US EPA ARCHIVE DOCUMENT

OBJECTIONS
TO THE ESTABLISHMENT OF TOLERANCES
FOR PESTICIDE CHEMICAL RESIDUES

OPP 301204 (Imidacloprid)
OPP 301209 (Mepiquat)
OPP 301206 (Bifenazate)
OPP 301207 (Zeta-Cypermethrin)
OPP 301213 (Diflubenzuron)

SUBMITTED BY THE NATURAL RESOURCES DEFENSE COUNCIL

ERIK D. OLSON
JON P. DEVINE, JR.
AARON COLANGELO
Natural Resources Defense Council
1200 New York Avenue, N.W., Suite 400
Washington, D.C. 20005
Phone: (202) 289-6868
Fax: (202) 289-1060

Dated: March 19, 2002

OBJECTIONS
TO THE ESTABLISHMENT OF TOLERANCES
FOR PESTICIDE CHEMICAL RESIDUES

OPP 301204 (Imidacloprid)
OPP 301209 (Mepiquat)
OPP 301206 (Bifenazate)
OPP 301207 (Zeta-Cypermethrin)
OPP 301213 (Diflubenzuron)

Pursuant to 21 U.S.C. § 346a(g) and 40 C.F.R. Part 180, the Natural Resources Defense Council (NRDC) makes the following objections:

(1) NRDC objects to the regulation issued under 21 U.S.C. § 346a(*l*)(6), establishing a time-limited tolerance for pesticide chemical residues of imidacloprid until December 31, 2003. 67 Fed. Reg. 2580 (Jan. 18, 2002).

(2) NRDC objects to the regulation issued under 21 U.S.C. § 346a(d)(4), establishing a tolerance for pesticide chemical residues of mepiquat. 67 Fed. Reg. 3113 (Jan. 23, 2002).

(3) NRDC objects to the regulation issued under 21 U.S.C. § 346a(d)(4), establishing a tolerance for pesticide chemical residues of bifenazate. 67 Fed. Reg. 4913 (Feb. 1, 2002).

(4) NRDC objects to the regulation issued under 21 U.S.C. § 346a(d)(4), establishing a tolerance for pesticide chemical residues of zeta-cypermethrin. 67 Fed. Reg. 6422 (Feb. 12, 2002).

(5) NRDC objects to the regulation issued under 21 U.S.C. § 346a(d)(4), establishing a tolerance for pesticide chemical residues of diflubenzuron. 67 Fed. Reg. 7085 (Feb. 15, 2002).

As discussed below in section III of these objections, NRDC requests a waiver of the tolerance objection fees pursuant to 40 C.F.R. 180.33(m).

I. INTRODUCTION

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), the Environmental Protection Agency (EPA) may only establish a tolerance for pesticide chemical residues in or on a food if EPA determines that the tolerance is "safe." 21 U.S.C. § 346a(b)(2)(A)(i). A tolerance will meet this requirement only if "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." *Id.* § 346a(b)(2)(A)(ii). The health-protective standard of the FQPA requires EPA to give special consideration to the health of infants and children, and EPA must "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue." *Id.* § 346a(b)(2)(C)(ii)(i).

EPA has violated the requirements of the FQPA in establishing new tolerances for imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, and diflubenzuron – published at 67 Fed. Reg. 2580 (Jan. 18, 2002) (imidacloprid), 67 Fed. Reg. 3113 (Jan. 23, 2002) (mepiquat), 67 Fed. Reg. 4913 (Feb. 1, 2002) (bifenazate), 67 Fed. Reg. 6422 (Feb. 12, 2002) (zeta-cypermethrin), and 67 Fed. Reg. 7085 (Feb. 15, 2002) (diflubenzuron). With respect to all five pesticides, EPA failed to apply the children's 10X safety factor, acknowledge and consider farm children as a major identifiable subgroup, take into consideration reliable data concerning occupational exposure, or fully assess aggregate exposures. For imidacloprid, mepiquat, and zeta-cypermethrin, EPA failed to regulate on

the basis of a no observed effect level (NOEL). With respect to imidacloprid and mepiquat, EPA additionally failed to protect all infants and children and not just those within a certain percentile, and as a result left potentially more than a million children unprotected. With respect to diflubenzuron, EPA failed to guarantee that legal food will be safe food based on exposure to pesticide chemical residues at the tolerance level. Finally, for imidacloprid, EPA also violated the FQPA by improperly relying on percent of crop treated in assessing dietary exposure.

II. GROUNDS FOR THE OBJECTIONS

A. In Establishing These Tolerances, EPA Improperly Failed To Apply The Children's 10X Safety Factor.

In establishing tolerances for imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, and diflubenzuron, EPA failed to include an additional 10X safety factor for infants and children as required by the FQPA. Under the Food Quality Protection Act's precautionary approach to protecting children, EPA must maintain an additional 10-fold margin of safety in its risk assessments for individual pesticides to "take into account potential pre– and post–natal developmental 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 can use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id.* Yet there are significant toxicity and exposure data gaps for each of these new tolerances established by EPA. In addition, EPA has acknowledged that it lacks necessary and required data to assess toxicity to the developing brain and nervous system for imidacloprid, mepiquat, and zeta-cypermethrin in particular, and therefore lacks the "reliable data" necessary under the FQPA to authorize a different margin of safety.

The regulations establishing new tolerances for imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, and diflubenzuron reveal toxicity and exposure data gaps for each pesticide:

- Imidacloprid. EPA is establishing time-limited tolerances for imidacloprid residues on blueberries in two states – New Jersey and Michigan. 67 Fed. Reg. 2581. But in measuring dietary exposure to imidacloprid as a result of these tolerances, EPA relied on estimated *national* consumption data and not regional or state-specific data. 64 Fed. Reg. 39045. EPA acknowledged that it "does not have available information on the regional consumption of food to which imidacloprid may be applied in a particular area." *Id.* This data gap is of particular importance because of the nature of the food at issue – fresh blueberries are likely to be most heavily consumed locally, near where they are picked. In other words, consumers in New Jersey and Michigan are most likely to eat blueberries grown in New Jersey and Michigan (and therefore treated with imidacloprid). Many "U-Pick" farms are located in New Jersey and Michigan, leading to likely elevated exposures due to immediate consumption and due to the presence of consumers in the fields. Use of national data to assess the dietary exposure of consumers in particular regions is especially inappropriate where the tolerance is approved only for specific regions. By using national data, EPA will underestimate the dietary exposure of consumers in New Jersey and Michigan, who are the most exposed to imidacloprid residues on blueberries. This is the case because consumers in New Jersey and Michigan are likely to eat more blueberries than the national average because of their ready availability, cost,

proximity to market, and freshness, and they are more likely to eat locally grown blueberries containing imidacloprid residues than the average U.S. consumer. A child eating blueberries in one of these two high-imidacloprid-use states will certainly stand a greater chance of consuming a greater amount of imidacloprid – when local blueberries are ripe and plentiful – than national consumption data (which is not seasonal, but is averaged throughout the year) would suggest. Additional outstanding data requirements include prospective groundwater monitoring studies, a residential short-term risk assessment, and a developmental neurotoxicity study that is two and a half years overdue (discussed further below). 64 Fed. Reg. 39045, 39046.

- Mepiquat. There are several outstanding data requirements for mepiquat, including side-by-side residue field trials and a developmental neurotoxicity study that is over two years overdue. 67 Fed. Reg. 3116; 65 Fed. Reg. 1790, 1794 (Jan. 12, 2000).
- Bifenazate. Data gaps for bifenazate include a developmental toxicity assessment, short-, medium-, and long-term inhalation exposure studies, and an assessment of drinking water exposure to bifenazate degradates. 67 Fed. Reg. 4915, 4917, 4918.
- Zeta-cypermethrin. The toxicity and exposure assessments of zeta-cypermethrin are incomplete because EPA explicitly failed to address drinking water exposure to zeta-cypermethrin degradates, and a required developmental neurotoxicity study has not been completed. 67 Fed. Reg. 6425, 6426.

- Diflubenzuron. Data gaps include missing residue chemistry and toxicology data for two diflubenzuron metabolites, deemed necessary by EPA to justify an unconditional registration. 67 Fed. Reg. 7090.

In addition to the above data gaps, for all five pesticides EPA has failed to collect pesticide-specific data on water-based exposure, rendering it impossible to find that "reliable data" exist to reduce the tenfold safety factor. 64 Fed. Reg. 39045 (imidacloprid); 67 Fed. Reg. 3115 (mepiquat); 67 Fed. Reg. 4918 (bifenazate); 67 Fed. Reg. 6425 (zeta-cypermethrin); 67 Fed. Reg. 7088 (diflubenzuron). The use of predictive models to estimate drinking water exposure to these pesticides serves as a stop-gap measure, but cannot take the place of actual "reliable data" that justify removing the statutory tenfold safety factor. Because EPA has used modeling scenarios to approximate drinking water exposure to these pesticides, it has not relied on any data at all – only predictions that are, in NRDC's view, not conservative. Relying only on modeling results, in the absence of any reliable and confirmatory monitoring data, results in an additional data gap that prevents EPA from overturning the presumptive 10X safety factor. In addition, for all five pesticides EPA failed adequately to consider important exposure routes for millions of infants and children, including exposure to children living on farms and who accompany their parents into farm fields (see discussion of farm children below), and exposure from spray drift. All of these deficiencies in toxicity and exposure data preclude EPA's removal of the presumptive 10X safety factor. 21 U.S.C. § 346a(b)(2)(C).

Furthermore, the absence of required developmental neurotoxicity (DNT) tests for imidacloprid, mepiquat, and zeta-cypermethrin is a crucial data gap that by itself should

prohibit EPA from overturning the default 10X safety factor. In its 1993 report, Pesticides in the Diets of Infants and Children, the National Academy of Sciences/National Research Council cited strong evidence that pesticide exposures may disrupt the normal development of a child's brain and nervous system. More conclusive evidence has since been published supporting this finding[1-7]. Studies by EPA staff scientist Dr. Makris show that DNT testing is more sensitive than other studies in measuring the effects of exposure on proper development of the brain and nervous system, and therefore DNT testing is more appropriate for protecting children's health. DNT testing is essential for pesticides, not only as a measure of toxicity to the developing brain and nervous system, but also as an often more sensitive measure of developmental and reproductive effects generally[8]. EPA's 10X Task Force has recommended that "developmental neurotoxicity testing be included as part of the minimum core toxicology data set for all chemical food-use pesticides for which a tolerance would be set." *See* 10X Task Force, U.S. Environmental Protection Agency, *Toxicology Data Requirements for Assessing Risks of Pesticide Exposure to Children's Health (draft)*, Nov. 30, 1998, at 11. Although DNT testing has not yet been incorporated in the minimum core toxicology data set for all pesticides, EPA has required DNT studies on a case-by-case basis for particular pesticides, including imidacloprid, mepiquat, and zeta-cypermethrin. 64 Fed. Reg. 39046 (imidacloprid); 67 Fed. Reg. 3116 (mepiquat); 67 Fed. Reg. 6426 (zeta-cypermethrin). In spite of this, in establishing new tolerances, the Agency failed to retain the presumptive FQPA 10X safety factor for any of these pesticides.

EPA has expressly acknowledged that DNT testing is necessary and required to assess the risks of imidacloprid, mepiquat, and zeta-cypermethrin, and these studies are

still missing. 64 Fed. Reg. 39046; 67 Fed. Reg. 3116; 67 Fed. Reg. 6426. These critical data gaps make it impossible to assess the neurotoxic effects of these pesticides to fetuses, infants, and children. The FQPA neither requires nor justifies regulatory delay in order to collect this additional data. The potential future submission of DNT studies for these pesticides does not justify removing 10X in anticipation of those studies; EPA must use the ten-fold safety factor to protect children's health while the data is missing. 21 U.S.C. § 346a(b)(2)(C). Even though these conditions have been unfulfilled, and DNT results are required and overdue, EPA has established new tolerances for imidacloprid, mepiquat, and zeta-cypermethrin. In doing so, EPA failed to apply the required 10X safety factor for children that is intended to compensate for just such data gaps. *Id.* (Interestingly, EPA justified removing 10X for diflubenzuron because a DNT test was *not* required for that pesticide, 67 Fed. Reg. 7089, yet EPA did not deem the *requirement* of DNT tests for the other pesticides sufficient justification to maintain 10X.)

EPA's recently released 10X policy paper attempts to justify the Agency's decision to ignore 10X even in the absence of required DNT studies. *See* Office of Pesticide Programs, U.S. Environmental Protection Agency, *Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment*, Feb. 28, 2002, at 23-25. EPA states: "[s]imply because OPP has required a DNT for a particular pesticide does not necessarily mean that a database uncertainty factor is needed. However, if the available information indicates that a DNT study is likely to identify a new hazard or effects at lower dose levels of the pesticide that could significantly change the outcome of its overall risk assessment, the database uncertainty factor should be considered." *Id.* at 24. This position is untenable. The FQPA requires that an additional 10X safety factor must

be applied; this burden can be overcome "only if, on the basis of reliable data, such margin will be safe for infants and children." 21 U.S.C. § 346a(b)(2)(C). EPA's approach to required DNT studies completely reverses this presumption and declares that, *even in the absence of required data on neurotoxicity for developing fetuses, infants, and children*, the default 10X safety factor can be removed if the missing data is not "expected" to "significantly change the outcome" of the overall risk assessment. Under this approach, the removal of the safety factor is based not upon the statutorily demanded "reliable data," but upon the risk assessor's expectation—his or her intuition or professional judgment. The FQPA cannot accommodate this counterintuitive and underprotective approach. 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.

Had EPA not removed 10X, many of these pesticide tolerances would have been acknowledged to be unsafe. Even ignoring all of the other flaws in EPA's tolerance regulations for these pesticides (addressed below), *this single decision to overturn 10X resulted in unsafe tolerances improperly being declared "safe."*

- For imidacloprid, EPA calculated that the margin of exposure (MOE) for chronic dietary and residential exposure for children aged one to six was 302. 64 Fed. Reg. 39047. Relying on an FQPA safety factor of 3X instead of 10X, EPA established a "safe" MOE of 300, and therefore the actual MOE was just barely outside the Agency's level of concern for chronic exposure. *Id.* But if EPA had applied 10X, as it was obligated to do under the FQPA, the safe MOE would have

been 1000 and the tolerance as proposed would have been found unsafe. (As it is, the actual margin of exposure of 302 for children aged one to six is shockingly close to the EPA-declared "safe" MOE of 300.).

- For zeta-cypermethrin, EPA calculated the following actual margins of exposure: MOE for combined aggregate exposure for children is 830; MOE for short-term aggregate exposure for children is 600; MOE for short-term aggregate exposure for infants is 1000; MOE for intermediate-term aggregate exposure for adult males is 640; MOE for intermediate-term aggregate exposure for adult females is 740; MOE for intermediate-term aggregate exposure for children is 300; and the MOE for intermediate-term aggregate exposure for infants is 530. 67 Fed. Reg. 6428. At the same time, EPA relied on an FQPA safety factor of only 1X (in other words, no FQPA safety factor at all), to establish a "safe" MOE of 100, and thus declared that all of these actual margins of exposure were safe. *Id.* Yet if EPA has properly applied the presumptive 10X FQPA safety factor, the safe MOE would have been set at 1000 instead of 100, *all of the above actual MOEs would have been acknowledged as unsafe*, and the new tolerances for zeta-cypermethrin could not have been established.

In light of the incomplete data and potential pre- and post-natal developmental toxicity for imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, and diflubenzuron, EPA's failure to apply the 10X children's safety factor violates the FQPA and EPA's own stated policy on proper application of the 10X safety factor. *See* Office of Pesticide Programs, U.S. Environmental Protection Agency, *Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment*, Feb. 28, 2002, at 11 ("Risk assessors . .

. should presume that the default 10X safety factor applies and should only recommend a different factor, based on an individualized assessment, when reliable data show that such a different factor is safe for infants and children."). The absence of required DNT studies for imidacloprid, mepiquat, and zeta-cypermethrin make EPA's failure to apply 10X for these pesticides especially egregious. EPA lacks reliable data to overturn the presumption of a 10X FQPA safety factor for any of the five pesticides addressed in these objections: imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, and diflubenzuron. Where there are no data or where there are gaps in data – either for particular toxic effects, for specific patterns of food consumption, or for particular routes of exposure – there cannot be the "reliable data" required by the FQPA to remove 10X.

B. Farm Children Are Especially Vulnerable To Pesticide Exposure, And Are Not Adequately Considered In These Tolerances.

Farm children should be deemed to comprise an especially vulnerable population, and their exposure to imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, and diflubenzuron must be considered in establishing tolerances where data is available. The FQPA requires that EPA consider exposure not just to consumers as a whole, but also to "major identifiable subgroups of consumers." 21 U.S.C. § 346a(b)(2)(D). In establishing tolerances, EPA must consider, among other relevant factors, "available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers); . . . available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers);" and "available information concerning the variability of the sensitivities of major identifiable subgroups of consumers." 21 U.S.C. § 346a(b)(2)(D)(iv); (vi); (vii). Farm children are a major identifiable subgroup under these statutory provisions, and their unique dietary

consumption patterns, aggregate exposure levels, and sensitivities to exposure should have been assessed by EPA in establishing new tolerances for imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, and diflubenzuron.

More than 320,000 children under the age of six live on farms in the United States. In addition, many hundreds of thousands of children play or attend schools on or near agricultural land, and others have family members who work on farms or handle pesticides as part of their jobs. The nation's 2.5 million farm workers have approximately one million children living in the United States. *See* NRDC et al., *Petition for a Directive that the Agency Designate Farm Children As a Major Identifiable Subgroup and Population at Special Risk to be Protected under the Food Quality Protection Act,* Oct. 22, 1998, at 1 (hereafter "NRDC, *Farm Kids Petition"*).

Children living in agricultural communities are heavily exposed to pesticides, whether or not they work in the fields[9-11]. Farm children come in contact with pesticides through residues from their parents' clothing, dust tracked into their homes, contaminated soil in areas where they play, food eaten directly from the fields, drift from aerial spraying, contaminated well water, and breastmilk. Furthermore, farm children often accompany their parents to work in the fields, raising their pesticide exposures even higher. *See* NRDC, *Farm Kids Petition,* at 2-3. Citing data from the Department of Labor, the U.S. General Accounting Office has reported that seven percent of farmworkers with children five years old or younger took their children with them when they worked in the fields. *See* U.S. General Accounting Office, *Pesticides: Improvements Needed to Ensure the Safety of Farmworkers and Their Children,* (RCED-00-40), March 14, 2000, at 6 (hereafter "GAO, *Safety of Farmworkers and Their*

Children"). Children age nine or older may and do work on large farms. Farm children are likely to have the highest exposure to pesticides of any group of people in the country. Many of the children with the greatest pesticide exposures are from migrant farmworker families, who are poor and usually people of color or recent immigrants. *See* NRDC, *Farm Kids Petition*, at 2-3.

Children have unique exposure patterns and sensitivities to pesticides. Per pound of body weight, children eat, drink, and breathe more than adults. Children also engage in more frequent hand-to-mouth contact, and therefore have higher rates of oral exposure from objects, dust, or soil. *See* NRDC, *Farm Kids Petition*, at 3; GAO, *Safety of Farmworkers and Their Children*, at 17. The GAO found that crawling, sitting, and lying on contaminated surfaces may also increase exposure rates of farm children to pesticides. *See* GAO, *Safety of Farmworkers and Their Children*, at 17. Furthermore, as the GAO concluded, "[b]ecause young children's internal organs and bodily processes are still developing and maturing, their enzymatic, metabolic, and immune systems may provide less natural protection than those of an adult." *Id.*

EPA's regulations establishing tolerances for imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, and diflubenzuron fail to consider information concerning the sensitivities and exposures of farm children as a major identifiable subgroup. 64 Fed. Reg. 39041 (imidacloprid); 67 Fed. Reg. 3113 (mepiquat); 67 Fed. Reg. 4913 (bifenazate); 67 Fed. Reg. 6422 (zeta-cypermethrin); 67 Fed. Reg. 7085 (diflubenzuron). Under 21 U.S.C. § 346a(b)(2)(D), EPA must consider data regarding farm children's dietary consumption patterns, aggregate exposure levels, and sensitivities to exposure. If

reliable data are lacking, EPA must require the pesticide chemical registrants to secure the necessary data and should not issue new tolerances until such data are available.

C. EPA Failed To Consider Worker Risk In Establishing These Tolerances.

The FQPA requires consideration of worker risk in establishing final tolerances. A tolerance is not considered safe under the statute unless 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) (emphasis added). Worker exposure is clearly included in this catch-all category of "all other exposures" to be considered in setting a tolerance. In establishing tolerances for imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, and diflubenzuron, EPA cites no provision of the statute or any other authority to support its repeated incantation that aggregate exposure "does not include occupational exposure." 64 Fed. Reg. 39042 (imidacloprid); 67 Fed. Reg. 3114 (mepiquat); 67 Fed. Reg. 4914 (bifenazate); 67 Fed. Reg. 6423 (zeta-cypermethrin); 67 Fed. Reg. 7086 (diflubenzuron). The statute's provision stating that EPA "shall consider, *among other relevant factors*...available information concerning the aggregate exposure from other non-occupational sources" does not justify ignoring farmworkers' exposure in setting tolerances. 21 U.S.C. § 408(b)(2)(D). This provision explicitly requires EPA to consider "relevant factors" other than those enumerated, and is plainly illustrative rather than exhaustive. Moreover, much of farmworkers' elevated exposure comes not only from their occupational activities, but also because of the high exposures in the homes in which they live, the air they breathe, the water they drink. Clearly farmworkers are a high risk population deserving of careful consideration and protection[12-23]. EPA's

failure to consider worker risks in establishing these tolerances violates the FQPA's mandate that aggregate exposure assessments include *all* exposures for which there is reliable information. 21 U.S.C. § 346a(b)(2)(A)(ii).

D. The Aggregate Risk Assessment Is Inadequate.

The FQPA, 21 U.S.C. § 346a(b)(2)(A)(ii) requires that, to establish a pesticide tolerance, there must be a "reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure is the total exposure to a single chemical or its residues that may occur from dietary (*i.e.*, food and drinking water), residential, and all known or plausible exposure routes (including oral, dermal and inhalation). *See id.* Therefore, in addition to food and water exposures, the aggregate assessment must take into account exposures due to air drift and migration of contaminated soil, residential exposures from registered uses, and residential "take-home" exposures to families of those directly exposed to the pesticides through its agricultural uses. Furthermore, the aggregate assessment must consider exposures from uses that do not conform with the label, if there is an indication that such uses occur.

EPA failed to conduct an adequate aggregate assessment in establishing tolerances for imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, and diflubenzuron. First, all of the exposure data gaps outlined above in section II.A. constitute missing information that properly should have been incorporated into EPA's aggregate exposure assessment. Also, none of the regulations establishing tolerances for these five pesticides consider exposure through air drift, migration of contaminated soil, or residential take-home exposures. The bifenazate aggregate assessment suffers from an additional defect:

EPA relied on unsupported and apparently arbitrary processing factors to reduce estimates of dietary exposure to bifenazate on apples and grapes. 67 Fed. Reg. 4917.

For all five pesticides, EPA incorrectly concluded that the new tolerances would not result in any increased residential exposure because the tolerances themselves were not for residential uses. 64 Fed. Reg. 39044 (imidacloprid); 67 Fed. Reg. 3116 (mepiquat); 67 Fed. Reg. 4918 (bifenazate); 67 Fed. Reg. 6425 (zeta-cypermethrin); 67 Fed. Reg. 7087 (diflubenzuron). This ignores reliable data concerning take-home exposure resulting from agricultural uses[9, 24]. NRDC's 1998 report, *Trouble on the Farm*, documents the scientific evidence supporting the potential for take-home exposures from pesticides, even when not registered for residential use. *See* NRDC, *Trouble on the Farm: Growing up with Pesticides in Agricultural Communities*, 1998. As many as a dozen different pesticide residues have been found in household dust in some homes, including agricultural insecticides and herbicides not registered for use in the home. *See* NRDC, *Farm Kids Petition* at 3.

In addition, EPA deliberately ignores known residential uses in establishing new tolerances for these pesticides. The Agency completely fails to assess and incorporate those residential uses as a source of aggregate exposure, in violation of the FQPA.

- Imidacloprid has significant residential uses, including uses on flowering plants, ground covers, turf, lawns, golf courses, walkways, recreation areas, household dwellings, and cats and dogs. 67 Fed. Reg. 39045. However, based on predictions of low toxicity, EPA concludes that a number of missing residential exposure assessments are not required, including both acute and chronic short-term dermal, intermediate-term dermal, long-term dermal, and inhalation. *Id.*

The one residential exposure assessment that EPA does require – short-term risk assessment of oral exposure – has not yet been completed, but EPA wrongly proceeded with an aggregate risk assessment of exposure to imidacloprid anyway. *Id.*

- Bifenazate is registered for use on landscape ornamentals at residential and recreational sites. 67 Fed. Reg. 4918. Nevertheless, EPA makes the unsupported conclusion that "no residential post-application assessment is warranted," and therefore this potential source of exposure is disregarded. 67 Fed. Reg. 4918.
- In establishing new tolerances for zeta-cypermethrin, EPA wrongly ignores indoor and outdoor residential uses of cypermethrin (which the agency states is toxicologically identical to zeta-cypermethrin for purposes of these tolerances). 67 Fed. Reg. 6427.
- Diflubenzuron is registered for use on outdoor residential and recreational areas. 67 Fed. Reg. 7089. But EPA wrongly chose not to evaluate exposure through these uses because diflubenzuron "is only applied to the tree canopy." *Id.*

The above deficiencies reveal that EPA improperly underestimated aggregate exposure to these pesticides and their residues that may occur from dietary, residential, and all other known or plausible exposure routes. The assumptions and missing data in EPA's analysis of aggregate exposure for these five pesticides systematically serve to underestimate exposure and therefore underestimate risk, contrary to the requirements of the FQPA.

E. EPA Improperly Failed To Rely On A NOEL For Dietary Risk Estimates.

EPA cannot lawfully establish tolerances in the absence of a no-observed-effect-level (NOEL). The report of the House Committee on Commerce clearly states its intent for all safety factors to be applied to the NOEL. *See* H.R. Rep. No. 104-669, Part 2, at 43, presented to the House on July 23, 1996. By using a NOEL, the risk assessor is assured that regulatory decisions are based on a dose at which no effect is elicited. The use of a lowest-observed-adverse-effect-level (LOAEL) carries no such assurances. "Adverse" effects are often crude toxicological endpoints, such as death, or dramatic loss of body or organ weight, and are not designed to coordinate to the vulnerable points in embryonic development. A LOAEL may represent a dose high enough to elicit significant unpleasant and harmful effects, and can not be considered as protective as a true NOEL.

For imidacloprid, mepiquat, and zeta-cypermethrin, EPA failed to regulate on the basis of a NOEL, and instead relied on a LOAEL in conducting particular assessments.

- For imidacloprid, EPA relied only on a LOAEL for acute toxicity, and was unable to discern a no-observed-adverse-effect-level (NOAEL) for the acute toxic effects of the pesticide. 64 Fed. Reg. 39044. EPA also assessed only a LOAEL for chronic toxicity (a level that produced an increased number of thyroid lesions). *Id.*
- To establish the new tolerances for mepiquat, EPA measured reproductive toxicity only on the basis of a LOAEL; the reproductive toxicity study did not establish a reproductive NOAEL. 65 Fed. Reg. 1792.

- For zeta-cypermethrin, a developmental toxicity study yielded only a LOAEL. 67 Fed. Reg. 6426.

Lacking a NOEL for these endpoints, EPA has no scientific basis upon which to conclude that there is a fully safe level at which infants and children will not suffer developmental harm because of imidacloprid, mepiquat, or zeta-cypermethrin exposure. Therefore, EPA cannot make a legal finding that any specific level of imidacloprid, mepiquat, or zeta-cypermethrin on food is "safe" for infants and children, or that there is a "reasonable certainty of no harm" to infants and children, at any specific level. 21 U.S.C. § 346a(b)(2). As a matter of law, under 21 U.S.C. § 346a(b)(2), EPA may not establish these new tolerances for imidacloprid, mepiquat, or zeta-cypermethrin.

F. EPA Failed To Ensure A Reasonable Certainty Of No Harm For All Infants And Children In Establishing These Tolerances.

Under the FQPA, EPA must ensure that there is a reasonable certainty that no children will be harmed through exposure to pesticide chemical residues. 21 U.S.C. § 346a(b)(2)(C). If the best evidence suggests that thousands of children will exceed the reference dose for a pesticide, EPA is barred by statute from finding a reasonable certainty of no harm to these particular infants and children, and the Agency may not issue a tolerance at that level.

However, in establishing tolerances for imidacloprid and mepiquat, EPA regulates dietary residues at only the *95th percentile*. 64 Fed. Reg. 39044 (acute dietary exposure to imidacloprid at the 95th percentile); 65 Fed. Reg. 1793 (acute dietary exposure to mepiquat at the 95th percentile). This runs contrary to EPA's previous policy of using the 99.9th percentile child (which itself is inadequate to fully protect children). Regulation at the 95th percentile means that five percent of all American children under

age six (*around 1.2 million children in all*) could exceed the chronic reference dose every day, based on the best information available to the agency. Both imidacloprid and mepiquat are used on common children's foods – imidacloprid on blueberries, and mepiquat on grapes. No reading of the FQPA will support any approach that allows millions of children to exceed the reference dose. Regulating dietary residues of imidacloprid and mepiquat at the 95th percentile violates the FQPA's requirement that EPA "ensure that there is a reasonable certainty that *no harm* will result to infants and children from aggregate exposure to the pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(C)(ii)(I).

G. EPA Failed To Guarantee That Legal Food Will Be Safe Food Based On Exposure To Pesticide Chemical Residues Of Diflubenzuron At The Tolerance Level.

To assess chronic dietary exposure, EPA relied on estimates of "anticipated residues" for diflubenzuron. 67 Fed. Reg. 7087-88. In doing so, EPA failed to account for the dietary exposure of a significant number of consumers who purchase produce at farmers markets, farm stands, and "U-Pick" farming operations. Over 1.9 million people buy vegetables and fruits from nearly 13,000 farmers, at more than 2,000 community-based farmers markets and farm stands in the United States. *See* National Association of Farmers' Market Nutrition Programs (http://www.nafmnp.org/). These consumers include pregnant women, infants, and children, and must be protected. By ignoring this significant community of consumers, EPA vastly underestimates dietary exposure and cannot ensure that exposure to residues of diflubenzuron at the tolerance level will be safe. Reliance on 21 U.S.C. § 346a(b)(2)(E) to factor in anticipated residues of diflubenzuron does not justify ignoring the known dietary exposure of potentially

millions of consumers to residues of these pesticides at the tolerance level. EPA must ensure that the legal level of pesticide chemical residue – the established tolerance levels – are themselves safe. 21 U.S.C. § 346a(b)(2)(A).

H. EPA Violated The FQPA By Relying On Percent Of Crop Treated In Assessing Dietary Exposure To Imidacloprid.

In establishing time-limited tolerances for imidacloprid on blueberries in New Jersey and Michigan, EPA relied on estimates of the percent of crop treated to measure chronic dietary risk. 64 Fed. Reg. 39044-45. The FQPA, however, authorizes EPA's use of data on the percent of crop treated to assess chronic dietary risk only if EPA can make certain findings. In particular, EPA must find that: (1) "the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;" (2) "the exposure estimate does not understate exposure for any significant subpopulation group;" and (3) "if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated." 21 U.S.C. § 346a(b)(2)(F)(i); (ii); (iii).

These statutory criteria are not satisfied in this instance. EPA's new time-limited tolerance for imidacloprid on blueberries is geographically restricted to two states, yet EPA relies on national percent crop treated data. 67 Fed. Reg. 2580; 64 Fed. Reg. 39044-45. National data cannot provide a valid basis for measuring the percent of the blueberry crop treated with imidacloprid in New Jersey and Michigan, given that the new tolerance restricts the use of imidacloprid to those two states. Furthermore, relying on national data will plainly understate exposure for significant subpopulation groups – blueberry consumers in New Jersey and Michigan, who will be exposed to higher levels of

imidacloprid residues than consumers in the rest of the nation. EPA therefore failed to meet the requirements of the FQPA to justify using percent of crop treated data to assess chronic risk. 21 U.S.C. § 408(b)(2)(F).

III. RELIEF REQUESTED

In light of the above outlined statutory violations, NRDC respectfully requests that EPA refrain from establishing the new tolerances for imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, and diflubenzuron until the pesticide tolerances have been assessed and determined to be safe consistent with the requirements of the FQPA.

IV. SUPPORTING MATERIAL

NRDC incorporates by reference the following attachments in support of these objections:

Attachment A: NRDC, et al., *Petition for a Directive that the Agency Consistently Fulfill Its Duty to Retain the Child-Protective Tenfold Safety Factor Mandated by the Food Quality Protection Act*, April 23, 1998.

Attachment B: NRDC, et al., *Petition for a Directive that the Agency Designate Farm Children As a Major Identifiable Subgroup and Population at Special Risk to be Protected under the Food Quality Protection Act,* Oct. 22, 1998.

Attachment C: NRDC, *Putting Children First: Making Pesticide Levels in Food Safer for Infants and Children*, April 1998.

Attachment D: NRDC, *Trouble on the Farm: Growing up with Pesticides in Agricultural Communities*, 1998.

Attachment E: U.S. General Accounting Office, *Pesticides: Improvements Needed to Ensure the Safety of Farmworkers and Their Children*, (RCED-00-40), March 14, 2000.

NRDC reserves the right to submit additional supplemental information in further support of these objections.

V. REQUEST FOR A FEE WAIVER

Pursuant to 40 C.F.R. 180.33(m), NRDC hereby requests a waiver of all tolerance objection fees imposed by 40 C.F.R. 180.33(i). A waiver of fees will promote the public interest. NRDC is a national non-profit, tax-exempt public policy research and environmental organization. NRDC makes information available to thousands of citizens by means of its numerous and varied publications, educational programs, seminars, and public-interest litigation. These objections to the tolerances established for imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, and diflubenzuron are intended to benefit primarily the public as opposed to NRDC. As outlined above, these objections challenge EPA regulations that fail to properly implement the FQPA and, as a result, pose threats to the public health, especially children's health. Furthermore, NRDC has no financial interest in the sale, manufacture, or use of imidacloprid, mepiquat, bifenazate, zeta-cypermethrin, or diflubenzuron. Requiring NRDC to pay the fees would work an unreasonable hardship.

Respectfully submitted,

ERIK D. OLSON
JON P. DEVINE, JR.
AARON COLANGELO
Natural Resources Defense Council
1200 New York Avenue, N.W., Suite 400
Washington, D.C. 20005
Phone: (202) 289-6868
Fax: (202) 289-1060

Dated: March 19, 2002

References

1. Crumpton TL, Seidler FJ, Slotkin TA. Developmental neurotoxicity of chlorpyrifos in vivo and in vitro: effects on nuclear transcription factors involved in cell replication and differentiation. Brain Res 2000; 857:87-98.

2. Dam K, Seidler FJ, Slotkin TA. Developmental neurotoxicity of chlorpyrifos: delayed targeting of DNA synthesis after repeated administration. Brain Res Dev Brain Res 1998; 108:39-45.

3. Dam K, Seidler FJ, Slotkin TA. Chlorpyrifos releases norepinephrine from adult and neonatal rat brain synaptosomes. Brain Res Dev Brain Res 1999; 118:129-33.

4. Dam K, Garcia SJ, Seidler FJ, Slotkin TA. Neonatal chlorpyrifos exposure alters synaptic development and neuronal activity in cholinergic and catecholaminergic pathways. Brain Res Dev Brain Res 1999; 116:9-20.

5. Dam K, Seidler FJ, Slotkin TA. Chlorpyrifos exposure during a critical neonatal period elicits gender- selective deficits in the development of coordination skills and locomotor activity. Brain Res Dev Brain Res 2000; 121:179-87.

6. Levin ED, Addy N, Nakajima A, Christopher NC, Seidler FJ, Slotkin TA. Persistent behavioral consequences of neonatal chlorpyrifos exposure in rats. Brain Res Dev Brain Res 2001; 130:83-9.

7. Raines KW, Seidler FJ, Slotkin TA. Alterations in serotonin transporter expression in brain regions of rats exposed neonatally to chlorpyrifos. Brain Res Dev Brain Res 2001; 130:65-72.

8. Kimmel CA, Makris SL. Recent developments in regulatory requirements for developmental toxicology. Toxicol Lett 2001; 120:73-82.

9. Lu C, Fenske RA, Simcox NJ, Kalman D. Pesticide exposure of children in an agricultural community: evidence of household proximity to farmland and take home exposure pathways. Environ Res 2000; 84:290-302.

10. Loewenherz C, Fenske RA, Simcox NJ, Bellamy G, Kalman D. Biological monitoring of organophosphorus pesticide exposure among children of agricultural workers in central Washington State. Environ Health Perspect 1997; 105:1344-53.

11. Fenske RA. Pesticide exposure assessment of workers and their families. Occup Med 1997; 12:221-37.

12. Fiedler N, Kipen H, Kelly-McNeil K, Fenske R. Long-term use of organophosphates and neuropsychological performance. Am J Ind Med 1997; 32:487-96.

13. Blair A, Grauman DJ, Lubin JH, Fraumeni JF, Jr. Lung cancer and other causes of death among licensed pesticide applicators. J Natl Cancer Inst 1983; 71:31-7.

14. Blair A, White DW. Leukemia cell types and agricultural practices in Nebraska. Arch Environ Health 1985; 40:211-4.

15. Blair A. Herbicides and non-Hodgkin's lymphoma: new evidence from a study of Saskatchewan farmers. J Natl Cancer Inst 1990; 82:544-5.

16. Ji BT, Silverman DT, Stewart PA, et al. Occupational exposure to pesticides and pancreatic cancer. Am J Ind Med 2001; 39:92-9.

17. Cantor KP, Blair A, Everett G, et al. Pesticides and other agricultural risk factors for non-Hodgkin's lymphoma among men in Iowa and Minnesota. Cancer Res 1992; 52:2447-55.

18. Hoar SK, Blair A, Holmes FF, Boysen C, Robel RJ. Herbicides and colon cancer. Lancet 1985; 1:1277-8.

19. Hoar SK, Blair A, Holmes FF, et al. Agricultural herbicide use and risk of lymphoma and soft-tissue sarcoma. Jama 1986; 256:1141-7.

20. Zahm SH, Weisenburger DD, Saal RC, Vaught JB, Babbitt PA, Blair A. The role of agricultural pesticide use in the development of non- Hodgkin's lymphoma in women. Arch Environ Health 1993; 48:353-8.

21. Zahm SH, Blair A. Pesticides and non-Hodgkin's lymphoma. Cancer Res 1992; 52:5485s-5488s.

22. Zahm SH, Blair A. Cancer among migrant and seasonal farmworkers: an epidemiologic review and research agenda. Am J Ind Med 1993; 24:753-66.

23. Zheng T, Zahm SH, Cantor KP, Weisenburger DD, Zhang Y, Blair A. Agricultural exposure to carbamate pesticides and risk of non-Hodgkin lymphoma. J Occup Environ Med 2001; 43:641-9.

24. Lu C, Knutson DE, Fisker-Andersen J, Fenske RA. Biological monitoring survey of organophosphorus pesticide exposure among pre-school children in the Seattle metropolitan area. Environ Health Perspect 2001; 109:299-303.