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**OBJECTIONS  
TO THE ESTABLISHMENT OF A TOLERANCE  
FOR PESTICIDE CHEMICAL RESIDUES OF 2,4-D**

**OPP 301219 (2,4-D)**

SUBMITTED BY: Boston Women's Health Book Collective  
Breast Cancer Action  
Californians for Pesticide Reform  
Commonweal  
Lymphoma Foundation of America  
Natural Resources Defense Council  
Northwest Coalition for Alternatives to Pesticides  
Pesticide Action Network, North America  
Piñeros y Campesinos Unidos del Noroeste  
SF-Bay Area Chapter of Physicians for Social Responsibility  
Women's Cancer Resource Center

Dated: May 7, 2002

Pursuant to 21 U.S.C. § 346a(g) and 40 C.F.R. Part 180, the Boston Women's Health Book Collective, Breast Cancer Action, Californians for Pesticide Reform, Commonweal, Lymphoma Foundation of America, Natural Resources Defense Council, Northwest Coalition for Alternatives to Pesticides, Pesticide Action Network -- North America, Piñeros y Campesinos Unidos del Noroeste, SF-Bay Area Chapter of Physicians for Social Responsibility, and Women's Cancer Resource Center (collectively referred to as the "Objectors") hereby object to the regulation issued under 21 U.S.C. § 346a(d), extending the time-limited tolerance for pesticide chemical residues of 2,4-D on soybeans. 67 Fed. Reg. 10622 (March 8, 2002). As discussed further below, Objectors request a waiver of the tolerance objection fees pursuant to 40 C.F.R. 180.33(m).

## **I. SUPPORTING MATERIAL**

Objectors incorporate 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 (available online at <http://www.ecologic-ipm.com/petition.html>).

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 (available online at <http://www.ecologic-ipm.com/farmkids.PDF>).

Attachment C: NRDC, *Putting Children First: Making Pesticide Levels in Food Safer for Infants and Children*, April 1998 (executive summary available online at <http://www.nrdc.org/health/kids/rpcfsum.asp>).

Attachment D: NRDC, *Trouble on the Farm: Growing up with Pesticides in Agricultural Communities*, October 1998 (available online at <http://www.nrdc.org/health/kids/farm/farminx.asp>).

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 (available online at <http://www.gao.gov/>).

Attachment F: Lymphoma Foundation of America, *Do Pesticides Cause Lymphoma?*, 2001 (available online at [http://www.lymphomahelp.org/docs/research/researchreport/rr\\_2000.pdf](http://www.lymphomahelp.org/docs/research/researchreport/rr_2000.pdf)).

Objectors reserve the right to submit additional supplemental information in further support of these objections.

## **II. 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 residue 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 2,4-D, published at 67 Fed. Reg. 10622 (March 8, 2002). 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, fully assess aggregate exposures, or guarantee that legal food will be safe food based on exposure to pesticide chemical residues at the tolerance level. Furthermore, EPA’s apparent reliance on human testing studies for 2,4-D violates the Agency’s current moratorium on consideration of such studies as well as international and federal law.

### **III. TOXICITY OF 2,4-D**

2,4-D (2,4-dichlorophenoxyacetic acid) is a common herbicide used around the home and garden, on golf courses, ball fields, parks, and in agriculture. This chemical is one of the first pesticides ever registered in the United States. Agricultural uses include pasture land, wheat, corn, soybeans, barley, rice, oats, and sugar cane. About 30 million pounds of this chemical are used each year in the U.S., primarily in the Midwest,

Washington State, and Louisiana. 2,4-D has a soil half-life of about one week. However, when tracked indoors, 2,4-D has been reported to persist in carpets for months or even a year.<sup>1</sup> This herbicide is found as a contaminant in about half of all surface water samples, and has also been detected in groundwater.

Numerous epidemiological studies have strongly implicated 2,4-D in non-Hodgkin's lymphoma among farmers.<sup>2</sup> Several studies in household dogs have also reported an association between exposure to 2,4-D and canine malignant lymphoma.<sup>3</sup> These epidemiological studies were not discussed in the EPA rule, and constitute a significant omission.

2,4-D causes significant suppression of thyroid hormone levels in ewes dosed with this chemical.<sup>4</sup> Similar findings have been reported in rodents, with suppression of thyroid hormone levels, increases in thyroid gland weight, and decreases in weight of the ovaries and testes.<sup>5</sup> The increases in thyroid gland weight are consistent with the suppression of thyroid hormones, since the gland generally hypertrophies in an attempt to compensate for insufficient circulating levels of thyroid hormones. Thyroid hormone is known to play a critical role in the development of the brain. Slight thyroid suppression

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<sup>1</sup> Nishioka MG, Burkholder HM, Brinkman MC, Gordon SM. Measuring lawn transport of lawn-applied herbicide acids from turf to home: Correlation of dislodgeable 2,4-D turf residues with carpet dust and carpet surface residues. *Environmental Science and Technology* 30: 3313-3320, 1996.

<sup>2</sup> Zahm SH. Mortality study of pesticide applicators and other employees of a lawn care service company. *J Occup Environ Medicine* 39: 1055-67, 1997; Fontana A, Picoco C, Masala G, Prastaro C, Vineis P. Incidence rates of lymphomas and environmental measurements of phenoxy herbicides: ecological analysis and case-control study. *Arch Environ Health* 53 :384-7, 1998; Zahm SH, Blair A. Pesticides and non-Hodgkin's lymphoma. *Cancer Res* 1992; 52:5485s-5488s; Morrison HI, Wilkins K, Semenciw R, Mao Y, Wigle D. Herbicides and cancer. *J Natl Cancer Inst* 992; 84:1866-74.

<sup>3</sup> Hayes HM, Tarone RE, Cantor KP. On the association between canine malignant lymphoma and opportunity for exposure to 2,4-dichlorophenoxyacetic acid. *Environ Res* 1995; 70:119-25.

<sup>4</sup> Rawlings NC, Cook SJ, Waldbillig D. Effects of the pesticides carbofuran, chlorpyrifos, dimethoate, lindane, triallate, trifluralin, 2,4-D, and pentachlorophenol on the metabolic endocrine and reproductive endocrine system in ewes. *J Toxicol Environ Hlth* 54:21-36, 1998.

<sup>5</sup> Charles JM, Cunny HC, Wilson RD, Bus JS. Comparative subchronic studies on 2,4-dichlorophenoxyacetic acid, amine, and ester in rats. *Fundamental & Applied Toxicol* 33:161-165, 1996.

has been shown to adversely affect neurological development in the fetus, resulting in lasting effects on child learning and behavior.<sup>6</sup>

2,4-D causes slight decreases in testosterone release and significant increases in estrogen release from testicular cells.<sup>7</sup> In rodents, this chemical also increases levels of the hormones progesterone and prolactin, and causes abnormalities in the estrus cycle.<sup>8</sup> Male farm sprayers exposed to 2,4-D had lower sperm counts and more spermatid abnormalities compared to men who were not exposed to this chemical.<sup>9</sup> In Minnesota, higher rates of birth defects have been observed in areas of the state with the highest use of 2,4-D and other herbicides of the same class. This increase in birth defects was most pronounced among infants who were conceived in the spring, the time of greatest herbicide use.<sup>10</sup> EPA failed to consider the epidemiological data on adverse reproductive outcomes and the data on steroid hormone disruption in the final rule on 2,4-D.

2,4-D also interferes with the neurotransmitters serotonin and dopamine. In young organisms, exposure to 2,4-D results in delays in brain development and abnormal behavior patterns, including apathy, decreased social interactions, repetitive movements, tremor, and immobility.<sup>11</sup> Females are more severely affected than males. Rodent studies have revealed a region-specific neurotoxic effect on the basal ganglia of the brain,

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<sup>6</sup> Haddow JE, Palomaki GE, Allan WC, Williams JR, Knight GJ, Gagnon J, O'Heir CE, Mitchell ML, Hermos RJ, Waisbren SE, Faix JD, Klein RZ. Maternal thyroid deficiency during pregnancy and subsequent neuropsychological development of the child. *New Eng J Med* 1999; 341(8):549-555.

<sup>7</sup> Liu RC, Hahn C, Hurtt ME. The direct effect of hepatic peroxisome proliferators on rat leydig cell function in vitro. *Fundamental & Applied Toxicol* 30:102-108, 1996.

<sup>8</sup> Duffard R, Bortolozzi A, Ferri A, Garcia G, Evangelista de Duffard AM. Developmental neurotoxicity of the herbicide 2,4-dichlorophenoxyacetic acid. *Neurotoxicology* 16(4):764, 1995.

<sup>9</sup> Lerda D, Rizzi R. Study of reproductive function in persons occupationally exposed to 2,4-D. *Mutation Research* 262:47-50, 1991.

<sup>10</sup> Garry VF, Schreinemachers D, Harkins ME, et al. Pesticide applicators, biocides, and birth defects in rural Minnesota. *Environ Hlth Perspect* 104:394-399, 1996.

<sup>11</sup> Evangelista de Duffard AM, Bortolozzi A, Duffard RO. Altered behavioral responses in 2,4-dichlorophenoxyacetic acid treated and amphetamine challenged rats. *Neurotoxicology* 16(3): 479-488, 1995.

resulting in an array of effects on critical neurotransmitters and adverse effects on behavior.<sup>12</sup> A peer-reviewed, developmental neurotoxicity study demonstrated severe neurotoxicity in young rats exposed to 2,4-D from postnatal days 12 to 25 at doses of 70 mg/kg/day. These pups showed decreases in GM1 level, diminution in myelin deposition and alterations in all behavioral tests at all doses.<sup>13</sup> This herbicide specifically appears to impair normal deposition of myelin in the developing brain.<sup>14</sup> The neurotoxic and anti-thyroid effects of 2,4-D make it highly likely that fetuses, infants, and children will be more susceptible to long-term adverse health effects from exposure to this chemical.

Young animals can also be exposed to 2,4-D through maternal milk. Recent research has revealed that 2,4-D is excreted in breast milk, thereby resulting in potentially significant exposures to the nursing. The researchers detected 2,4-D residues in stomach content, blood, brain and kidney of 4-day-old neonates breast-fed by 2,4-D exposed mothers.<sup>15</sup> When maternal exposures stopped, the chemical continued to be excreted in maternal milk for a week. Thus, postnatal exposures to this chemical during the critical period for development of the infant brain are of serious scientific concern.

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<sup>12</sup> Bortolozzi A, Evangelista de Duffard AM, Dajas F, Duffard R, Silveira R. Intracerebral administration of 2,4-dichlorophenoxyacetic acid induces behavioral and neurochemical alterations in the rat brain. *Neurotoxicology* 2001 Apr;22(2):221-32

<sup>13</sup> Rosso SB, Garcia GB, Madariaga MJ, Evangelista de Duffard AM, Duffard RO. 2,4-Dichlorophenoxyacetic acid in developing rats alters behaviour, myelination and regions brain gangliosides pattern. *Neurotoxicology* 2000 Feb-Apr;21(1-2):155-63.

14. Duffard R, Garcia G, Rosso S, Bortolozzi A, Madariaga M, di Paolo O, Evangelista de Duffard AM. Central nervous system myelin deficit in rats exposed to 2,4-dichlorophenoxyacetic acid throughout lactation. *Neurotoxicol Teratol* 1996 Nov-Dec;18(6):691-6

15. Sturtz N, Evangelista de Duffard AM, Duffard R. Detection of 2,4-dichlorophenoxyacetic acid (2,4-D) residues in neonates breast-fed by 2,4-D exposed dams. *Neurotoxicology* 2000 Feb-Apr;21(1-2):147-54.

#### IV. GROUNDS FOR THE OBJECTIONS

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

In establishing a tolerance for 2,4-D on soybeans, 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 the 2,4-D tolerance 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 2,4-D, and therefore lacks the "reliable data" necessary under the FQPA to authorize a different margin of safety.

The regulation establishing a new tolerance for 2,4-D reveals both toxicity and exposure data gaps. Short- and intermediate-term dermal exposure assessments and a developmental neurotoxicity study have not been completed for 2,4-D. 67 Fed. Reg. 10626, 10627. EPA has also failed to collect pesticide-specific data on water-based exposure, rendering it impossible to find that "reliable data" exist to modify the tenfold safety factor. 67 Fed. Reg. 10626. 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 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, EPA failed adequately to consider important exposure routes for millions of infants and children, including 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.

Furthermore, the absence of required developmental neurotoxicity (DNT) tests for 2,4-D 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.<sup>16</sup> 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

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<sup>16</sup> 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; 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; 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; 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; 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; 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; 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.

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.<sup>17</sup> 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 2,4-D. 67 Fed. Reg. 10627. In spite of this, in establishing the new tolerance, the Agency failed to retain the presumptive FQPA 10X safety factor for 2,4-D.

EPA has expressly acknowledged that DNT testing is necessary and required to assess the risks of 2,4-D, and these studies are still missing. 67 Fed. Reg. 10627. This critical data gap makes it impossible to assess the neurotoxic effects of this pesticide 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 2,4-D 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 this condition has been unfulfilled, and DNT results are required and overdue, EPA has established new tolerances for 2,4-D. In doing so, EPA

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<sup>17</sup> Kimmel CA, Makris SL. Recent developments in regulatory requirements for developmental toxicology. *Toxicol Lett* 2001; 120:73-82.

failed to apply the required 10X safety factor for children that is intended to compensate for just such data gaps. *Id.*

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 2,4-D, and these studies have

not been conducted. EPA therefore cannot argue that “reliable data” justifies removing the presumptive 10X FQPA safety factor.

Had EPA not removed 10X, 2,4-D would have been acknowledged to be unsafe. Even ignoring all of the other flaws addressed below in EPA’s tolerance regulation for this pesticide, this single decision to overturn 10X resulted in unsafe tolerances improperly being declared “safe.” For 2,4-D, EPA calculated actual margins of exposure for short-term aggregate risk to be 853 for the U.S. population, 943 for infants less than one year old, 912 for children one to six years old, and 859 for females 13 years and older. 67 Fed. Reg. 10629. Relying on a “safe” MOE of 300, EPA declared that none of these actual MOEs exceeded the Agency’s level of concern for aggregate exposure to food and residential uses. *Id.* However, if EPA had applied the 10X FQPA safety factor as required by the statute, the safe MOE would have been set at 1000, *all of the above actual MOEs for aggregate exposure would have been acknowledged as unsafe*, and the time-limited tolerance for residues of 2,4-D on soybeans could have not been established.

In light of the incomplete data and potential pre- and post-natal developmental toxicity for 2,4-D, 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 2,4-D make EPA’s failure to apply 10X for this pesticide

especially egregious. EPA lacks reliable data to overturn the presumption of a 10X FQPA safety factor for 2,4-D. 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 2,4-D 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 2,4-D.

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.<sup>18</sup> 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

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<sup>18</sup> 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; 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; Fenske RA. Pesticide exposure assessment of workers and their families. *Occup Med* 1997; 12:221-37.

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 regulation establishing tolerances for 2,4-D fails to consider information concerning the sensitivities and exposures farm children as a major identifiable subgroup. 67 Fed. Reg. 10622. 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 should require the pesticide chemical registrant 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 The 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 2,4-D, EPA cites no provision of the statute or any other authority to support its conclusion that aggregate exposure “does not include occupational exposure.” 67 Fed. Reg. 10623. 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) (emphasis added). 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.<sup>19</sup> EPA’s failure to

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<sup>19</sup> 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; 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; Blair A, White DW. Leukemia cell types and agricultural practices in Nebraska. *Arch Environ Health* 1985; 40:211-4; Blair A. Herbicides and non-Hodgkin's lymphoma: new evidence from a study of Saskatchewan farmers. *J Natl Cancer Inst* 1990; 82:544-5; Ji BT, Silverman DT, Stewart PA, et al. Occupational exposure to pesticides and pancreatic cancer. *Am J Ind Med* 2001; 39:92-9; 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; Hoar SK, Blair A, Holmes FF, Boysen C, Robel RJ. Herbicides and colon cancer. *Lancet* 1985; 1:1277-8; Hoar SK, Blair A, Holmes FF, et al. Agricultural herbicide use and risk of lymphoma and soft-tissue sarcoma. *Jama* 1986; 256:1141-7; 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; Zahm SH, Blair A. Pesticides and non-Hodgkin's lymphoma. *Cancer Res* 1992; 52:5485s-5488s; Zahm SH, Blair A. Cancer among migrant and seasonal farmworkers: an epidemiologic review and research agenda. *Am J Ind Med* 1993; 24:753-66; 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.

consider worker risks in establishing 2,4-D 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 this tolerance for 2,4-D. First, all of the exposure data gaps outlined above in section III.A. constitute missing information that properly should be incorporated into EPA's aggregate exposure assessment. Also, EPA's regulation establishing a tolerance for 2,4-D does not consider exposure through air drift, migration of contaminated soil, or residential take-home exposures. EPA incorrectly concluded that the new tolerance for 2,4-D would not result in any increased residential exposure because the tolerance itself was not for

residential uses. 67 Fed. Reg. 10626. This ignores reliable data concerning take-home exposure resulting from agricultural uses.<sup>20</sup> 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 (available online at <http://www.nrdc.org/health/kids/farm/farminx.asp>). 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 2,4-D. The Agency completely fails to assess and incorporate those residential uses as a source of aggregate exposure, in violation of the FQPA. 2,4-D has significant residential uses, including use on turf, lawns, grasses, golf courses, and other recreational areas. 67 Fed. Reg. 10626. Yet EPA failed to conduct assessments of residential exposure through these uses and include those results in its aggregate risk assessment, apparently relying on an expectation that residue levels rapidly decline after turf treatment. 67 Fed. Reg. 10626-27.

Ample data demonstrate that 2,4-D migrates indoors after application on lawns. One investigation revealed that 3% of dislodgeable residues of 2,4-D on a lawn was tracked indoors and accumulated in carpet dust.<sup>21</sup> Although 2,4-D normally degrades

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<sup>20</sup> 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

<sup>21</sup> Nishioka M, Burkholder H, Brinkman M, Gordon S. Measuring Transport of Lawn-Applied Herbicide Acids from Turf to Home: Correlation of Dislodgeable 2,4-D Turf Residues with Carpet Dust and Carpet Surface Residues. *Environ Sci Technol* 1996; 30:3313-3320; Nishioka MG, Lewis RG, Brinkman MC, Burkholder HM, Hines CE, Menkedick JR. Distribution of 2,4-D in air and on surfaces inside residences

relatively rapidly outside, it has been shown to linger in the indoor environment.<sup>22</sup> Calculations based on a single lawn application of 2,4-D indicate that detectable levels of the pesticide would remain in carpet dust up to one year after a one-time outdoor application.<sup>23</sup> An in-depth study of a home in San Antonio, Texas, revealed detectable residues of 16 pesticides in the living room carpet. Gradients of many of these pesticides were apparent from the lawn and garden onto the front doorstep and into the carpet indicating that the pesticides were transported into the home primarily on shoes.<sup>24</sup> A study published recently in *Environmental Health Perspectives*, found that track-in by an active dog and by the homeowner applicator were the most significant factors for intrusion of 2,4-D into the home. Resuspension of floor dust was the major source of 2,4-D in indoor air, with highest levels of 2,4-D found in the particle size range of 2.5-10 microns. Resuspended floor dust was also a major source of 2,4-D on tables and window sills. Estimated postapplication indoor exposure levels for young children from nondietary ingestion were 1-10 µg/day from contact with floors, and 0.2-30 µg/day from contact with table tops. These are estimated to be about 10 times higher than the preapplication exposures. By comparison, dietary ingestion of 2,4-D is approximately

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after lawn applications: comparing exposure estimates from various media for young children. *Environ Health Perspect* 2001 Nov;109(11):1185-91.

<sup>22</sup> Lewis R, Bond A, Fortmann R, Sheldon L, Camann D. Determination of routes of exposure of infants and toddlers to household pesticides: a pilot study to test methods, Air and Waste Management Association, 84th Annual Meeting, Vancouver, British Columbia, 1991.

<sup>23</sup> Nishioka M, Burkholder H, Brinkman M, Gordon S. Measuring Transport of Lawn-Applied Herbicide Acids from Turf to Home: Correlation of Dislodgeable 2,4-D Turf Residues with Carpet Dust and Carpet Surface Residues. *Environ Sci Technol* 1996; 30:3313-3320.

<sup>24</sup> Camann D, Lewis R. Trapping of particle-associated pesticides in indoor air by polyurethane foam and exploration of soil track-in as a pesticide source, *Indoor Air '90: Proc 5th Intl Conf on Indoor Air Quality and Climate*, Toronto, 1990. Vol. 2.

1.3 µg/day.<sup>25</sup> Thus, "tracking-in" of pesticides is likely to be both common and significant, and must be included in the aggregate risk assessment.

In the case of farmers and farm workers, a wide range of agricultural pesticides may be tracked into the home on shoes and brought into the home on clothing. A report of pilot portions of the Agricultural Health Study in Minnesota, Iowa, and North Carolina reported on analyses of carpet dust performed before, during, and after pesticide applications on the farm. House dust levels of herbicides including alachlor, metolachlor, atrazine, and 2,4-D increased by 10-100 fold in one home following field applications.<sup>26</sup>

On three farms, investigators detected a total of 17 different pesticides on the hands of children ranging from age three to age 15.<sup>27</sup> These exposures were not to workers but rather to non-working children. Nine pesticides, including alachlor, atrazine, 2,4-D, dicamba, pentachlorophenol, captan, chlorpyrifos, propoxur, and DDT were all found on the hands of a three-year-old child living on a farm.<sup>28</sup>

The above deficiencies reveal that EPA improperly underestimated aggregate exposure to 2,4-D and its residues that may occur from dietary, residential, and all other known or plausible exposure routes. The use of 2,4-D in and around the home could itself exceed appropriate risk levels if properly calculated. The assumptions and missing data in EPA's analysis of aggregate exposure for 2,4-D serve to underestimate exposure and therefore underestimate risk, contrary to the requirements of the FQPA.

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<sup>25</sup> Nishioka MG, Lewis RG, Brinkman MC, Burkholder HM, Hines CE, Menkedick JR. Distribution of 2,4-D in air and on surfaces inside residences after lawn applications: comparing exposure estimates from various media for young children. *Environ Health Perspect* 2001 Nov;109(11):1185-91.

<sup>26</sup> Camann DE, Akland GG, Buckley JD, Bond AE, Mage DT. Carpet dust and pesticide exposure of farm children, Intl Soc Exp Anal Ann Mtg, Research Triangle Park, NC, November 5, 1997, 1997.

<sup>27</sup> Geno P, Camann D, Harding H, Villalobos K, Lewis R. Handwipe sampling and analysis procedure for the measurement of dermal contact with pesticides. *Arch Environ Contam Toxicol* 1996; 30:132-138.

<sup>28</sup> *Id.*

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

To assess chronic dietary exposure, EPA relied on estimates of “anticipated residues” for 2,4-D. 67 Fed. Reg. 10625. EPA similarly relied on anticipated residues to measure the acute dietary risk of 2,4-D as well. 67 Fed. Reg. 10625. 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 US. *See, e.g.*, 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 2,4-D at the tolerance level will be safe. Reliance on 21 U.S.C. § 346a(b)(2)(E) to factor in anticipated residues of 2,4-D 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 – is itself safe. 21 U.S.C. § 346a(b)(2)(A).

**F. EPA’s Apparent Use Of Human Testing Studies To Establish A Tolerance For 2,4-D Is Unethical And Contrary To International And Federal Law.**

EPA’s use of chemical industry-funded studies in which human “volunteers” are intentionally dosed with toxic pesticides is unethical, scientifically invalid, contrary to international law and agreements, and in violation of federal statutes and regulations – including the Nuremberg Code, the Helsinki Declaration, and EPA’s Common Rule. On

December 14, 2001, EPA requested recommendations from the National Academy of Sciences (NAS) regarding the scientific validity and ethical propriety of intentionally dosing human subjects with pesticides. At the same time, EPA announced through a press release that, pending consideration of the issues by NAS, the Agency would continue in effect its longstanding refusal to rely on any such human studies. However, in extending a time-limited tolerance for the pesticide 2,4-D on soybeans, EPA's reliance on studies of "volunteers exposed to sprayed turf" raises grave concerns whether the Agency is complying with its own moratorium and the dictates of international law and federal regulations. 67 Fed. Reg. 10626.

EPA justified failing to conduct residential exposure assessments for 2,4-D by citing a study in which "[n]o detectable residues were found in urine samples supplied by volunteers exposed to sprayed turf 24 hours following application." 67 Fed. Reg. 10626. EPA fails to clarify whether these "volunteers" endured occupational exposure to sprayed turf, or whether they were the subjects of a third-party human testing study. If these data concerning urine sample residues are not epidemiological and are instead the result of third-party human tests, then EPA's consideration of these data to undermine the aggregate exposure assessment for 2,4-D is an arbitrary departure from the Agency's stated policy on considering human tests and a violation of international and federal law.

## **V. RELIEF REQUESTED**

In light of the above outlined statutory violations, Objectors respectfully request that EPA refrain from establishing the new tolerance for 2,4-D until the pesticide

tolerance has been assessed and determined to be safe consistent with the requirements of the FQPA.

## **VI. REQUEST FOR A FEE WAIVER**

Pursuant to 40 C.F.R. 180.33(m), Objectors hereby request 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; each of the Objectors is committed to furthering public interest objectives. Boston Women's Health Book Collective is a nonprofit, public interest women's health education, advocacy, and consulting organization, begun in 1970 with the publication of the first edition of *Our Bodies, Ourselves*. Breast Cancer Action carries the voices of people affected by breast cancer to inspire and compel the changes necessary to end the breast cancer epidemic. Californians for Pesticide Reform is a coalition of over 150 public interest groups dedicated to protecting human health and the environment from the dangers of pesticide use. Commonweal is a small 25-year-old health and environmental research institute whose principal areas of work are with people with cancer and health professionals who work with people with life-threatening illnesses; children and young adults with learning and social difficulties, and the childcare professionals who work with them; and the global search for a healthy and sustainable future. Lymphoma Foundation of America is a national organization devoted solely to helping lymphoma patients and their families, founded in 1986 by people with lymphoma who came together to help each other recover from cancer. The Natural Resources Defense Council 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. Pesticide Action Network, North America (PANNA) works to replace pesticide use with ecologically sound and socially just alternatives. PANNA links local and international consumer, labor, health, environment and agriculture groups into an international citizens' action network that challenges the global proliferation of pesticides, defends basic rights to health and environmental quality, and works to ensure the transition to a just and viable society. Piñeros y Campesinos Unidos del Noroeste (PCUN), founded in 1985, is Oregon's union of farmworkers, nursery and reforestation workers and Oregon's largest Latino organization. PCUN's goal is to empower farmworkers to understand and take action against systematic exploitation and all of its effects. Northwest Coalition for Alternatives to Pesticides works to protect people and the environment by advancing healthy solutions to pest problems. SF-Bay Area Chapter, Physicians for Social Responsibility represents more than 20,000 physicians, nurses, health care professionals, and concerned citizens devoted to nuclear disarmament, violence prevention and environmental health. Women's Cancer Resource Center works to empower women with cancer to be active and informed consumers and survivors; to provide community for women with cancer and their supporters; to educate the general community about cancer; and to be actively involved in the struggle for a life-affirming, cancer-free society.

These objections to the tolerance established for 2,4-D are intended to benefit primarily the public as opposed to the Objectors. As outlined above, these objections challenge an EPA regulation that fails to properly implement the FQPA and, as a result, poses threats to the public health, especially children's health. Furthermore, none of the

objecting parties has any financial interest in the sale, manufacture, or use of 2,4-D.

Requiring Objectors to pay the fees would work an unreasonable hardship.

Respectfully submitted,

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David Chatfield Executive Director Californians for Pesticide Reform	Michael Lerner President Commonweal
Susan Osburn Executive Director Lymphoma Foundation of America	Erik Olson Senior Attorney Natural Resources Defense Council
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