Laws, Pymetrozine – Acute, Chronic and Cancer Combined Dietary (Food + Drinking Water) Exposure and Risk Assessments (April 2, 2010).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 27, 2010.

Steven Bradbury,

Director, Office of Pesticide Programs.

[FR Doc. 2010–19423 Filed 8–5–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0190; FRL–8836–7]

Acetamiprid, Mepiquat; Order Denying NRDC's Objections on Remand: Environmental Protection Agency

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final order.

SUMMARY: In this order, EPA again denies objections by the Natural Resources Defense Council (NRDC) to actions establishing tolerance regulations for the pesticides acetamiprid and mepiquat under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA's previous denial of NRDC's objections, published in the **Federal Register** on August 10, 2005, was remanded to EPA by the U.S. Court of Appeals, Ninth Circuit, for further explanation of EPA's decision on the application of the FFDCA's requirement concerning an additional safety factor for the protection of infants and children to these pesticide tolerances. On remand, EPA is denying NRDC's objections because the objections are now either moot or not sufficient to justify the relief requested.

DATES: This order is effective August 6, 2010.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0190. To access the electronic docket, go to *http://www.regulations.gov*, and search for the docket number. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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: Meredith Laws, Registration Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–7038; e-mail address: *laws.meredith@epa.gov*.

SUPPLEMENTARY INFORMATION:.

I. General Information

A. Does this Action Apply to Me?

In this document EPA denies objections by the Natural Resources Defense Council ("NRDC") to EPA's to establishment of certain pesticide tolerances. This action may also be of interest to agricultural producers, food manufacturers, or pesticide manufacturers. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

II. Introduction

A. What Action Is the Agency Taking?

In this order, EPA denies objections filed by the NRDC to regulations establishing pesticide tolerances for acetamiprid and mepiquat under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA previously denied NRDC's objections in an order dated August 10, 2005. (70 FR 46706 (August 10, 2005)). NRDC sought judicial review of the August, 2005 order, and the U.S. Court of Appeals, Ninth Circuit, remanded the order to EPA on the sole ground that EPA had not provided an adequate explanation as to one aspect of its decision. (NCAP v. EPA, 544 F.3d 1043, 1052 (9th Cir. 2008)). Specifically, the court held that EPA did not provide "enough information" on why it chose to deviate from the presumptive ten-fold (10X) additional safety factor for the protection of infants and children in FFDCA section 408(b)(2)(C). (Id.). In response to the remand, EPA is again denying the objections; however, EPA has not provided further information on its decision on the children's safety factor because that issue is now either moot or not outcome-determinative with regard to the challenged tolerances.

B. What Is the Agency's Authority for Taking This Action?

EPA's authority for issuing pesticide tolerances is contained in FFDCA section 408(d) and the statutory provisions governing the administrative review process for tolerances is in FFDCA section 408(g)(2). (21 U.S.C. 346a(d) and (g)(2)).

III. Statutory and Regulatory Background

In this unit, EPA provides background on the relevant statutes and regulations governing NRDC's objections as well as on pertinent Agency policies and practices. Unit III.A. summarizes the requirements and procedures in section 408 of the FFDCA and applicable regulations pertaining to pesticide tolerances. Unit III.B. provides an overview of EPA's risk assessment process. It contains an explanation of how EPA identifies the hazards posed by pesticides, how EPA determines the level of exposure to pesticides that pose a concern ("level of concern"), how EPA measures human exposure to pesticides, and how hazard, level of concern conclusions, and human exposure estimates are combined to evaluate risk. Further, this unit presents background information on the EPA's policy with regard to the statutory safety factor for the protection of infants and children.

A. FFDCA

1. *In general*. EPA establishes maximum residue limits, or "tolerances," for pesticide residues in food under section 408 of the FFDCA. (21 U.S.C. 346a). Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce. (21 U.S.C. 331, 342).

2. *Safety standard for pesticide tolerances*.A pesticide tolerance may only be promulgated by EPA if the tolerance is "safe." (21 U.S.C. 346a(b)(2)(A)(i)). "Safe" is defined by the statute 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." (21 U.S.C. 346a(b)(2)(A)(ii)). In making this safety determination, risks to infants and children are given special consideration. Specifically, this provision creates a presumptive additional safety factor for the protection of infants and children. It directs that "[i]n the case of threshold effects, ... an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." (21 U.S.C. 346a(b)(2)(C)). EPA is permitted to "use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." (Id.). The additional safety margin for infants and children is referred to throughout this Order as the "children's safety factor." These provisions on pesticide safety were a part of major revisions to section 408 enacted by the Food Quality Protection Act of 1996 (FQPA). (Pub. L. 104–170, 110 Stat. 1489).

3. *Procedures for establishing, amending, or revoking tolerances*. Tolerances are established, amended, or revoked by rulemaking under the unique procedural framework set forth in the FFDCA. Generally, a tolerance rulemaking is initiated by the party seeking to establish, amend, or revoke a tolerance by means of filing a petition with EPA. (See 21 U.S.C. 346a(d)(1)). EPA publishes in the **Federal Register** a notice of the petition filing and requests public comment. (21 U.S.C. 346a(d)(3)). After reviewing the petition, and any comments received on it, EPA may issue a final rule establishing, amending, or revoking the tolerance, issue a proposed rule to do the same, or deny the petition. (21 U.S.C. 346a(d)(4)).

Once EPA takes final action on the petition by establishing, amending, or revoking the tolerance or denying the petition, any person may file objections with EPA and seek an evidentiary hearing on those objections. (21 U.S.C. 346a(g)(2)). Objections and hearing requests must be filed within 60 days. (Id.). EPA's final order on the objections is subject to judicial review. (21 U.S.C. 346a(h)(1)).

B. EPA Risk Assessment for Tolerances – Policy and Practice

1. *The safety determination - risk assessment*. To assess risk of a pesticide tolerance, EPA combines information on pesticide toxicity with information regarding the route, magnitude, and duration of exposure to the pesticide. The risk assessment process involves four distinct steps: Identification of the toxicological hazards posed by a pesticide; determination of the "level of concern" with respect to human exposure to the pesticide; estimation of human exposure to the pesticide; and characterization of the risk posed to humans by the pesticide based on comparison of human exposure to the level of concern.

a. *Hazard identification*. In evaluating toxicity or hazard, EPA reviews toxicity studies, primarily in laboratory animals, to identify any adverse effects on the test subjects. Animal studies typically involve investigating a broad range of endpoints including gross and microscopic effects on organs and tissues, functional effects on bodily organs and systems, effects on blood parameters (such as red blood cell count, hemoglobin concentration, hematocrit, and a measure of clotting potential), effects on the concentrations of normal blood chemicals (including glucose, total cholesterol, urea nitrogen, creatinine, total protein, total bilirubin, albumin, hormones, and enzymes such as alkaline phosphatase, alanine aminotransfersase and cholinesterases), and behavioral or other gross effects identified through clinical observation and measurement. EPA examines whether adverse effects are caused by either short-term (e.g., "acute") or longer-term (e.g., "chronic") pesticide exposure and the effects of pre-natal and post-natal exposure in animals. EPA also considers whether the adverse effect has a threshold - a level below which exposure has no appreciable chance of causing the effect.

b. *Level of concern/dose-response analysis*. Once a pesticide's potential hazards are identified, EPA determines a toxicological level of concern for evaluating the risk posed by human exposure to the pesticide. In this step of the risk assessment process, EPA essentially evaluates the levels of exposure to the pesticide at which effects might occur. An important aspect of this determination is assessing the relationship between exposure (dose) and response (often referred to as the dose-response analysis). EPA follows differing approaches to identifying a level of concern for threshold and non-threshold hazards. Because this document is only concerned with pesticide hazards that pose a hazard above a defined threshold, only such threshold effects are discussed.

In examining the dose-response relationship for a pesticide's threshold effects, EPA evaluates an array of toxicity studies on the pesticide. In each of these studies, EPA attempts to identify the lowest observed adverse effect level (LOAEL) and the next lower dose at which there are no observed adverse affect levels (NOAEL). Generally, EPA will use the lowest NOAEL from the available studies as a starting point (called "the Point of Departure") in estimating the level of concern for humans. (Ref. 1 at 9 (The Point of Departure "is simply the toxic dose that serves as the 'starting point' in extrapolating a risk to the human population.")). At times, however, EPA will use a LOAEL from a study as the Point of Departure when no NOAEL is identified in that study and the LOAEL is close to, or lower than, other relevant NOAELs. The Point of Departure is in

turn used in choosing a level of concern. EPA will make separate determinations as to the Points of Departure, and correspondingly levels of concern, for both short and long exposure periods as well as for the different routes of exposure (oral, dermal, and inhalation).

In estimating and describing the level of concern, the Point of Departure is at times used differently depending on whether the risk assessment addresses dietary or non-dietary exposures. For dietary risks, EPA uses the Point of Departure to calculate an acceptable level of exposure or reference dose (RfD). The RfD is calculated by dividing the Point of Departure by applicable safety or uncertainty factors. Typically, EPA uses a baseline safety/uncertainty factor of 100X. That value includes a factor of ten (10X) where EPA is using data from laboratory animals to reflect potentially greater sensitivity in humans than animals and a factor of 10X to account for potential variations in sensitivity among members of the human population as well as other unknowns. Additional safety factors may be added to address data deficiencies or concerns raised by the existing data. Under the FQPA, an additional safety factor of 10X is presumptively applied to protect infants and children, unless reliable data support selection of a different factor. This FQPA additional safety factor largely replaces pre-FQPA EPA practice regarding additional safety factors. (Ref. 2 at 4-11).

In implementing FFDCA section 408, EPA's Office of Pesticide Programs, also calculates a variant of the RfD referred to as a Population Adjusted Dose (PAD). A PAD is the RfD divided by any portion of the FQPA safety factor that does not correspond to one of the traditional additional safety factors used in general Agency risk assessments. (Ref. 2 at 13-16). The reason for calculating PADs is so that other parts of the Agency, which are not governed by FFDCA section 408, can, when evaluating the same or similar substances, easily identify which aspects of a pesticide risk assessment are a function of the particular statutory commands in FFDCA section 408. Today, RfDs and PADs are generally calculated for both acute and chronic dietary risks although traditionally a RfD or PAD was only calculated for chronic dietary risks. Throughout this document general references to EPA's calculated safe dose are denoted as a RfD/PAD.

Because this order only addresses dietary risks, EPA's approach to non-dietary risk assessment is not further discussed.

c. *Estimating human exposure*. Risk is a function of both hazard and exposure. Thus, equally important to the risk assessment process as determining the hazards posed by a pesticide and the toxicological level of concern for those hazards is estimating human exposure. Under FFDCA section 408, EPA is concerned not only with exposure to pesticide residues in food but also exposure resulting from pesticide contamination of drinking water supplies and from use of pesticides in the home or other non-occupational settings. (See 21 U.S.C. 346a(b)(2)(D)(vi)).

i. *Exposure from food*. There are two critical variables in estimating exposure in food:

- The types and amount of food that is consumed; and
- The residue level in that food.

Consumption is estimated by EPA based on scientific surveys of individuals' food consumption in the United States conducted by the United States Department of Agriculture. (Ref. 1 at 12). Information on residue values comes from a range of sources including crop field trials, data on pesticide reduction (or concentration) due to processing, cooking, and other practices, information on the extent of usage of the pesticide, and monitoring of the food supply. (Id. at 17).

In assessing exposure from pesticide residues in food, EPA, for efficiency's sake, follows a tiered approach in which it, in the first instance (i.e., "Tier 1"), assesses exposure using the worst case assumptions that 100 percent of the crops for which tolerances exist or are proposed are treated with the pesticide and 100 percent of the food from those crops contain pesticide residues at the tolerance level. (Id. at 11). When such an assessment shows no risks of concern, a more complex risk assessment is unnecessary. By avoiding a more complex risk assessment, EPA's resources are conserved and regulated parties are spared the cost of any additional studies that may be needed. If, however, a Tier 1 assessment suggests there could be a risk of concern, EPA then attempts to refine its exposure assumptions to yield a more realistic picture of residue values through use of data on the percent of the crop actually treated with the pesticide and data on the level of residues that may be present on the treated crop. These latter data are used to estimate what has been traditionally referred to by EPA as "anticipated residues." More information on how EPA refines estimates of exposure from pesticides in food can be found in U.S. EPA, *A User's Guide to Available EPA Information on Assessing Exposure to Pesticides in Food* (June 21, 2000). (See 73 FR 42683, 42687 (July 23, 2008)).

ii. *Exposure from water*. EPA may use either or both field monitoring data and mathematical water exposure models to generate pesticide exposure estimates in drinking water. Monitoring and modeling are both important tools for estimating pesticide concentrations in water and can provide different types of information. Monitoring data can provide estimates of pesticide concentrations in water that are representative of specific agricultural or residential pesticide practices and under environmental conditions associated with a sampling design. Although monitoring data can provide a direct measure of the concentration of a pesticide in water, it does not always provide a reliable estimate of exposure because sampling may not occur in areas with the highest pesticide use, and/or the sampling may not occur when the pesticides are being used.

In estimating pesticide exposure levels in drinking water, EPA most frequently uses mathematical water exposure models. EPA's models are based on extensive monitoring data and detailed information on soil properties, crop characteristics, and weather patterns. (69 FR 30042, 30058-30065 (May 26, 2004)). These models calculate estimated environmental concentrations of pesticides using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment. These concentrations can be estimated continuously over long periods of time, and for places that are of most interest for any particular pesticide. Modeling is a useful tool for characterizing vulnerable sites, and can be used to estimate peak concentrations from infrequent, large storms.

Typically EPA uses a two-tiered approach to modeling pesticide concentrations in surface and ground water. The first tier model uses high-end and worst-case assumptions as a screen to identify pesticides that will not result in residues in water that pose a concern. If the first tier model suggests that pesticide levels in water may be unacceptably high, a more refined model is used as a second tier assessment. Second tier models substitute more detailed information for the high-end or worst-case assumptions used in first tier models. For example, a second tier model may incorporate information on the maximum percentage of acreage surrounding a drinking water reservoir that may be devoted to agriculture instead of

assuming that 100 percent of the watershed is, in fact, farmland.

iii. *Residential exposures*. Generally, in assessing residential exposure to pesticides EPA relies on its Residential Standard Operating Procedures (SOPs). (Ref. 3). The SOPs establish models for estimating application and post-application exposures in a residential setting where pesticide-specific monitoring data are not available. SOPs have been developed for many common exposure scenarios including pesticide treatment of lawns, garden plants, trees, swimming pools, pets, and indoor surfaces including crack and crevice treatments. The SOPs are based on existing monitoring and survey data including information on activity patterns, particularly for children. Where available, EPA relies on pesticide-specific data in estimating residential exposures.

d. *Risk characterization*. The final step in the risk assessment is risk characterization. In this step, EPA combines information from the first three steps (hazard identification, level of concern/dose-response analysis, and human exposure assessment) to quantitatively estimate the risks posed by a pesticide. Separate characterizations of risk are conducted for different durations of exposure. Additionally, separate and, where appropriate, aggregate characterizations of risk are conducted for the different routes of exposure (dietary and non-dietary).

For threshold dietary risks, EPA typically estimates risk by expressing human exposure as a percentage of the RfD/PAD. Exposures lower than 100 percent of the RfD/PAD are generally not of concern. Under current procedures, EPA aggregates pesticide exposure from food and drinking water prior to comparing exposure to the RfD/PAD.

Prior to developing appropriate modeling techniques for combining pesticide exposures from food and drinking water, EPA evaluated aggregate dietary exposure and risk in two separate steps. (Ref. 4 at 3-5). First, EPA would compare pesticide exposure from food to the safe level of exposure (i.e., the RfD/PAD). If pesticide exposure from food was less than 100 percent of the RfD/PAD, then EPA would calculate what was called a Drinking Water Level of Comparison (DWLOC) and compare the pesticide exposure concentration in water to the DWLOC. The DWLOC represented the maximum safe concentration of pesticide residue that could be present in drinking water taking into account the level of pesticide exposure from food. The DWLOC was calculated by subtracting pesticide exposure in food from the RfD/PAD and dividing that amount by the maximum water consumption level. So long as the actual pesticide concentration in drinking water was below the DWLOC, aggregate exposure to the pesticide (exposure from food and water) was generally regarded as safe. A numerical example may help explicate this procedure. (To simplify the example, units of exposure are expressed in terms of milligrams of pesticide per day (mg/day) instead of the more standard milligrams of pesticide per kilogram of human body weight per day (mg/kg/day).) Suppose the safe level of exposure to a pesticide (i.e., the RfD/PAD) is 10 mg/day and consumption of food results in exposure to residues of this pesticide at a level of 2 mg/day. Under these facts, exposure to the pesticide from food represents 20 percent of the RfD/PAD. If it is assumed that a person drinks 2 liters of water per day, the DWLOC can be calculated by subtracting pesticide exposure from food from the RfD/PAD (10 mg/day – 2 mg/day = 8 mg/day) and dividing by 2 liters. The resulting DWLOC of 4 mg/liter is the maximum safe concentration of pesticide in drinking water. It follows that so long as actual water concentrations of the pesticide do not exceed 4 mg/liter, EPA can conclude that aggregate dietary exposure to the pesticide from food and water do not exceed the RfD/PAD. If the actual level of the pesticide residue in drinking water were 0.1 mg/liter, then the pesticide concentration in drinking water would be 2.5 percent of the allowable amount or DWLOC ((0.1 mg/liter ÷ 4 mg/liter) x 100 percent) and would represent 2 percent of the RfD/PAD (((2 liters/day x0.1 mg/liter) ÷ 10 mg/kg/day) x 100 percent).

2. *EPA policy on the children's safety factor*. As the brief summary of EPA's risk assessment practice in this unit indicates, the use of safety factors plays a critical role in the process. This is true for the use of traditional 10X safety factors to account for potential differences between animals and humans when relying on studies in animals (inter-species safety factor) and potential differences among humans (intra-species safety factor) as well as the use of the FQPA's additional 10X children's safety factor.

In applying the children's safety factor provision, EPA has interpreted it as imposing a presumption in favor of applying an additional 10X safety factor. (Ref. 2 at 4, 11). Thus, EPA generally refers to the additional 10X factor as a presumptive or default 10X factor. EPA has also made clear, however, that this presumption or default in favor of the additional 10X is only a presumption. The presumption can be overcome if reliable data demonstrate that a different factor is safe for children. (Id.). In determining whether a different factor is safe for children, EPA focuses on the three factors listed in section 408(b)(2)(C) - the completeness of the toxicity database, the completeness of the exposure database, and potential pre- and post-natal toxicity. In examining these factors, EPA strives to make sure that its choice of a safety factor, based on a weight-of-the-evidence evaluation, does not understate the risk to children. (Id. at 24-25, 35).

IV. Challenged Tolerance Regulations for Mepiquat and Acetamiprid

A. Mepiquat

1. *In general*. NRDC challenged a January 23, 2002 action establishing tolerances for mepiquat on cotton gin byproducts and meat byproducts of cattle, goats, hogs, horses and sheep. (67 FR 3113 (January, 23, 2002)). Given mepiquat's exposure pattern and toxicological characteristics, EPA determined that mepiquat potentially presented acute and chronic risks and EPA quantitatively assessed these risks in making its safety determination. (67 FR at 3116). All of these risks were found to be below the Agency's level of concern. (Id.).

2. *Children's safety factor determination*. For mepiquat, EPA identified increased uncertainty regarding effects on the young because a developmental neurotoxicity (DNT) study was outstanding. (65 FR 1790, 1794 (January 12, 2000)). EPA concluded, however, that this uncertainty was offset by a number of factors and removed the additional 10X safety factor. First, EPA noted that no increased sensitivity in young animals was observed in the pre- and post-natal studies with mepiquat. (65 FR at 1794). In fact, in two out of the three studies involving young animals no effects were seen in the offspring at all (developmental study in rats; 2-generation reproduction study in rats). (Ref. 5 at 2). Further, even in the third study concerning pre- and post-natal effects there were reasons to accord reduced weight to the pre- or post-natal effects observed given that effects were seen in the offspring and the parents only at the highest dose tested (developmental study in rabbits). (Id.). Second, although neurotoxic behavioral effects in adult animals were found (triggering the DNT study requirement), there was no evidence reflecting special

concern for developing fetuses or the young such as "neuropathy in adult animals; [central nervous system] malformations following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring." (65 FR at 1794). Finally, exposure estimates were found not to understate exposure given that the estimates for food were "Tier 1" conservative assumptions which would not underestimate exposure. (65 FR at 1793).

B. Acetamiprid

1. *In general*. NRDC challenged a March 27, 2002, action establishing tolerances for acetamiprid on dried citrus pulp, the citrus fruit crop group, cotton gin byproducts, cotton undelinted seed, grapes, the fruiting vegetable crop group, the leafy brassica vegetable crop group, the leafy vegetable crop group, the pome fruit group, tomato paste, as well as various animal products. (67 FR 14649 (March 27, 2002)). Given acetamiprid 's exposure pattern and toxicological characteristics, EPA determined that acetamiprid potentially presented acute, chronic, short-term, and intermediate-term risks and EPA quantitatively assessed these risks in making its safety determination. (Id. at 14656-14657). All of these risks were found to be below the Agency's level of concern. (Id.).

2. *Children's safety factor determination*. For acetamiprid, two factors increased uncertainty or raised concern about the impacts on children: That a DNT study was outstanding; and that increased sensitivity in the young was observed in the 2-generation reproduction study. (67 FR at 14655). EPA concluded, however, that these concerns were offset by other considerations. First, the DNT study had been required based only on neurotoxic behavioral effects seen in adults, and not out of a special concern for developing fetuses or the young. Second, the increased sensitivity observed in the 2-generation reproduction study was only qualitative. Sensitivity is considered to be qualitative only when effects occur at the same dose levels in adult and juvenile animals but the effects in the juvenile animals are qualitatively more severe than the effects in the adults. Third, the other two studies investigating pre- or post-natal effects in the young showed either no adverse effects even at levels that showed toxicity in parental animals, or adverse effects of the same qualitative nature at the same dose in parental and young animals. (Id.). Finally, exposure estimates were judged unlikely to underestimate exposure, especially because "highly conservative" "Tier 1" assumptions were used for exposure in food. (67 FR at 14654). Weighing all of these considerations EPA retained a 3X additional safety factor to address chronic risks and waived the factor entirely for acute risks. No additional factor was deemed necessary as to acute risks because qualitative sensitivity in the young was only observed in a study involving chronic dosing and as to an adverse effect related to repeat dosing.

V. Subsequent Tolerance Actions for Mepiquat and Acetamiprid

A. Mepiquat

Since January, 2002, EPA has received no further tolerance petitions concerning mepiquat and EPA has undertaken no tolerance rulemakings for mepiquat.

B. Acetamiprid

Since March, 2002, EPA has received several petitions for additional acetamiprid tolerances and has established tolerance regulations on four occasions. Because section 408 requires EPA in setting a pesticide tolerance to consider aggregate exposure to the pesticide, "including dietary exposure under . . . all other tolerances for the pesticide chemical residue," in each of these subsequent actions EPA took into account exposure to acetamiprid under challenged tolerances established on March 27, 2002 (dried citrus pulp, the citrus fruit crop group, cotton gin byproducts, cotton undelinted seed, grapes, the fruiting vegetable crop group, the leafy brassica vegetable crop group, the leafy vegetable crop group, the pome fruit group, tomato paste, as well as various animal products). Each of the subsequent tolerance rulemakings is described below.

1. *2005 – Tolerances for tuberous and corm vegetables*. On April 13, 2005, EPA established tolerances for acetamiprid on tuberous and corm vegetables. (70 FR 19283 (April 13, 2005)). EPA concluded that the additional exposure from these new tolerances, when aggregated with exposure under existing tolerances, was safe.

With regard the children's safety factor, EPA relied on a revised analysis taking into account its Children's Safety Factor Policy, which had not been released at the time of the risk assessment for the NRDC-challenged tolerances and recently-submitted data on acetamiprid and other similar pesticides. EPA concluded that the presumptive 10X children's safety factor could be removed entirely. (70 FR at 19289). Although increased sensitivity to the young had been observed in the 2-generation rat study and a recently-submitted DNT study had not been fully evaluated, EPA determined that other factors outweighed these concerns. As to the increased sensitivity, EPA noted that: "i. There is a clear NOAEL for [the effects seen in] the offspring, and; ii. These effects occurred in the presence of parental toxicity and only at the highest dose tested." (Id.). Further, EPA noted that either the NOAEL for the offspring in the reproduction study or some lower NOAEL was used in each risk assessment for acetamiprid. That meant the standard 10X factor to account for intra-human variability (in addition to the 10X factor for inter-species variability) was applied to the clearly-defined NOAEL for offspring effects or to some lower NOAEL. As to the recently-submitted DNT, EPA stated that a "preliminary review of the study indicates the results are not likely to have a significant impact on risks for the currently proposed use, or on existing uses of acetamiprid . . . [and that] developmental neurotoxicity data received and reviewed for other compounds in this chemical class indicate that the results of the required DNT will not likely impact the regulatory doses selected for the proposed uses of acetamiprid." (Id.). Finally, EPA relied upon the fact that the exposure assessment for acetamiprid was conservative in that it assumed all foods with tolerances are treated with acetamiprid and bear tolerance-level residues (i.e., a Tier 1 assessment).

2. *2007 – Tolerances for almond hulls, et al*. On November 28, 2007, EPA established tolerances for acetamiprid on almond, hulls; fruit, stone, group 12, except plum, prune; nut, tree, group 14; pea and bean, succulent shelled, subgroup 6B; pistachio; plum, prune, dried; plum, prune, fresh; vegetable, cucurbit, group 9; and vegetable, legume, edible podded, subgroup 6A. (72 FR 67256 (November 28, 2007)). EPA concluded that the additional exposure from these new tolerances, when aggregated with exposure under existing tolerances, was safe.

With regard to the children's safety factor, EPA relied on a revised analysis taking into account its now-completed review of the acetamiprid DNT study. EPA again concluded that the presumptive 10X children's safety factor could be removed entirely. Although qualitatively increased sensitivity to the young had been observed in the 2-generation rat study and the DNT study, EPA "characterized the degree of concern for the effects observed in the acetamiprid DNT and the 2-generation

reproduction study as low, noting that there is a clear NOAEL for the offspring effects in both studies, the toxicology database is complete, and regulatory doses [Points of Departure] were selected to be protective of potential offspring effects in both the DNT and the 2-generation study." (72 FR at 67260). Specifically, as to the last consideration, EPA cited the fact that the Points of Departure for calculating the RfD/PADs were at or below the clearly-defined NOAELs from the 2-generation reproduction and DNT studies. That means that at least a 100-fold margin of safety was being provided with respect to the clearly-defined NOAELs from these studies. Further, even though the exposure assessment was more refined than in prior acetamiprid tolerance actions, EPA still relied on conservative values from field trial studies and drinking water modeling.

3. *2008 – Tolerances for bushberries, et al.* On January 16, 2008, EPA established tolerances for acetamiprid on the bushberry subgroup 13-07B; the caneberry subgroup 13-07A; the low growing berry subgroup 13-07G; the onion, bulb, subgroup 3-07A; and the onion, green, subgroup 3-07B. (73 FR 2809 (January 16, 2008)). EPA concluded that the additional exposure from these new tolerances, when aggregated with exposure under existing tolerances, was safe. EPA relied upon its November 28, 2007 acetamiprid rulemaking to make its safety determination, noting that the tolerances in this action had been included in the risk assessment performed to support the 2007 action. (73 FR at 2811).

4. *2010 – Tolerances for small vine climbing fruit, et al.* On February 10, 2010, EPA established tolerances for acetamiprid on the small vine climbing fruit, except fuzzy kiwifruit, subgroup 13-07F; and tea, dried. (75 FR 6576 (February 10, 2010)). EPA concluded that the additional exposure from these new tolerances, when aggregated with exposure under existing tolerances, was safe. With regard the children's safety factor, EPA concluded that the presumptive 10X children's safety factor could be removed entirely based on the rationale in the 2007 acetamiprid rulemaking. (75 FR at 6581).

VI. Summary of NRDC Objections, Administrative Review of the Objections, and Judicial Review of EPA's Order Denying the Objections

A. NRDC's Objections

On four occasions in the first half of 2002, the NRDC and various other parties filed objections with EPA to final rules under FFDCA section establishing pesticide tolerances for various pesticides. (69 FR 30042 (May 26, 2004)). The objections applied to 14 pesticides and 112 separate pesticide tolerances. The challenged tolerances included the tolerances for mepiquat and acetamiprid addressed in today's order. The objections to the mepiquat tolerances were filed on March 19, 2002, and grouped with objections to tolerances for imidacloprid, bifenazate, zeta-cypermethrin, and diflubenzuron. The objections to the acetamiprid tolerances were filed on May 21, 2002, and grouped with objections to tolerances for isoxadifen-ethyl, propiconazole, fenhexamid, and fluazinam.

Although NRDC's petitions raised dozens of issues, most of the issues related to two main claims: That EPA had not properly applied the additional 10X safety factor for the protection of infants and children in section 408(b)(2)(C); and that EPA had not accurately assessed the aggregate exposure of farm children to pesticide residues. Many of the issues were not fact-specific to the challenged tolerances but rather represented a generic challenge to EPA's implementation of the FQPA.

Two specific issues raised by NRDC are worthy of greater description because they later figured in the judicial review of EPA's disposition of the objections. First, as to several of the pesticides, NRDC argued that EPA had unlawfully removed the 10X children's safety factor because EPA had required that a DNT study be submitted for the pesticides but such study had not yet been completed. NRDC framed the issue as follows:

> EPA has required DNT tests for imidacloprid, mepiquat, and zeta-cypermethrin, and these studies have not been conducted. EPA, therefore cannot argue that "reliable data" justifies removing the statutory presumptive 10X FQPA safety factor.

(Ref. 6 at 9). Second, NRDC argued that EPA could not lawfully remove the children's safety factor as to all of the challenged pesticides because EPA relied on a drinking water exposure models to estimate pesticide exposure levels in water instead of "collect[ing] pesticide-specific data on water-based exposure." (Ref. 6 at 6; Ref. 7 at 5). According to NRDC, drinking water models, as a definitional matter, could not supply the "reliable data" needed to choose a children's safety factor differing from the presumptive value. (Ref. 6 at 6; Ref. 7 at 5-6).

B. EPA's Denial of the Objections

EPA denied NRDC's objections in two separate orders. The first was issued on May 26, 2004, and addressed only the tolerances for imidacloprid. (69 FR 30042 (May 26, 2004). The second was released on August 10, 2005 and addressed the tolerances for the remaining 14 pesticides. (70 FR 46706 (August 10, 2005)). The second order relied heavily on the imidacloprid order because, in the process of resolving the claims pertaining to imidacloprid, EPA resolved many of NRDC's generic attacks on EPA's interpretation of the FQPA.

As to the DNT study and the children's safety factor, EPA rejected "NRDC's contention that an EPA finding that a DNT study is needed in evaluating the risks posed by the pesticide is outcome-determinative as regards to retaining the children's safety factor until such time as the DNT study is submitted and reviewed." (70 FR at 46724). EPA carefully reviewed all of the evidence cited by NRDC regarding the DNT study and concluded that NRDC had not shown that the DNT was so critical to the protection of children that in the absence of that study EPA was conclusively precluded from exercising its statutory authority to make a case-by-case determination regarding the appropriate children's safety factor. EPA specifically did not address the factual considerations relating to its individual children's safety factor decisions as to mepiquat and acetamiprid (and the other pesticides), noting that "NRDC has offered no pesticide-specific arguments as to the pesticides in this proceeding as to why the absence of a DNT study requires the retention of the default 10X additional factor." (Id.)

With regard to whether reliance on drinking water models precluded lowering of the children's safety factor, EPA exhaustively reviewed the underlying factual basis for its models, the scientific peer review they had received, and how the models had worked in practice. EPA concluded that "the models are based on reliable data and will produce estimates that are unlikely to underestimate exposure to pesticides in drinking water." (Id. at 46726). Accordingly, NRDC's claim that only actual pesticide-specific water monitoring data could provide "reliable data" on the levels of pesticides in drinking water was rejected.

C. Judicial Review

1. *NRDC's Petition for Review*. In August, 2005, NRDC and the Northwest Coalition for Alternatives to Pesticides (NCAP) filed petitions for review of EPA's August 10, 2005 order. No challenge had been filed to the May 26, 2004 order. The petitions were filed in the Second and Ninth Circuits and the matter was assigned to the Ninth Circuit. The consolidated petitions sought review as to EPA's denial of NRDC's objections as they pertained to the tolerances of the following seven pesticides: acetamiprid, fenhexamid, halosulfuron-methyl, isoxadifen-ethyl, mepiquat, pymetrozine, and zeta-cypermethrin.

NRDC/NCAP's brief argued that EPA had unlawfully removed or lowered the children's safety factor as to these seven pesticides and that EPA's establishment of tolerances for the seven pesticides was arbitrary and capricious. (Ref. 8). As to the contentions regarding the children's safety factor, NRDC/NCAP made several independent claims as to why EPA's action was unlawful. These claims were:

i. As to acetamiprid, halosulfuron-methyl, mepiquat, pymetrozine, and zeta-cypermethrin, EPA had no discretion to alter the children's safety factor because it had determined that a DNT study was specifically needed to address concerns regarding these pesticides (DNT studies were not required on fenhexamid and isoxadifen-ethyl);
ii. EPA's decision on the children's safety factor could not be upheld because EPA provided "no pesticide-specific response to NRDC's objections with respect to the missing DNT studies, and does not offer any explanation or justification for the agency's departure from the tenfold children's safety factor for these five pesticides;"
iii. EPA lacked reliable data on pesticide exposure levels in drinking water for each of the pesticides and such data are necessary to justify altering the children's safety factor; and
iv. EPA must retain the children's safety factor for each of the pesticides because data showed that they resulted in pre- or post-natal toxicity.

NRDC argued EPA's decision was arbitrary and capricious because EPA determined that additional data were needed on the pesticides but EPA had not waited for submission of that data before establishing the pesticide tolerances and because EPA had not offered a sufficient explanation of its decisions on the children's safety factor.

2. *The Ninth Circuit's decision*. On September 19, 2008, the Ninth Circuit unanimously determined that:

i. It was not arbitrary and capricious for EPA to have established the tolerances for acetamiprid, mepiquat, and pymetrozine without waiting for DNT studies for these pesticides;

ii. EPA had offered a reasoned explanation for why, as a general matter, the children's safety factor could be reduced in the absence of a DNT study; and
iii. It was reasonable for EPA to rely on drinking water models in estimating pesticide levels in water in making children's safety factor determinations.

(*NCAP* v. *EPA*, 544 F.3d 1043, 1049-1051 (9th Cir. 2008)). Additionally, by a 2-to-1 vote, the court remanded to EPA its decision on the children's safety factor for acetamiprid, mepiquat, and pymetrozine. The majority found that EPA's order on NRDC's objections had not adequately explained the pesticide-specific reasons for removing or reducing the children's safety factor as to these pesticides in the absence of a required DNT study. (Id. at 1052). Without elaborating, the court dismissed all other issues raised by NRDC/NCAP. (Id. at 1053).

Although NRDC/NCAP's petition for review concerned seven pesticides, the court only remanded to EPA the tolerance decisions on acetamiprid, mepiquat, and pymetrozine. The petition for review was denied as to the other four pesticides because the remand only pertained to pesticides for which there was a question concerning EPA's pesticide-specific choice of a children's safety factor in the absence of a required DNT study. As to the fenhexamid and isoxadifen-ethyl tolerances, a DNT study had not been required by EPA. For halosulfuron-methyl and zeta-cypermethrin tolerances a DNT study had been required and had not been submitted at the time of the tolerance action; however, by the time of the oral argument, the circumstances had changed. As to zeta-cypermethrin, the DNT study had been submitted and reviewed by EPA and EPA had established further tolerances in reliance on the DNT study. As to halosulfuron-methyl, EPA had withdrawn the requirement for a DNT. EPA notified the court that there was no longer a live controversy as to the tolerances for halosulfuron-methyl and zeta-cypermethrin and NRDC/NCAP and the court agreed the petition was moot as to these pesticides. (544 F.3d at 1048 n.4; Refs. 9, 10).

VII. Revised Order on Remand

On remand, EPA has determined that NRDC's objections should again be denied. NRDC's objections to the acetamiprid tolerances are now moot for the same reasons that the objections to the zeta-cypermethrin and halosulfuron-methyl tolerances were found to be moot. The objections to the mepiquat tolerance are denied because all issues which could have affected EPA's decision on that tolerance have been resolved by the Ninth Circuit.

A. Acetamiprid and Mepiquat

Like zeta-cypermethrin, EPA has received a DNT study for acetamiprid and relied on that study in establishing additional tolerances for acetamiprid. (72 FR 67256 (November 28, 2007); 73 FR 2809 (January 16, 2008); 75 FR 6576 (February 10, 2010)). In establishing new tolerances for acetamiprid, EPA concluded that aggregate exposure under the new tolerances as well as all existing tolerances (including the ones challenged in NRDC's 2002 objections) is safe. No objections to these new acetamiprid tolerances were filed within the 60 day statutory timeframe for objections. Accordingly, just as the Ninth Circuit concluded (and NRDC agreed) that there was no live controversy concerning the zeta-cypermethrin tolerances and "EPA's [alleged] failure to explain why it had reliable data in the absence of [a DNT study]," (544 F.3d at 1408), there is no live controversy as to whether EPA provided an adequate explanation for its now-superseded tolerance decision that it had reliable data to reduce or remove the children's safety factor for acetamiprid in the absence of a DNT study.

B. Mepiquat

EPA has not taken regulatory action as to mepiquat subsequent to the challenged tolerance action and, thus, NRDC's challenge to the mepiquat tolerance is not moot. Nonetheless, due to the circumstances of the mepiquat tolerance, EPA does not need to address the merits of the only remaining objection before EPA — that EPA lacks reliable data justifying removal of the children's safety factor for mepiquat. As EPA ruled in a prior order, it may "refuse to adjudicate the merits of claims where it can be shown that the claims - even if true - do not justify the relief requested." (72 FR 39318, 39323-

39324 (July 18, 2007)). That principle applies to the mepiquat objection because, as explained below, even if EPA retains the 10X children's safety it would not change EPA's safety determination. Thus, NRDC's objection to the removal of the children's safety factor, even if upheld, would not support the relief it requested - "that EPA refrain from establishing the new tolerances for . . .mepiquat . . . until the pesticide tolerances have been assessed and determined to be safe[,] consistent with the requirements of the FQPA." (Ref. 6 at 22).

An EPA decision to retain the 10X children's safety factor has the effect of decreasing the "safe dose" or RfD/PAD by a factor of 10. Thus, if prior to application of the 10X children's safety factor, the level of exposure from a particular pesticide constituted 5 percent of the RfD/PAD, after application of the safety factor the level of exposure to the pesticide would rise by a factor of 10 to 50 percent of the RfD/PAD. Similarly, a pesticide which had an exposure level at 50 percent of the RfD/PAD before applying the 10X children's safety factor, would have an exposure level of 500 percent of the RfD/PAD after application of the factor. Only in the latter case, would retention of the children's safety factor raise a safety concern. Thus, for pesticides with sufficiently low risks, the decision on retention or removal of the children's safety factor is not outcome-determinative as to EPA's safety finding. (71 FR 43906, 43916-43917 (August 2, 2006)).

Mepiquat is one of those low risk pesticides. As EPA noted in the challenged tolerance document, acute exposure to mepiquat from residues in food equaled 1.5 percent of the acute RfD/PAD and acute exposure to mepiquat in water was an infinitesimal. (67 FR at 3115; 65 FR 1790, 1793 (January 12, 2000) (acute exposure to mepiquat in drinking water is 0.031 percent of the allowable amount – i.e. the acute DWLOC was 6,000 ppb and estimated acute exposure level was 1.9 ppb); see Unit III.B.1.d. (explaining how allowable amounts of pesticide residues in drinking water were calculated)). Similarly, chronic exposure to mepiquat from residues in food equaled 0.3 percent of the chronic RfD/PAD and chronic exposure to mepiquat in water was also infinitesimal. (67 FR at 3115; 65 FR at 1794 (chronic exposure to mepiquat in drinking water is 0.018 percent of the allowable amount — i.e. the chronic DWLOC was 6,000 ppb and the estimated chronic exposure level was 1.1 ppb)). Retention of the 10X children's safety would raise the percentage exposure to approximately 15 percent of the acute RfD/PAD and 3 percent of the chronic RfD/PAD. Because these exposure levels would still be well below the applicable RfD/PADs, they would not change EPA's determination that the petitioned-for mepiquat tolerances are safe. Accordingly, because NRDC's objection to removal of the children's safety factor does not justify its request for EPA to refrain from establishing the mepiquat tolerances, it is denied.

VIII. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's final order regarding objections filed under section 408 of FFDCA. The FFDCA specifically directs that objections be resolved by "order," and thus this action is an adjudication and not a rule. (21 U.S.C. 346a(g)(2)(C)). The regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

X. References

1. USEPA, *A User's Guide to Available EPA Information on Assessing Exposure to Pesticides in Food* (June 21, 2000).

2. Office of Pesticide Programs, USEPA, Office of Pesticide Programs' Policy on the Determination of the Appropriate FQPA Safety Factor(s) For Use in the Tolerance Setting Process (February 28, 2002).

3. Office of Pesticide Programs, USEPA, Standard Operating Procedures (SOPs) for Residential Exposure Assessments (Draft December 19, 1997).

4. Office of Pesticide Programs, USEPA, "Estimating the Drinking Water Component of a Dietary Exposure Assessment" (November 2, 1999).

5. Office of Prevention, Pesticides and Toxic Substances, USEPA, Memorandum from Brenda Tarplee to Margarita Collantes, "Mepiquat Choloride – Report of the FQPA Safety Factor Committee" (November 1, 1999).

6. NRDC, Objections to the Establishment of Tolerances for Pesticide Chemical Residues: Imidacloprid, Mepiquat, Bifenazate, Zeta-cypermethrin, and Diflubenzuron Tolerances (filed March 19, 2002).

7. NRDC, Objections to the Establishment of Tolerances for Pesticide Chemical Residues: Isoxadifen-ethyl, Acetamiprid, Propiconazole, Furilazole, Fenhexamid, and Fluazinam Tolerances (filed May 20, 2002).

8. Petitioners' Brief, *NCAP* v. *EPA*, Case Nos. 75255, 76807 (9th Cir. March 6, 2006).

9. Letter from Kent E. Hanson, U.S. Department of Justice to Cathy Catterson, Clerk of the Court, United States Court of Appeals, Ninth Circuit, Notice of Supplemental Authority in *Northwest Coalition for Alternatives to Pesticides* v. *EPA*, Nos. 05-75255 & 05-76807 (May 25, 2007).

10. Letter from Aaron Colangelo, U.S. Department of Justice to Cathy Catterson, Clerk of the Court, United States Court of Appeals, Ninth Circuit, Response to EPA's Notice of Supplemental Authority in *Northwest Coalition for Alternatives to Pesticides* v. *EPA*, Nos. 05-75255 & 05-76807 (May 29, 2007).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 27, 2010.

Steven Bradbury,

Director, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2000–0006; FRL–9185–4]

National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List: Deletion of the Peter Cooper Corporation (Markhams) Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA), Region 2 is publishing a direct final notice of deletion of the Peter Cooper Corporation (Markhams) Superfund Site (Markhams Site) located in the Town of Dayton, Cattaraugus County, New York from the National Priorities List (NPL).

The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response,