheat); however, as explained in Unit III.D.3.iv.c., EPA does not expect these studies to have a measurable impact on exposure estimates for imazosulfuron.

a. *Storage stability.* The final reports of the storage stability studies must be submitted, reflecting frozen storage intervals of up to 11.8 months for peppers, up to 34.5 months for rice grain, and up to 17.3 months for tomatoes. Interim data suggest that imazosulfuron is stable in frozen storage, and similar sulfonylurea chemicals are known to be stable. Therefore, EPA expects imazosulfuron to be stable in frozen storage but is requiring the final study reports as confirmation.

b. *Metabolic profile.* The HPLC profile for the pyrimidinyl (Py)-label grain storage stability analysis must be submitted to confirm that the metabolite profile was stable in Py-label grain. Grain samples from the confined rotational crop study were stored for a relatively long interval (9 months) prior to completion of the analyses. Analysis of an imidozolyl (Im)-label sample after the 9-month period yielded a metabolic profile similar to that of a sample analyzed at the start of the period. A similar comparison must be made for the Py-label sample of grain. This is of no practical consequence for risk assessment because total residue levels on grain were small (<0.01 ppm at a 365-day plantback interval), imazosulfuron was not present, and no metabolites/degradates were considered toxicologically significant.

c. *Field accumulation in rotational crops (grain).* The grain (wheat) rotational crop study is needed to identify maximum levels of residues in grain and livestock feed items (forage, straw) as a function of the plantback interval. On an interim basis, a plantback interval of 12 months is being required for grains and soybeans. The results of the rotational crop study may allow a shorter plantback interval. The confined rotational crop study showed that imazosulfuron and metabolites will be negligible (<0.01 ppm) on forage, hay, straw, stover, and grain at a 365-day plantback interval and will, therefore, make no contribution to dietary exposure.

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 imazosulfuron in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by imazosulfuron.

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 imazosulfuron will occupy 1.4% 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 imazosulfuron from food and water will utilize 2.7% 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 imazosulfuron 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). Imazosulfuron 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 imazosulfuron.

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 40,000 for adults and 7,000 for children. For adults, the aggregate MOE includes short-term residential handler inhalation exposure plus chronic dietary exposure to imazosulfuron from food and water. For children, the aggregate MOE includes short-term incidental oral residential exposure plus chronic dietary exposure to imazosulfuron from food and water. Because EPA's level of concern for imazosulfuron is a MOE of 100 or below, 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). An intermediate-term adverse effect was identified; however, imazosulfuron is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure 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 intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for imazosulfuron.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, imazosulfuron 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 imazosulfuron residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) Method RM–42C–3) is available to enforce the tolerance expression. 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 a MRL for imazosulfuron.

C. Revisions to Petitioned-For Tolerances

EPA is revising the proposed commodity terms for "pepper, bell, fruit"; "pepper, non-bell, fruit"; and "tomato, fruit"; to read "pepper, bell"; "pepper, non-bell"; and "tomato". The commodity terms have been changed in accordance with the guidance in the Agency's Food and Feed Commodity Vocabulary.

EPA is also 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 imazosulfuron, including its metabolites and degradates, but that compliance with the tolerance levels is to be determined by measuring only imazosulfuron, 2-chloro-*N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]imidazo-[1,2-α]pyridine-3-sulfonamide, in or on the commodities.

V. Conclusion

Therefore, tolerances are established for residues of imazosulfuron, including its metabolites and degradates, in or on pepper, bell at 0.02 ppm; pepper, non-bell at 0.02 ppm; rice, grain at 0.02 ppm; and tomato at 0.02 ppm. Compliance with the tolerance levels is to be determined by measuring only imazosulfuron, 2-chloro-*N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]imidazo-[1,2-α]pyridine-3-sulfonamide, 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: December 13, 2010.

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 180.651 is added to read as follows:

§ 180.651 Imazosulfuron; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide imazosulfuron, including its metabolites and degradates, in or on the following commodities. Compliance with the tolerance levels specified in the following table below is to be determined by measuring only imazosulfuron, 2-chloro-*N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]imidazo-[1,2-α]pyridine-3-sulfonamide, in or on the commodity.

Commodity	Parts per million
Pepper, bell	0.02
Pepper, non-bell	0.02
Rice, grain	0.02
Tomato	0.02

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

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

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

[FR Doc. 2010–32451 Filed 12–28–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 422, and 495

[CMS–0033–F2]

RIN 0938–AP78

Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Correcting Amendment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correcting amendment.

SUMMARY: This document corrects typographical and technical errors identified in the final rule entitled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program" that appeared in the July 28, 2010 **Federal Register**.

DATES: *Effective Date:* This correcting amendment is effective December 29, 2010.

FOR FURTHER INFORMATION CONTACT: Rachel Maisler, (410) 786–5754.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2010–17207 (75 FR 44314) the final rule entitled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program" (hereinafter referred to as the Medicare and Medicaid EHR Incentive Program), there were several technical and typographical errors that are identified in the Summary of Errors section and corrected in the Correction of Errors section and in the regulations text of this correcting amendment.

II. Summary of Errors

A. Errors in the Preamble

In the preamble to this final rule, we made the following technical and typographical errors.

On page 44314, in the **FOR FURTHER INFORMATION CONTACT**, we are correcting the contact information for Medicaid incentive payment issues for better accuracy.

On page 44337, in our response to a comment on the objective generate and transmit permissible prescriptions electronically, we inadvertently referenced only the restrictions established by the Department of Justice (DOJ) on electronic prescribing for controlled substances in Schedule II, when in fact we meant to include Schedule II–V. We intended to encompass all prescriptions where e-prescribing is not permitted, so we are including Schedules III–V. At the time of the publication of the our January 13, 2010 proposed rule, the Drug Enforcement Agency (DEA) had not published its March 31, 2010 final rule (75 FR 16236) on the electronic prescribing of controlled substances. We are aligning our regulation with the DEA regulations regarding electronic prescribing of controlled substances by adding schedules II–V so that we are in line with DEA regulation.

On page 44351, in our discussion of the proposed rule EP/Eligible Hospital Measure, we erroneously referred to "five rules" related to clinical decision support although we reduced that requirement to one rule.

On page 44359, in our response to a comment regarding charging fees, we inadvertently omitted a word. Also, in our discussion of the numerator and denominator for the clinical summary objective, we inadvertently referred to unique patients, rather than to office visits. As the measure for this objective relies on office visits (*see* § 495.6(d)(13)), we are correcting the preamble to also refer to office visits. We have also eliminated a reference in the preamble to eligible hospitals and CAHs in the threshold for this objective, as the objective applies only to EPs.

On pages 44440 and 44442, we are revising our discussions of hospital-based EPs, so that they correctly refer to EPs that furnish "90 percent or more," (rather than "more than 90 percent") of their covered professional services in an inpatient or emergency department setting. This is in keeping with the definition in § 495.4.

On page 44487, we are correcting the preamble to more precisely state that the 90-day period for deriving hospitals' patient volume is based on the preceding fiscal year. This is in keeping with § 495.306, which specifically references the fiscal year.

Also, on page 44487 and page 44488 we inadvertently referred to hospitals when discussing the patient panel methodology for estimating Medicaid patient volume. As the patient panel methodology will be used only by EPs (and as our regulation cites only to EPs when discussing the patient panel methodology—*see* § 495.306(d)), we are eliminating the references to hospitals.

On page 44488, we incorrectly included "unduplicated Medicaid encounters" in the last sentence, instead of "unduplicated encounters." This correction allows for us to keep the numerator and denominator consistent when determining the Medicaid patient volume.

On pages 44499, 44518, 44549, and 44562, we made typographical errors which include errors in mathematical symbols, column headings, and the numbering and referencing of tables.

B. Errors in the Regulation Text

On page 44568, in § 495.6(d)(14)(i), we erroneously omitted medication allergies in the list of examples. Therefore, we are including this reference to be consistent with the preamble of the July 28, 2010 final rule.

On page 44568, in § 495.6(e)(1), we inadvertently omitted a reference to the exclusion for any EP who writes fewer than 100 prescriptions during the EHR reporting period (as discussed in the preamble of the final rule (see page 44336)). Therefore, we are correcting § 495.6(e)(1) by referencing this exclusion in accordance with § 495.6(a)(2) "Implement drug-formulary checks."

On page 44587, in § 495.366(b)(3), we made inadvertent errors by citing to inpatient and outpatient settings, rather than the inpatient or emergency room settings in a discussion of "hospital-based."

On page 44588, in § 495.368(c) regarding overpayments, we are correcting the period of consideration for overpayments. We note that section 1903(d)(2) of the Act was amended by section 6506 of the Patient Protection and Affordable Care Act (known as the Affordable Care Act (ACA)). This amendment changed the mandatory time period for collection of overpayments from 60 days to 1 year. Therefore, we are correcting § 495.368(c) to implement this statutory change.

III. Correction of Errors in the Preamble

In FR Doc. 2010–17207 of July 28, 2010, we make the following corrections: