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# An Agricultural Law Research Article

# Farm Children as a "Major Identifiable Subgroup" for Setting Tolerances Under the Food Quality Protection Act of 1996

by

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# Notes

# Farm Children as a "Major Identifiable Subgroup" for Setting Tolerances Under the Food Quality Protection Act of 1996<sup>†</sup>

On August 3, 1996, the Food Quality Protection Act of 1996 ("FQPA") became law, ushering in a new regime of food safety law and pesticide regulation in the United States.<sup>1</sup> The new law was the result of a bipartisan effort and was supported by a wide variety of interest groups, from environmental groups to agricultural groups to chemical companies.<sup>2</sup> The FOPA substantially amended the two regulatory pesticide statutes, the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")<sup>3</sup> and the Federal Food, Drug, and Cosmetic Act ("FFDCA").<sup>4</sup> While the FQPA enacted many substantive changes to pesticide law, a primary function and goal of the law was to protect the public-and specifically infants and children-from the dangers of pesticides in food products.<sup>5</sup> The FQPA sought reform through amendments to the standards for setting pesticide tolerances<sup>6</sup> in food, which required many new considerations in establishing a legally permissible amount of pesticide residue in food products. Among these new considerations are attention to aggregate exposure, specific safety provisions for infants and children, and an examination of exposures with a common mechanism of toxicity.<sup>7</sup>

<sup>&</sup>lt;sup>†</sup> Thanks go to Gretchen Sween, Brent Troyan, Heather Jones, Heidi Frahm, and other members of the Texas Law Review that helped to edit and put together this Note. I also appreciate the help and guidance of Professor Tom McGarity in the selection of this topic and the development of its substance. Lastly, special thanks go to my family for all of their continued support in this law school endeavor.

<sup>1.</sup> The Food Quality Protection Act of 1996, Pub. L. No. 104-70, 109 Stat. 773.

<sup>2.</sup> See ENVTL. PROT. AGENCY, THE FOOD QUALITY PROTECTION ACT (FQPA) BACKGROUND, at http://www.epa.gov/opppsps1/fqpa/backgrnd.htm (last visited Oct. 26, 2002).

<sup>3. 7</sup> U.S.C. § 136–136(y) (2000).

<sup>4. 21</sup> U.S.C. § 301–395 (1994).

<sup>5.</sup> See infra subpart I(C).

<sup>6.</sup> The Environmental Protection Agency is required to set tolerances for pesticides before allowing their use on food crops. A tolerance is the maximum residue limit, "which is the amount of pesticide residue allowed to remain in or on each treated food commodity. The tolerance is the residue level that triggers enforcement actions. That is, if residues are found above that level, the commodity will be subject to seizure by the government." ENVTL. PROT. AGENCY, SETTING TOLERANCES FOR PESTICIDE RESIDUES IN FOODS, at http://www.epa.gov/pesticides/citizens/ stprf.htm (updated July 1, 2002). For a discussion of the EPA's tolerance-setting process, see *infra* subpart II(B)(1).

<sup>7.</sup> See ENVTL. PROT. AGENCY, SUMMARY OF FQPA AMENDMENTS TO FIFRA AND FFDCA, at http://www.epa.gov/opppsps1/fqpa/fqpa-iss.htm (updated Aug. 19, 1999). Aggregate exposure

One important provision of the FQPA for setting pesticide tolerances was the identification and consideration of "major identifiable subgroups" of the population.<sup>8</sup> Focusing on this provision, the Natural Resources Defense Council ("NRDC") and other groups petitioned the Environmental Protection Agency ("EPA") in 1998 to identify farm children as a "major identifiable subgroup" under the FQPA.<sup>9</sup> They argued that farm children constitute a population whose disproportionate exposure to pesticides should be considered in the tolerance-setting process.<sup>10</sup> Agri-chemical interests quickly responded and objected to the petition in their own submission to the EPA.<sup>11</sup> The EPA has failed to act on the NRDC petition.

This Note will argue that farm children should be identified and considered by the EPA as a "major identifiable subgroup" for the purposes of setting pesticide tolerance levels under the FQPA. Part I will discuss the Food Quality Protection Act of 1996 generally—including its background, its substance, and its focus on the protection of infants' and children's health. Part II will discuss the specific statutory requirements of the FQPA for setting tolerances and the tolerance-setting procedure of the EPA. Part III will analyze the arguments for and against identifying farm children as a "major identifiable subgroup." It will argue that the statute on its face requires such an identification and, alternatively, that, in the absence of a clear statutory mandate, policy considerations dictate an interpretation of the statute that would reach the same result.

# I. The Food Quality Protection Act of 1996

On August 3, 1996, President Clinton signed the Food Quality Protection Act of 1996, enacting a new law for pesticide food safety in the United States.<sup>12</sup> Clinton proclaimed that the Act would "revolutionize the

10. See id. at 2.

includes human exposures to pesticide residue other than dietary intake. For example, aggregate exposure would include exposure to pesticides in the home environment, including pesticides used to kill such common household pests as roaches and ants. Pesticides with a common mechanism of toxicity, such as organophosphates and carbamates, have a similar mode of action in killing pests. See id.

<sup>8.</sup> See 21 U.S.C. § 346a(b)(2)(D) (2000).

<sup>9.</sup> NATURAL RES. DEF. COUNCIL 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 (1998), available at http://www.ecologic-ipm.com/farmkids.PDF [hereinafter NRDC PETITION]. In the petition, "farm children" are defined as "all children living on and near farms, and all children of farmers, farm workers, and others who handle pesticides professionally." *Id.* at 2. This Note will use the same definition of farm children.

<sup>11.</sup> COMMENTS OF WOMEN INVOLVED IN FARM ECONOMICS, AMERICAN AGRI-WOMEN ET AL., IN OPPOSITION TO THE PETITION OF THE NATURAL RESOURCES DEFENSE COUNCIL, ET AL. TO DESIGNATE FARM CHILDREN AS A "MAJOR IDENTIFIABLE SUBGROUP" UNDER THE FOOD QUALITY PROTECTION ACT (Dec. 1998) [hereinafter WIFE COMMENTS ON NRDC PETITION].

<sup>12.</sup> The Food Quality Protection Act of 1996, Pub. L. No. 104-70, 109 Stat. 773.

way we protect food from harmful pesticides" and that it "prove[d] we don't have to choose between a healthy environment and a healthy economy."<sup>13</sup> Congress had unanimously passed the Act, which had been supported "by the Administration and a broad coalition of environmental, public health, agricultural and industry groups."<sup>14</sup> The Act amended large parts of both the FIFRA and the FFDCA, the two federal statutes governing the EPA's regulation of pesticides.<sup>15</sup>

#### A. Background of the FQPA

While there had been efforts for more than two decades to reform inconsistencies between the FIFRA and the FFDCA and to update their provisions,<sup>16</sup> the direct impetus for the FQPA came from two main factors.<sup>17</sup> The first was the decision in *Les v. Reilly*,<sup>18</sup> which required the EPA to fully enforce the Delaney Clause without de minimis exceptions.<sup>19</sup> The Delaney Clause prohibited any residue of carcinogenic pesticides in processed food.<sup>20</sup> In the past, the EPA had not enforced the Delaney Clause and had created a de minimis exception to bolster its refusal to apply the Clause.<sup>21</sup> The *Les* court's holding striking down the de minimis exception and requiring the EPA to enforce the Delaney Clause placed many widely used pesticides in jeopardy of losing their registrations.<sup>22</sup> In the face of this risk, agri-chemical interest groups were prepared to compromise, and they lobbied for legislation that would prevent bans on pesticides that were so important to their businesses.<sup>23</sup>

18. 968 F.2d 985 (9th Cir. 1992).

21. Id. at 283-86, 293.

22. See McGarity, supra note 17, at 112. A pesticide cannot be used legally unless it is registered with the EPA's Office of Pesticide Programs. See ENVTL. PROT. AGENCY, OFFICE OF PESTICIDE PROGRAMS, PESTICIDE REGISTRATION, at http://www.epa.gov/pesticides/chemreg.htm (last modified Dec. 6, 2001).

23. See McGarity, supra note 17, at 114-16.

<sup>13.</sup> REMARKS BY PRESIDENT CLINTON AT THE SIGNING OF H.R. 1627, available at http://www.pmac.net/wthouse.htm (last visited Dec. 2, 2002) [hereinafter CLINTON REMARKS].

<sup>14.</sup> ENVTL. PROT. AGENCY, supra note 2.

<sup>15.</sup> This note will refer to these statutes as "the pesticide statutes."

<sup>16.</sup> ENVTL. PROT. AGENCY, supra note 2.

<sup>17.</sup> See Thomas O. McGarity, Politics by Other Means: Law, Science, and Policy in EPA's Implementation of the Food Quality Protection Act, 53 ADMIN. L. REV. 103, 111–17 (2001) (discussing the steps leading up to the enactment of the FQPA by Congress); James Smart, All the Stars in the Heavens Were in the Right Places: The Passage of the Food Quality Protection Act of 1996, 17 STAN. ENVTL. L.J. 273, 305–09 (1998) (stating that "[t]he National Academy of Sciences report on pesticides in the diets of children, the Les decision, and EPA's response to it created unprecedented pressure to reform the law on pesticide residues"); Scott Douglas Bauer, Note, The Food Quality Protection Act of 1996: Replacing Old Impracticalities with New Uncertainties in Pesticide Regulation, 75 N.C. L. REV. 1369, 1381–86 (1997) (discussing the influence of the Les decision on the passage of the FQPA).

<sup>19.</sup> McGarity, supra note 17, at 112.

<sup>20.</sup> See Smart, supra note 17, at 275 (indicating that the Delaney Clause required zero tolerance for any residue of carcinogenic pesticides in processed food).

The second and perhaps more important factor was the 1993 report by the National Research Council, Pesticides in the Diets of Infants and Children.<sup>24</sup> In 1988, Congress requested the National Academy of Sciences ("NAS") to appoint a committee to study the potential vulnerability of infants and children to dietary pesticides.<sup>25</sup> Specifically, the committee was charged to "examine the adequacy of current risk assessment policies and methods; to assess information on the dietary intakes of infants and children; to evaluate data on pesticide residues in the food supply; to identify toxicological issues of greatest concern; and to develop relevant research priorities."<sup>26</sup> In its report, the National Research Council suggested that "[t]he federal government should change some of its scientific and regulatory procedures to afford infants and children greater protection from possible adverse health effects of pesticides in their diets."<sup>27</sup> The report emphasized that "children are not 'little adults,'"28 stating that the committee found quantitative and qualitative differences between adults and children in both exposure to pesticide residues in foods<sup>29</sup> and in toxicity of pesticides.<sup>30</sup> The report further found that due to these differences, properly assessing the risk of pesticide residues in food to infants and children required new information on "(1) food consumption patterns of infants and children, (2) concentrations of pesticide residues in foods consumed by infants and children, and (3) toxic effects of pesticides, especially effects that may be unique to infants and

28. NAT'L RESEARCH COUNCIL, supra note 25, at 3.

29. The report found that:

Id. at 4.

<sup>24.</sup> The influence of this report on the enactment of the Food Quality Protection Act of 1996 may be seen by comparing the recommendations and findings of this report to the material changes in pesticide law found in the FQPA. Many aspects of the FQPA are identical to suggestions contained in this report.

<sup>25.</sup> NAT'L RESEARCH COUNCIL, PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN 2 (1993). The executive summary of the report is available at http://pmep.cce.cornell.edu/issues/nasexc.html (last visited Nov. 11, 2002).

<sup>26.</sup> Id.

<sup>27.</sup> Press Release, National Academies, Pesticides in the Diets of Infants and Children (June 28, 1993), available at http://www.nationalacademies.org/news (last visited Nov. 11, 2002).

Children consume more calories of food per unit of body weight than do adults. But at the same time, infants and children consume far fewer types of foods than do adults. Thus, infants and young children may consume much more of certain foods, especially processed foods, than do adults. And children's and adults' water consumption, both as drinking water and as a food component, is very different.

<sup>30.</sup> The report also asserted that:

Profound differences exist between children and adults. Infants and children are growing and developing. Their metabolic rates are more rapid than those of adults. There are differences in their ability to activate, detoxify, and excrete xenobiotic compounds. All these differences can affect the toxicity of pesticides in infants and children, and for these reasons the toxicity of pesticides is frequently different in children and adults.

children.<sup>31</sup> Among other things, the report specifically recommended the establishment of new exposure estimates for infants and children, the setting of new tolerance levels for pesticides based on human health, the addition of an uncertainty safety factor of tenfold in establishing health guidelines, and the consideration of all exposures, dietary and non-dietary, in evaluating risks to infants and children.<sup>32</sup> In sum, the committee found that the pesticide laws at that time were at best uncertain and at worst inadequate to protect infants' and children's health from the dangers of dietary pesticide exposure.

With pressure from agri-chemical interests to repeal the Delaney Clause and mounting evidence that infants and children were not adequately protected by the statutes, congressional leaders Representative Henry Waxman and Representative Thomas Bliley created compromise legislation that would address both concerns.<sup>33</sup> In July of 1996, this legislation, titled the Food Quality Protection Act of 1996, unanimously passed both the House and the Senate.<sup>34</sup> In August, President Clinton signed the piece of legislation in the presence of children.<sup>35</sup> The final bill "represented a compromise between environmental groups and agri-chem groups," but most importantly, it enacted a "strong policy preference for protecting the health of all infants and children from the risks posed by pesticides."<sup>36</sup>

# B. Substantive Amendments of the FQPA to the Pesticide Statutes

The FQPA of 1996 enacted substantial amendments to both the FIFRA and the FFDCA. The FIFRA requires that all pesticides be registered with the EPA and prescribes labeling and other regulatory requirements that seek to prevent adverse effects by pesticides on human health and the environment.<sup>37</sup> In contrast, the FFDCA, in its pesticide provisions, directs the EPA to set tolerances for pesticide residues in food.<sup>38</sup>

The majority of the FQPA's amendments to the FFDCA set up new general requirements for the establishment of tolerances, thereby placing new restrictions on residue levels.<sup>39</sup> However, the amendments also include special provisions for infants and children, consumer "right-to-know" provisions, and a mandate for a comprehensive screening program for estrogenic and endocrine effects.<sup>40</sup> Among the special provisions for infants and

40. Id.

<sup>31.</sup> Id. at 6.

<sup>32.</sup> Id. at 7-12.

<sup>33.</sup> See McGarity, supra note 17, at 115-16.

<sup>34. 142</sup> CONG. REC. 18573, 18867 (1996).

<sup>35.</sup> CLINTON REMARKS, supra note 13.

<sup>36.</sup> See McGarity, supra note 17, at 116-17.

<sup>37.</sup> ENVTL. PROT. AGENCY, supra note 2.

<sup>38.</sup> Id.

<sup>39.</sup> See ENVTL. PROT. AGENCY, SUMMARY OF FQPA AMENDMENTS TO FIFRA AND FFDCA, at http://www.epa.gov/opppsps1/fqpa/fqpa-iss.htm (updated Aug. 19, 1999).

children, the new law requires that the EPA should specifically address pesticide risks to infants and children in the setting of tolerance levels.<sup>41</sup> Before a tolerance can be established, the EPA must now publish specific safety findings and ensure "that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."<sup>42</sup> The law further requires that, in the case of threshold effects, an additional safety factor of tenfold be used to ensure that tolerance levels provide adequate safety for infants and children.<sup>43</sup>

The main thrust of the FQPA's amendments to the FFDCA consisted of changes in the standards for the setting of pesticide tolerances. The former FFDCA required the EPA to establish pesticide tolerances that would "protect the public health."<sup>44</sup> For chemicals that posed a carcinogenic risk, the EPA used a "negligible risk standard," except when the Delaney Clause applied.<sup>45</sup> The new law provides a "single, health-based standard,"<sup>46</sup> requiring that all tolerances be "safe"—defining safe as "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."<sup>47</sup> The amendments further require new factors to be considered in setting tolerances,<sup>48</sup> reevaluation of existing tolerances under the new standards,<sup>49</sup> development of a new standard for

48. See ENVTL. PROT. AGENCY, supra note 39. The new law requires EPA to consider the validity, completeness and reliability of available study data; the nature of potential toxic effects and available information on the relationship of study results to human risk; dietary consumption patterns and variations in the sensitivities of major identifiable subpopulations; cumulative and aggregate (dietary and nondietary) effects of exposure to the pesticide and other substances with common mechanisms of toxicity; effects on the endocrine system; and scientifically recognized appropriate safety factors. *Id.; see also* 21 U.S.C. § 346a(b)(2)(D) (2000) (listing many of the relevant factors to be considered "in establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue").

49. The FQPA requires that all existing tolerances be reevaluated under the following schedule: 33% by 1999, 66% by 2002, and 100% by 2006. ENVTL. PROT. AGENCY, *supra* note 39; 21 U.S.C. § 346a(q)(1) (2000).

<sup>41.</sup> See 21 U.S.C. § 346a(b)(2)(C) (2000).

<sup>42.</sup> Id. § 346a(b)(2)(C)(ii)(I).

<sup>43.</sup> Id. A safety factor requires "agencies to act cautiously when large uncertainties hinder attempts to assess risks based upon scientific facts. It also represents a congressional prescription for protective regulatory policy as a hedge against human error and as an added protection for especially sensitive subpopulations." McGarity, *supra* note 17, at 149. In this context, in providing a safety factor for infants and children, "Congress was concerned not only about knowledge gaps ('completeness of the data') but also about the special sensitivity of infants and children to environmental toxins ('potential pre- and post-natal toxicity')." *Id.* at 150. In establishing the required margin of safety, the "Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." 21 U.S.C. § 346a(b)(2)(C) (2000).

<sup>44.</sup> ENVTL. PROT. AGENCY, supra note 39.

<sup>45.</sup> Id.

<sup>46.</sup> Id.

<sup>47. 21</sup> U.S.C. § 346a(b)(2)(A)(ii) (2000).

considering pesticide benefits,<sup>50</sup> and establishment of new international standards for pesticide residue levels.<sup>51</sup>

The FQPA also significantly amended the FIFRA. Because the FIFRA relates mainly to the registration of pesticides, and thus has little bearing on the focus of this Note, these amendments will only be discussed summarily.<sup>52</sup> In its amendments to the FIFRA, the FQPA requires a new emergency suspension authority for pesticide registrations, new funds for the reregistration program, new incentives for the development and maintenance of minor use registrations, periodic review of pesticide registrations, a review of antimicrobial pesticides, and the expedition of review for safer pesticides.<sup>53</sup> In sum, the amendments changed the manner in which the EPA reviews and approves pesticides, and emphasizes regular reviews and more expeditious registration and approval of new and safer pesticides.

# C. Focus of the FQPA

While the FQPA enacted multiple and diverse amendments to both the FIFRA and the FFDCA, the primary focus of the FQPA is on food safety generally and, specifically, on the protection of infants and children from the danger of pesticides in foods. President Clinton emphasized this in his speech at the signing of the bill:

I like to think of [the FQPA] as the "peace of mind" act, because it'll give parents the peace of mind that comes from knowing that the fruits, the vegetables, the grains that they put down in front of their children are safe....

... [W]eaknesses in the present law cause real problems for everyone involved in producing and distributing our food, and for, most of all, the people who consume it—especially our children. According to the National Academy of Sciences, infants and young people are especially vulnerable to pesticides—chemicals can go a long way in a small body.

52. For a more thorough summary of the FQPA amendments to the FIFRA, see ENVTL. PROT. AGENCY, *supra* note 39.

<sup>50.</sup> The former standard "required EPA to set tolerances to protect public health and to give appropriate consideration to the necessity for production of an adequate, wholesome and economical food supply." ENVTL. PROT. AGENCY, *supra* note 39. The new law permits a residue only if it "protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue," or "is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b)(2)(B)(iii) (2000). This standard effectively negates any attempts to balance the benefits of pesticides against their harms when setting a tolerance level.

<sup>51.</sup> ENVTL. PROT. AGENCY, supra note 39; see also 21 U.S.C. § 346a(b)(4) (2000) (outlining the procedures for determining international standards and how to proceed when deciding not to comply with those standards).

This Act puts the safety of our children first. It sets a clear, consistent standard for all pesticide use on all foods for all health risks. It sets a standard high—if a pesticide poses a danger to our children, it won't be in our food, period.<sup>54</sup>

In consonance with the President's interpretation of the statute, the amendments to the FFDCA demonstrate that a primary role of the FQPA is protecting infants and children; the FFDCA has clear provisions for considering infants and children when setting tolerances.<sup>55</sup> Furthermore, the legislative history of the FOPA and the role that the NAS report played in getting the legislation passed highlight the fact that an overarching purpose of the FOPA was to protect infants' and children's health.<sup>56</sup> While the FOPA legislation resulted from a compromise among many interests with many individual and conflicting goals, "[t]he FQPA reflected a broad consensus in favor of protecting kids with an ample margin of safety, whatever the economic costs."<sup>57</sup> "A strong policy preference for protecting the health of all infants and children from the risks posed by pesticides permeate[d] the statute's new child protection provisions."<sup>58</sup> With this purpose of the FQPA in mind, this Note will now turn to the specific statutory protections of the FOPA for infants and children and the way in which the EPA implements these protections in the tolerance-setting process.

II. The FQPA's Specific Statutory Requirements for the Protection of Infants and Children and the EPA's Tolerance-Setting Process

# A. Statutory Requirements

As previously discussed, the provisions of the FQPA that seek to protect infants and children from the harms of pesticides in foods are found in its amendments to the FFDCA. These provisions are found in 21 U.S.C. § 346a(b)(2)(C) and require that all pesticide tolerances set by the EPA meet certain standards.<sup>59</sup> The statute first provides that, in setting tolerances, the Administrator must assess and evaluate the risk of pesticide residue to infants and children. Specifically, the Administrator

<sup>54.</sup> CLINTON REMARKS, supra note 13.

<sup>55.</sup> See 21 U.S.C. § 346a(b)(2)(C) (2000); ENVTL. PROT. AGENCY, supra note 39 (both stating that the provisions are specifically for the protection of "infants and children").

<sup>56.</sup> See Valerie Watnick, Risk Assessment: Obfuscation of Policy Decisions in Pesticide Regulation and the EPA's Dismantling of the Food Quality Protection Act's Safeguards for Children, 31 ARIZ. ST. L.J. 1315, 1331 (1999) (finding that "committee reports leave no doubt that the main legislative intent of the FQPA was to increase significantly protections for children by requiring that all future quantitative assessments of risks from pesticide residues consider the special susceptibilities of children").

<sup>57.</sup> McGarity, supra note 17, at 117.

<sup>58.</sup> Id.

<sup>59.</sup> See 21 U.S.C. § 346a(b)(2)(B)(vi) (2000) (requiring that pesticide tolerances set by the EPA comply with the standards of 21 U.S.C. § 346a(b)(2)(C)).

shall assess the risk of the pesticide chemical residue based on—(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population; (II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and (III) available information concerning the substances that have a common mechanism of toxicity .....<sup>60</sup>

The statute further requires that in setting tolerances, the Administrator "shall... ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."<sup>61</sup> Additionally, surveys are to be conducted that "document dietary exposure to pesticides among infants and children."<sup>62</sup> Lastly, "[i]n the case of threshold effects, ... an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity."<sup>63</sup>

An examination of these requirements demonstrates the FQPA's specific emphasis on the protection of infants and children. These special statutory protections for infants and children complement the other new and more stringent EPA requirements for setting pesticide tolerances. As discussed, the most significant requirement is that all pesticide residues must be "safe"---meaning that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."64 The most significant change that extends from this requirement is that now aggregate exposure, including exposures other than dietary exposures, will be considered in setting tolerances to ensure a level of safety for American consumers. These considerations have a major consequence: "Presumably, if other routes of exposure are not easily controlled, EPA must ensure a reasonable certainty of no harm by reducing dietary exposure through the tolerance-setting exercise."65

62. Id. § 346a(b)(2)(C)(ii)(II).

63. Id. The EPA may determine, in some cases, that a less than tenfold margin of safety is acceptable. See supra note 43.

- 64. 21 U.S.C. § 346a(b)(2)(A)(i)-(ii) (2000).
- 65. McGarity, supra note 17, at 119.

<sup>60.</sup> Id. § 346a(b)(2)(C)(i).

<sup>61.</sup> Id. § 346a(b)(2)(C)(ii)(I). The statute also requires that the Administrator "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children." Id. § 346a(b)(2)(C)(ii)(II).

The statute is even more stringent in listing further factors that the Administrator must consider in setting tolerances.<sup>66</sup> Among the factors that the Administrator must consider are:

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue; (ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies; [and] (iii) available information concerning the relationship of the results of such studies to human risk.<sup>67</sup>

Furthermore, and of great importance to the protection of infants and children, the Administrator must consider "available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity."<sup>68</sup>

Finally, and of most significance for this Note, the statute seeks to protect certain segments of the population that face a higher risk from and are more susceptible to the dangers of pesticides. The statute first requires the Administrator to consider "available information concerning the dietary consumers)."<sup>69</sup> Second, the statute requires the Administrator to consider "available information concerning the dietary to consider "available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources."<sup>70</sup> Finally, the Administrator must consider "available information concerning the sensitivities of major identifiable subgroups of consumers."<sup>71</sup>

The statute requires the EPA to specifically consider the safety for infants and children in the tolerance-setting process.<sup>72</sup> Furthermore, the EPA must consider the vulnerability of "major identifiable subgroups" of the population.<sup>73</sup> I will discuss the meaning of this statutory language and its implications for the protection of farm children shortly. First, however, I will briefly examine how the EPA sets tolerances for the purposes of the FQPA.

- 67. Id. § 346a(b)(2)(D)(i)-(iii).
- 68. Id. § 346a(b)(2)(D)(v).
- 69. Id. § 346a(b)(2)(D)(iv) (emphasis added).
- 70. Id. § 346a(b)(2)(D)(vi) (emphasis added).
- 71. Id. § 346a(b)(2)(D)(vii) (emphasis added).
- 72. Id. § 346a(b)(2)(C).
- 73. Id. § 346a(b)(2)(D)(iv), (vi)-(vii).

<sup>66. 21</sup> U.S.C. § 346a(b)(2)(D) (2000).

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# B. Implementation: The EPA's Establishment of Tolerances Under the FQPA

1. Setting Tolerances Generally.—The FQPA requires the EPA to set tolerance levels for pesticides at a level at which the Administrator has determined "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."<sup>74</sup> The FQPA further requires the EPA to consider a variety of other factors—from the safety of infants and children to available information on "major identifiable subgroups"—in the tolerance-setting process.<sup>75</sup> The tolerance level, or maximum residue limit, is the amount of pesticide amount found on food above this level is subject to enforcement actions, including seizure by the government.<sup>77</sup>

The tolerance-setting process of the EPA is not transparent on its face. Rather, this process is extremely complex, and the setting of a tolerance level requires a great deal of scientific information and study.<sup>78</sup> With the new requirements of the FQPA, the EPA must consider a much larger amount of information in the tolerance-setting process than previously required. This information is used in the EPA's risk assessment process, the general process by which the EPA evaluates the risks of pesticides and establishes a tolerance level.<sup>79</sup>

2. EPA's Risk Assessment Process.—In assessing risk, the EPA uses the National Research Council's four-step process: (1) hazard identification; (2) dose-response assessment; (3) exposure assessment; and (4) risk characterization.<sup>80</sup> The first step involves the identification of potential health effects that may result from pesticide exposure, including the identification and assessment of the hazard posed by a pesticide to human health.<sup>81</sup> In doing so, the EPA reviews toxicity studies conducted by pesticide companies. The EPA may also independently consult other literature or

80. ENVTL. PROT. AGENCY, ASSESSING HEALTH RISKS FROM PESTICIDES (Jan. 1999), available at http://www.epa.gov/pesticides/citizens/riskassess.htm (last visited Nov. 11, 2002).

81. Id.; McGarity, supra note 17, at 120.

<sup>74.</sup> Id. § 346a(b)(2)(A)(ii).

<sup>75.</sup> Id. § 346a(b)(2)(C)-(D); see also supra subpart II(A).

<sup>76.</sup> ENVTL. PROT. AGENCY, supra note 6.

<sup>77.</sup> Id.

<sup>78.</sup> Id.

<sup>79. &</sup>quot;Risk assessment is an analytical process that 'uses available scientific information on the properties of an agent and its effects in biological systems to provide an evaluation of the potential for harm as a consequence of environmental exposure to the agent." Thomas McGarity, A Brief Primer on Risk Assessment (Jan. 29, 2002) (unpublished manuscript, on file with the Texas Law Review).

sources with scientific information.<sup>82</sup> The second step attempts to ascertain dose levels that will cause adverse effects in humans.<sup>83</sup> The third step assesses how humans are exposed to pesticides.<sup>84</sup> The EPA has determined that humans are exposed to pesticides in three ways: inhalation, dermal exposure, and oral exposure.<sup>85</sup> Such exposure can originate from pesticides in foods, home- and personal-use pesticides, pesticides in drinking water, and workplace exposure to pesticides.<sup>86</sup> The last step "is the process of explaining risk assessments to the regulated companies and members of the public who are affected by them."<sup>87</sup> Risk characterization combines the first three steps to establish a single quantitative or qualitative risk assessment.<sup>88</sup>

To aid in the visualization of its risk assessment process for setting tolerances, the EPA uses the idea of a risk cup. The risk cup represents the acceptable pesticide tolerance and holds the "total amount of a given pesticide that a person could be exposed to every day, for 70 years, without additional health risks."<sup>89</sup> This amount correlates directly with an EPA-determined "reference dose" that meets the statutory requirements of the FQPA for safety. A reference dose, sometimes called an "acceptable daily intake," is "an estimate of a daily exposure to the human population that is assumed to be without appreciable risk of deleterious reproductive or developmental effects."<sup>90</sup> The risk cup is filled with all of the residues that a person encounters through dietary and non-dietary exposures.<sup>91</sup> In accordance with the mandates of the FQPA, the risk cup will be filled with residues of pesticides with a common mechanism of toxicity.<sup>92</sup> The size of the risk cup is determined by risk assessment and safety factors, including those required for the additional safety of infants and children.<sup>93</sup> When the

<sup>82.</sup> ENVTL. PROT. AGENCY, *supra* note 80. The EPA recognizes three primary ways to assess the hazards of pesticides to human health: human testing, epidemiological studies, and animal testing. McGarity, *supra* note 17, at 122; McGarity, *supra* note 79, at 2–6.

<sup>83.</sup> ENVTL. PROT. AGENCY, *supra* note 80. "Dose-Response Assessment is 'the process of characterizing the relation between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations and estimating the incidence of the effect as a function of human exposure to the agent." McGarity, *supra* note 79, at 7.

<sup>84.</sup> ENVTL. PROT. AGENCY, supra note 80.

<sup>85.</sup> Id.

<sup>86.</sup> Id. The EPA notes "[p]esticide applicators, vegetable and fruit pickers and others who work around pesticides can be exposed due to the nature of their jobs. To address the unique risks workers face from occupational exposure, [the] EPA evaluates occupational exposure through a separate program." Id.

<sup>87.</sup> McGarity, supra note 17, at 133.

<sup>88.</sup> Id. For a more thorough discussion of risk characterization and what it entails, including the number of ways that risk characterization can portray risks, see *id.* at 133–34.

<sup>89.</sup> UNIV. OF CONN., INTEGRATED PEST MANAGEMENT, RISK CUP, at http://www.hort.uconn.edu/ipm/nursery/htms/riskcup.htm (last visited Nov. 11, 2002).

<sup>90.</sup> McGarity, supra note 17, at 126.

<sup>91.</sup> UNIV. OF CONN., supra note 89.

<sup>92.</sup> Id.

<sup>93.</sup> Id.

risk cup for a given pesticide is full or overflows, the EPA must act by limiting the use of this pesticide.<sup>94</sup>

The risk assessment process and the concept of the risk cup are methods for translating the FQPA's statutory requirements for food tolerances into quantifiable food tolerance levels. I will not analyze these methods here; instead, I will question whether considerations of farm children should play a role in this tolerance-setting process.

# III. Farm Children as a "Major Identifiable Subgroup"

## A. The Debate

In October of 1998, the NRDC and other organizations petitioned the EPA to designate farm children as a "major identifiable subgroup" and as a high-risk population that merited protection under the Food Quality Protection Act.<sup>95</sup> Relying primarily on a previous NRDC report,<sup>96</sup> the petition argued that farm children<sup>97</sup> "are at dramatically greater risk than other children for exposure to more pesticides from a wider range of sources."<sup>98</sup> Furthermore, the petition pointed out that "[t]hese children make up a significant segment of the U.S. population, and deserve protection no less than other children."<sup>99</sup> It emphasized that the Act requires "that the EPA administrator should consider the special sensitivities and exposure patterns of 'major identifiable subgroups of consumers."<sup>100</sup>

Agri-chemical interests responded to this petition, arguing that exposures to children of farmers and farmworkers were occupational in nature and thus not to be considered in setting tolerances.<sup>101</sup> They further noted that considering such exposures would set tolerance levels "at levels far lower than would be needed to assure the health of the vast majority of the population."<sup>102</sup> Since these submissions, the EPA has failed to rule on or take action on the petition to identify farm children as a "major identifiable subgroup."

<sup>94.</sup> Frank B. Cross, Incorporating Hormesis in Risk Regulation, 30 ENVTL. L. REP. 10778, 10784 (2000).

<sup>95.</sup> NRDC PETITION, supra note 9, at 2.

<sup>96.</sup> NATURAL RES. DEF. COUNCIL, TROUBLE ON THE FARM: GROWING UP WITH PESTICIDES IN AGRICULTURAL COMMUNITIES (1998), *available at* http://www.nrdc.org/health/kids/farm/farminx.asp (last visited Jan. 31, 2003).

<sup>97.</sup> The term "farm children" in the NRDC petition refers to "all children living on and near farms, and all children of farmers, farm workers, and others who handle pesticides professionally." NRDC PETITION, *supra* note 9, at 2.

<sup>98.</sup> Id.

<sup>99.</sup> Id.

<sup>100.</sup> Id.

<sup>101.</sup> See WIFE COMMENTS ON NRDC PETITION, supra note 11, at 8-12.

<sup>102.</sup> Id. at 10.

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1. The NRDC Petition.<sup>103</sup>—The NRDC petition contended that farm children are disproportionately exposed to pesticides and should be designated by the EPA as a "major identifiable subgroup" for the tolerance-setting purposes of the FQPA.<sup>104</sup> The petition described the large number of farm children living in the United States<sup>105</sup> and the large amounts of pesticides used in American agriculture.<sup>106</sup> The petition argued that as a consequence, farm children are heavily exposed to pesticides. Relying on the NRDC report, *Trouble on the Farm: Growing Up with Pesticides in Agricultural Communities*,<sup>107</sup> the petition asserted that farm children are exposed to pesticides from a wide variety of sources. These sources include "pesticide[] residues from their parents' skin and clothing, dust tracked into the house, contaminated soil in outdoor play areas, drift from aerial spraying, indoor air contamination, food eaten directly from the fields, contaminated well-water, and even breastmilk."<sup>108</sup>

The petition also argued that "children of all ages spend time in the fields," whether working in the fields, walking through fields, or accompanying their parents to the fields.<sup>109</sup> The petition suggested that this is a major reason why pesticide residues, evidenced by biomonitoring data and residential exposure studies, have been found at greater levels in farm homes and on farm children.<sup>110</sup> Studies have discovered dangerous levels of pesticides both on the hands of farm children and in their urine.<sup>111</sup> The petition concluded that "farm children may be the most pesticide-exposed group of people in the nation."<sup>112</sup> Furthermore, "[i]n some cases, these exposures appear to result in elevated exposures above current reference doses,<sup>113</sup> and

106. See id. (emphasizing that 950 million pounds of pesticides go into agricultural production in the United States each year).

- 107. NATURAL RES. DEF. COUNCIL, supra note 96.
- 108. NRDC PETITION, supra note 9, at 2.
- 109. Id. at 2-3.
- 110. Id. at 3.

111. See id. (stating, for example, that "[i]n California, two pesticides, diazinon and chlorpyrifos, were found on the hands of three out of five farmworker children sampled, at levels predicted by a screening risk assessment to result in exposures over the reference dose").

112. Id. at 3. At first glance, this conclusion seems a bit far-fetched, as it would seem that people applying pesticides or other similar persons would be the most pesticide-exposed group. But the petition noted that its conclusion was valid because of "children's unique exposure patterns from activity close to the ground, hand-to-mouth behavior, and the fact that, per pound of body weight, children eat, drink and breathe more than adults." Id.

113. A reference dose is a "dose of a pesticide that the U.S. EPA considers safe for regular daily consumption by humans without adverse health effects." NATURAL RES. DEF. COUNCIL,

<sup>103.</sup> This petition was not submitted solely by the NRDC. In addition to the NRDC, fifty groups and eight individuals signed it. For a complete list of signatures, see NRDC PETITION, supra note 9, at 16–18.

<sup>104.</sup> See id. at 9.

<sup>105.</sup> See id. at 1-2 (noting that 320,000 children under the age of six live on United States farms, hundreds of thousands of children play or go to school near agricultural land, and the nation's 2.5 million farmworkers have approximately one million children living in the United States).

are leading to quantifiable pesticide residues in these children's bodies."<sup>114</sup> Based on this data and thus the paramount necessity of protecting farm children, the petition requests that:

the U.S. Environmental Protection Agency (EPA) issue a directive stating that the agency will recognize farm children as a "major identifiable subgroup" under the FQPA §408 (b)(2)(D)(iv, vi & vii), treating them as a "population at special risk" whose exposures and health status serve as an indicator of potential problems for other population groups and whose health, if protected, would assure a greater level of confidence in protection for the rest of the population.<sup>115</sup>

While this request constituted the main thrust of the petition, the petition further requested other agency actions to ensure the protection of farm children in establishing tolerances.<sup>116</sup> The signatories urged the EPA to "honor the President's Executive Order on Environmental Justice which directs that when there is a group disproportionately exposed to an environmental toxicant, [the] EPA should fully enforce environmental laws."<sup>117</sup>

This petition was submitted on October 22, 1998. As I mentioned above, agri-chemical interests quickly responded to the petition, and the EPA has not yet taken a stance.

2. The Agri-Chemical Position.—In December of 1998, a variety of agricultural interests joined in submitting Comments opposing the NRDC petition to designate farm children as a "major identifiable subgroup" for purposes of setting tolerances under the FQPA.<sup>118</sup> The Comments made two principal arguments: first, farm children are not at special risk from exposure to pesticides; and second, pesticide exposures stemming from occupational sources should not be regulated under the tolerance-setting mechanisms of the FQPA.<sup>119</sup> In making the first argument, the Comments asserted that there is no reliable statistical data, medical evidence, or health study demonstrating

118. See WIFE COMMENTS ON NRDC PETITION, supra note 11. For a listing of all groups that participated in the submission of the WIFE Comments, see id. at 1–2.

119. See id. at 2 (addressing what the Comments call the "two flawed premises" of the NRDC petition).

supra note 96 (defining "reference dose" in the glossary of the report); see also supra text accompanying note 90.

<sup>114.</sup> NATURAL RES. DEF. COUNCIL, supra note 96, at 4.

<sup>115.</sup> Id.

<sup>116.</sup> See id. at 4-5 (listing five additional EPA requests, including the utilization of the tenfold children's safety factor where the EPA lacks complete exposure data on farm children, the exploration of exposure pathways, and an increase in research on farm children's health and exposure to pesticides).

<sup>117.</sup> Id. at 5 (referring to Exec. Order No. 12,898, 3 C.F.R. 859 (1994), reprinted in 42 U.S.C. § 4321 (2000) (entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations")).

that farm children are less healthy than the general population.<sup>120</sup> Rather, the Comments argued that more reliable and relevant studies indicate that farm children "are at least as healthy as the population as a whole."<sup>121</sup> Dismissing the NRDC conclusions as lacking grounds, evidence, and scientific justification, the Comments stated that current data did not support the "supposition that potential exposure to pesticides translates into real and significant health effects."<sup>122</sup> They urged the EPA to use relevant and reliable data in making decisions regarding agricultural pesticides and their effects on the public health.<sup>123</sup> In concluding, the Comments reiterated that "[c]urrently available studies of the relative health of farmers and their families show that they are at least as healthy as the population as a whole and that, consequently, there is no reason to believe that these individuals' actual exposure to agricultural pesticides significantly diminishes their health."<sup>124</sup>

The second argument that the Comments made was that Congress did not intend to base food tolerances on the consideration of occupational exposures to pesticides.<sup>125</sup> The Comments pointed to § 408(b)(2)(D)(vi) of the FQPA, and noted Congress's express exclusion of occupationally related sources from the calculation of aggregate exposure when setting tolerances.<sup>126</sup> Furthermore, the Comments warned that setting tolerances based on the consideration of occupationally related exposures, which involve an "extremely limited number of individuals," would likely result in tolerance levels "far lower than would be needed to assure the health of the vast majority of the population."<sup>127</sup> And such a setting would result in a substantial loss of "many safe and effective pesticides . . . which are critical to the production of a diverse, abundant, and wholesome food supply."<sup>128</sup>

The Comments further argued that lowering tolerance settings would not effectively protect farm children, because lower tolerance settings would

<sup>120.</sup> Id. at 4-8.

<sup>121.</sup> *Id.* at 5; *see also id.* at 4–6 (relying on a National Health and Nutrition Examination Survey, a Swedish study, and a South Carolina study to argue that farm children and farmers are as healthy as the rest of the population).

<sup>122.</sup> *Id.* at 7; *see also id.* at 4 (stating that "agricultural pesticides have been used for decades in this country and there are no reliable data suggesting that, as a result, farmers or farm children are any less healthy than the population as a whole").

<sup>123.</sup> Id. at 7-8.

<sup>124.</sup> Id. at 8.

<sup>125.</sup> Id. at 8-12.

<sup>126.</sup> *Id.* at 9. Section 408(b)(2)(D)(vi) of the FQPA corresponds to 21 U.S.C. § 346a(b)(2)(D)(vi), which states that in setting tolerances, the EPA shall consider, among other factors, "available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other *non-occupational sources.*" 21 U.S.C. § 346a(b)(2)(D)(vi) (2000) (emphasis added).

<sup>127.</sup> WIFE COMMENTS ON NRDC PETITION, *supra* note 11, at 10. 128. *Id.* 

not keep children out of the fields, where occupational source and other exposures occur.<sup>129</sup> The Comments suggested that stronger and more effective protections are already found in safety laws and regulations that are intended to protect against just such exposures.<sup>130</sup> These existing laws and regulations include the pesticide application restrictions of the FIFRA and the worker protection standards codified at 40 C.F.R. § 170.<sup>131</sup> The Comments noted that "these use restrictions and worker protection standards address practically all of the potential exposure pathways identified in the NRDC Petition."<sup>132</sup> Finally, the Comments discussed important initiatives promoted by the EPA intended to further assess exposure pathways, such as the Spray Drift Task Force, which will aid in reducing occupational exposures.<sup>133</sup> The Comments concluded that "our food protection laws assure a safe, diverse, and abundant food supply while offering seamless protection against the potential hazards associated with the use of pesticides."<sup>134</sup>

With these two main arguments, the agri-chemical interests' Comments urged the EPA to ignore the NRDC petition and its suggestion that farm children should be considered as a "major identifiable subgroup" in setting tolerances for the purposes of the FQPA. The EPA has apparently accepted this position to some degree, because, as of this Note's publication, it has not acted in any way on the NRDC petition. In the next sections, I will analyze the arguments of both the NRDC and the agri-chemical interests.

#### B. Assessing the Statutory Arguments

1. The NRDC's Statutory Argument.—In making their arguments for and against the identification of farm children as a "major identifiable subgroup" for the tolerance-setting purposes of the FQPA, both the agrichemical interests and the NRDC focused on § 346a(b)(2)(D) of the FQPA.<sup>135</sup> This section lists nine factors that "the Administrator shall consider" in the setting of tolerance levels.<sup>136</sup> In advancing its argument, the NRDC pointed to the requirement that the Administrator consider

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) to the pesticide

135. See supra subpart III(A).

<sup>129.</sup> Id. at 8.

<sup>130.</sup> Id. at 10.

<sup>131.</sup> Id. at 10-11.

<sup>132.</sup> Id. at 11 (explaining, as an example, how existing worker-protection standards address potential pesticide exposures from laundering workclothes together with children's clothes).

<sup>133.</sup> Id.

<sup>134.</sup> Id. at 12.

<sup>136. 21</sup> U.S.C. § 346a(b)(2)(D) (2000).

chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources[; and] available information concerning the variability of the sensitivities of major identifiable subgroups of consumers.<sup>137</sup>

Based on these statutory requirements, the NRDC asserted that the EPA should "find that farm children are a major identifiable subgroup and must be protected under the FQPA when setting allowable levels of pesticide residue in food."<sup>138</sup> In developing this argument, the NRDC made two primary assumptions: (1) the statute requires the EPA to consider available information regarding "major identifiable subgroups" in setting tolerance levels; and (2) farm children constitute such a "major identifiable subgroup." Based on these premises, available information regarding the "major identifiable subgroup" of farm children must be considered in setting tolerance levels.

If its assumptions are valid, the NRDC has constructed a legitimate statutory argument. On its face, the sections to which the NRDC refers appear to overtly require the EPA to consider available information regarding "major identifiable subgroups" for the purpose of establishing "safe" tolerance levels. This requirement involves assessing information relating to the dietary consumption patterns, aggregate exposure levels, and variability of sensitivities of consumers within these "subgroups."<sup>139</sup> However, there is a problem with their second premise—that farm children constitute a "major identifiable subgroup"—if one considers what the statute intends to recognize as a "major identifiable subgroup."

The statute fails to define "major identifiable subgroup" and offers very little context to further illuminate its meaning.<sup>140</sup> A plain reading of the statute suggests that a "major identifiable subgroup" is a large, identifiable number of individuals within the larger group of consumers who share a common characteristic.<sup>141</sup> Farm children would certainly be considered a "major identifiable subgroup" under this meaning—they are a large and identifiable number of individuals that share the common characteristic of growing up in an agricultural environment. However, such a broad definition

<sup>137.</sup> NRDC PETITION, *supra* note 9, at 4 (citing 21 U.S.C. § 346a(b)(2)(D)(iv), (vi), (vii) (2000)).

<sup>138.</sup> Id. at 2.

<sup>139.</sup> See 21 U.S.C. § 346a(b)(2)(D)(iv), (vi), (vii) (2000).

<sup>140.</sup> Likewise, the formal legislative history of the FQPA fails to provide a definition or discussion of the term "major identifiable subgroup." In general, the legislative history of the FQPA is unhelpful in the interpretation of ambiguous terms within the statute. It presumably fails as an interpretive aide because "the negotiations [of the FQPA] were carried out behind the closed doors of Representatives Bliley and Waxman." McGarity, *supra* note 17, at 116.

<sup>141.</sup> See WEBSTER'S NEW WORLD DICTIONARY 597 (Victoria Neufeldt ed., 3d College ed. 1988) (defining "group" as a number of persons or things classified together because of common characteristics).

would encompass an infinite number of "major identifiable subgroups" within the scope of the statute, making this statutory provision meaningless and the EPA's job impossible.<sup>142</sup> Such a broad meaning is implausible, and thus a narrower meaning must be discussed.

A narrower, alternative interpretation of "major identifiable subgroup" may be developed if Congress's intention is considered. As heretofore discussed, the overall purpose of the FQPA is to better protect consumers (especially infants and children) from the dangers of pesticide residues in food. Therefore, the most reasonable interpretation of this language suggests that Congress intended to protect subgroups of consumers who—for a number of possible reasons—differ from consumers in general and need specific protections. Thus, a preliminary working definition of the term "major identifiable subgroup" would be a large, identifiable number of individuals whose common differences distinguish them from consumers as a whole and place the group at a greater risk from pesticides—thereby creating the need for greater protections from the harms of pesticide residues in foods.<sup>143</sup>

The differences of a hypothetical group that spawn the need for greater protections can only involve dietary exposures, aggregate exposures, or a variability of sensitivities that make them more susceptible than the general public. This limitation arises from the context in which the term "major identifiable subgroup" is actually used within the statute. The term "major identifiable subgroup" is not used in conjunction with other factors that the EPA must consider in setting tolerances. Thus, presumably, the reason Congress placed this term in connection with these limited factors was that the distinguishing characteristics of "major identifiable subgroups" should relate to these specific characteristics. A group falling within this preliminary definition of "major identifiable subgroup" would share a common difference from consumers in general, placing them at a greater risk of harm from pesticide residues in foods.<sup>144</sup>

<sup>142.</sup> For example, under this interpretation, consumers with black hair or left-handed consumers could be considered a "major identifiable subgroup." Both groups are large and identifiable, and they possess a common feature distinguishing them from the larger group of consumers. Certainly, consideration of such "major identifiable subgroups" could not have been Congress's intent.

<sup>143.</sup> This definition is much more limited and does not render the term "major identifiable subgroup" mere surplusage. For example, under this definition, consumers with black hair or left-handed consumers would not amount to a "major identifiable subgroup" because their distinguishing characteristics do not place the group at greater risk from exposure to pesticides in foods.

<sup>144.</sup> Such groups might be vegetarians or Native Americans, who are potentially at greater risk from pesticides in foods as a result of their special diets. Likewise, pregnant women could be considered a "major identifiable subgroup," whose variability of sensitivities might place them at greater risk from pesticide residues in foods. Finally, individuals living near pesticide manufacturing plants could be considered a "major identifiable subgroup." Invariably, pesticide

A further limitation on the interpretation of "major identifiable subgroup" is suggested by the word "identifiable." Presumably, for a "subgroup" to be identified, information regarding that "subgroup"specifically, information that shows the "subgroup" possesses a difference in their variability of sensitivities, aggregate exposure, or dietary exposure to pesticides, placing them at greater risk---must be available. But it is difficult to imagine how the EPA would determine that a "subgroup" merits attention without good information about the specific relationship of that "subgroup" to pesticides. Indeed, the term "available information" further qualifies the consideration of "major identifiable subgroups."<sup>145</sup> Because the statute only calls for the consideration of "available information" and does not, for example, require further research or the gathering of information, a "major identifiable subgroup" can only be defined as a "subgroup" on the basis of information already on hand. Thus, a final working definition of the term "major identifiable subgroup" must also include the requirement that information has already been compiled, demonstrating that the subgroup warrants special treatment.

If farm children can fall within this final working definition, then the statute requires the EPA to identify them and consider certain factors relevant to their group in the tolerance-setting process. Whether farm children meet this definition will be discussed shortly.<sup>146</sup> If one assumes that they do, the NRDC has a valid argument that the EPA is required to consider farm children as a "major identifiable subgroup" under 21 U.S.C. § 346a(b)(2)(D).

The NRDC made the final argument that farm children must be considered a "major identifiable subgroup" because "[t]hese children represent a significant proportion of the population, and any tolerance that does not protect them cannot be found to provide 'a reasonable certainty of no harm' under the law."<sup>147</sup> This argument appears to be misdirected. Simply because these children represent a significant portion of the population does not bring them within the working definition of "major identifiable subgroup."<sup>148</sup> Only a demonstrated difference, at-risk qualification, and the need for further protection will bring them within the definition. The NRDC is correct that if farm children are at risk, a tolerance established to protect the population as a whole will not sufficiently protect farm children who are disproportionately exposed to pesticides in the agricultural setting. On its face, the statute does not limit its concern to *some* 

residues from these plants extend into the environment surrounding the plants, resulting in heightened aggregate exposure and greater risk to individuals living nearby.

<sup>145.</sup> See 21 U.S.C. § 346a(b)(2)(D)(iv), (vi), (vii) (2000).

<sup>146.</sup> See infra subpart III(B)(3).

<sup>147.</sup> NRDC PETITION, *supra* note 9, at 9.

<sup>148.</sup> Again, if a group could qualify as a "major identifiable subgroup" under the statute simply because it includes a significant portion of the population, countless "major identifiable subgroups" would exist—rendering the language meaningless.

children or the *majority* of children, but rather that the EPA "shall ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."<sup>149</sup> Therefore, "[w]hile the lower tolerances needed to protect farm children would generally not be necessary to protect other children, the FQPA requires EPA to protect *all* infants and children, not just the 'vast majority."<sup>150</sup> This argument supports the contention that the FQPA requires the consideration of farm children in the tolerance-setting process in general, in contrast to the idea that the EPA should specifically consider farm children by identifying them as a "major identifiable subgroup."

2. The Agri-Chemical Interest Group's Statutory Argument.—The agrichemical interest groups made one major statutory argument in their opposition to the NRDC petition. They argued that farm children should not be identified by the EPA as a "major identifiable subgroup" because § 346a(b)(2)(D)(vi) excludes occupational sources when considering the aggregate exposure levels of consumers and determining "major identifiable subgroups" of consumers.<sup>151</sup> They suggest that this exclusion preempts the identification of farm children as a "major identifiable subgroup," because such an identification would regulate levels of pesticide residues based on occupational exposures—in direct opposition to Congress's intent.<sup>152</sup>

This argument is flawed for two reasons. First, this position fails to recognize that the statutorily required identification of "major identifiable subgroups" is not used solely in the context of considering the subgroups' aggregate exposure. The statute requires the consideration of "major identifiable subgroups" in setting tolerances in three instances.<sup>153</sup> While these "subgroups" are to be included in the consideration of available information regarding aggregate exposure, they are also to be included in the consideration of available information patterns.<sup>154</sup> Furthermore, the statute requires the consideration of "the variability of the sensitivities" of these "subgroups."<sup>155</sup> Even if the occupational exposure exclusion precluded the consideration of farm children as a

154. Id. § 346a(b)(2)(D)(iv), (vi).

155. Id. § 346a(b)(2)(D)(vii). While the statute requires the EPA to consider "available information concerning the variability of the sensitivities of major identifiable subgroups of consumers," the argument that "major identifiable subgroups" refers exclusively to population subgroups that are identifiable because of peculiar susceptibilities to the toxic effects of pesticides cannot be sustained. The statute's use of the term "major identifiable subgroup" in the context of aggregate exposure and dietary exposures precludes such an argument and supports a much broader meaning of the term.

<sup>149. 21</sup> U.S.C. § 346a(b)(2)(C)(ii)(I) (2000).

<sup>150.</sup> McGarity, supra note 17, at 186 (emphasis added).

<sup>151.</sup> See WIFE COMMENTS ON NRDC PETITION, supra note 11, at 9.

<sup>152.</sup> See id. at 2.

<sup>153. 21</sup> U.S.C. § 346a(b)(2)(D)(iv), (vi), (vii) (2000).

"major identifiable subgroup" in the context of aggregate exposure, two possible statutory requirements for the consideration of farm children as a "major identifiable subgroup" would remain.<sup>156</sup>

That said, however, the agri-chemical interests' argument is also flawed because occupational exposure exclusion from the aggregate exposure consideration does *not* preclude the consideration of farm children in this context. The statute requires the consideration of aggregate exposure for "major identifiable subgroups" in considering available information concerning the aggregate exposure levels to pesticide residue, including dietary exposure and exposure from nonoccupational sources.<sup>157</sup> Farm children should be identified and considered as a "major identifiable subgroup" if available information demonstrates that their aggregate exposure to pesticides, excluding occupational sources, causes them to differ from consumers as a whole and to be at a risk that necessitates greater protection—thus meeting the working definition of "major identifiable subgroup." The agri-chemical interests argued that all of the farm children's exposure that would lead to such an identification is occupational.

The argument hinges on the definition of "occupational exposure."<sup>158</sup> If "occupational exposure" is defined as any exposure of, or relating to, work, then the agri-chemical group's argument is most likely correct. The vast majority of conceivable exposures that put farm children at greater risk on the basis of aggregate exposure are exposures relating to farm work. Presumably, what distinguishes the agricultural environment are the large amounts of pesticides present due to agricultural work. However, this meaning of "occupational exposure" may not be what Congress intended. Perhaps Congress intended to exclude occupational exposures from aggregate exposure because those exposures were in a sense voluntary and the result of a choice to work with or near pesticides.<sup>159</sup> Such an intent would suggest that the meaning of "occupational exposure" should only include exposures incurred while actually working.<sup>160</sup> For example, exposures resulting from pesticide drift, clothes tainted with pesticide residue and brought home, and playing in fields that contain pesticide residue would not be voluntary and thus could not be considered occupational exposures. If farm

<sup>156.</sup> Whether the statute requires consideration of farm children in these contexts—due to their variability of sensitivities or dietary exposure—will be discussed in subpart III(B)(3), *infra*.

<sup>157. 21</sup> U.S.C. § 346a(b)(2)(D)(vi) (2000).

<sup>158.</sup> Again, the legislative history is unhelpful in interpreting the meaning of "occupational." Likewise, "occupational" is not defined in the statute.

<sup>159.</sup> See McGarity, supra note 17, at 186.

<sup>160.</sup> If Congress intended to exclude only occupational exposures that were in some sense voluntary, exposures incurred by working children might not be considered occupational exposures. Many children engage in agricultural work at the behest of their parents or due to the severe economic needs of their families, not because they "choose" to undertake this work. *See* NATURAL RES. DEF. COUNCIL, *supra* note 96, Executive Summary.

children differ from consumers as a whole in their exposures to pesticides, excluding those incurred while working, and are at a greater health risk, they should be identified and considered as a "major identifiable subgroup" for the purposes of considering available information on aggregate exposure.

In sum, nothing in the statute precludes the consideration of farm children as a "major identifiable subgroup." Rather, the statute appears on its face to require that the EPA identify farm children as a "major identifiable subgroup" for the purposes of setting tolerances under the FQPA.

3. The Deciding Factor: Are Farm Children at an Identifiable Risk?— Both arguments outlined above depend on whether farm children are at an identifiable risk in any of the three contexts in which the term "major identifiable subgroups" is used. If they are, then the statute apparently requires that farm children be identified as a "major identifiable subgroup" for the purposes of setting food tolerances under the FQPA.

Whether farm children are at an identifiable risk in the context of aggregate exposure will be explored first.<sup>161</sup> The NRDC argued that farm children are at special risk from aggregate exposure to pesticides due to their extensive exposure to pesticides from a wide variety of sources.<sup>162</sup> In opposition, the agri-chemical interest groups asserted that farm children are not at special risk from exposure to pesticides and that farm children are as healthy as the population as a whole.<sup>163</sup> While the agri-chemical interests offer three studies that purportedly support their position, <sup>164</sup> the vast majority of information on this topic supports the contention that farm children are at special risk.<sup>165</sup>

In establishing the provisions of the FQPA for infants and children, Congress relied on the NAS report, which found that children were at a greater health risk than adults when exposed to pesticides.<sup>166</sup> Thus, if farm children are disproportionately exposed to pesticides in their agricultural setting, then they may be appropriately deemed a population at special risk.<sup>167</sup>

The agri-chemical interest groups did not assert that farm children are less or equally exposed to pesticides compared to the general population.

167. At this point, when discussing exposures to pesticides, exposures incurred in the occupational setting, as previously defined, will not be considered because they appear to be excluded by the statute in 21 U.S.C. § 346a(b)(2)(D)(vi) (2000). See supra subpart III(B)(2).

<sup>161.</sup> This context correlates with 21 U.S.C. § 346a(b)(2)(D)(vi) (2000).

<sup>162.</sup> See supra subpart III(A)(1).

<sup>163.</sup> See supra subpart III(A)(2).

<sup>164.</sup> See WIFE COMMENTS ON NRDC PETITION, supra note 11, at 4-6.

<sup>165.</sup> This Note does not seek to evaluate the scientific data to determine if farm children are less healthy than the population as a whole; rather, it asks whether farm children have heightened health risks.

<sup>166.</sup> See NAT'L RESEARCH COUNCIL, supra note 25.

Two of the three studies to which they referred in their argument do not address exposure at all, but rather the general health of farmers and farm children.<sup>168</sup> The third study upon which they relied is a South Carolina study that demonstrates that, in a five-year period, only one child was hospitalized for pesticide poisoning, and that, over a twenty-five-year period, hospitalizations for pesticide poisonings had declined.<sup>169</sup> This information fails to convince, however, because a record of hospitalizations only accounts for acute illnesses arising from pesticide exposure and does not account for aggregate exposure that may lead to more chronic illnesses. In sum, the agrichemical interests' evidence was extremely limited, lacking detail, and irrelevant to the central question.

In contrast, the NRDC provided substantial and convincing evidence that farm children are disproportionately exposed to pesticides and therefore constitute a population at risk. In its report, Trouble on the Farm, the NRDC provided extensive data to support the conclusion that farm children have greater pesticide exposure. First, they noted that farm children are often present in agricultural fields where pesticides are commonly present.<sup>170</sup> While many of these children are working (thus incurring occupational exposures), many are present in the fields because they are accompanying their parents, presumably due to a lack of childcare options.<sup>171</sup> Second, the report explained that pesticides are often brought home to farm children on the skin and clothing of both farmers and farmworkers.<sup>172</sup> These pesticides may lead to direct exposure of farm children through contact or through contamination of the home environment.<sup>173</sup> Third, the report demonstrated that farm children, because of the agricultural setting in which they live, are routinely exposed to higher pesticide levels in drinking water, outdoor air, indoor air, and house dust.<sup>174</sup> Finally, the report sought confirmations of these exposures by suggesting that evidence exists that "farm families experience elevated levels of pesticide residues in their blood and urine."<sup>175</sup> Trouble on the Farm effectively demonstrated that farm children are at risk from exposure to pesticide residues because of their disproportionate aggregate exposure to pesticides in the agricultural setting.

<sup>168.</sup> See WIFE COMMENTS ON NRDC PETITION, supra note 11, at 4-6 (discussing the NHANES survey and the Swedish study).

<sup>169.</sup> Id. at 6.

<sup>170.</sup> NATURAL RES. DEF. COUNCIL, supra note 96.

<sup>171.</sup> Id. (citing a 1994 study by the Program for Appropriate Technology in Health in the mid-Atlantic states).

<sup>172.</sup> Id. ch. 4 (referring to numerous studies on pesticide-contaminated clothing of farmers and farmworkers).

<sup>173.</sup> See id.

<sup>174.</sup> See id.

<sup>175.</sup> Id.

Other studies, research, and sources bolster the NRDC report's conclusion. Farmworker advocates continually argue that farmworkers and their children are exposed to pesticides while working in the fields.<sup>176</sup> Such exposures are not purely occupational in nature-though many children at early ages begin working in the fields-but rather are the result of being present in the fields or having exposed parents who unwillingly bring pesticide residues home.<sup>177</sup> Furthermore, independent research has confirmed that farm children are exposed to more pesticide residues because of the agricultural setting in which they live.<sup>178</sup> Even the General Accounting Office has recently concluded that current laws fail to protect farm children from the dangers of pesticides and that they constitute a group at risk.<sup>179</sup> Based on all of these findings, farm children seem vulnerable to heightened risks from the dangers of pesticide residues because of their aggregate exposure to pesticides. Since farm children are at an identifiable risk in the context of aggregate exposure to pesticides, they should be considered a "major identifiable subgroup" for the tolerance-setting purposes of the FOPA. 180

176. See, e.g., SHELLEY DAVIS & JAMES B. LEONARD, FARMWORKER JUSTICE FUND, THE ONES THE LAW FORGOT: CHILDREN WORKING IN AGRICULTURE 34 (2002) (discussing the death of a seventeen-year-old farmworker who had been soaked with pesticides), *available at* http://www.fwjustice.org/child.htm (last visited Jan. 10, 2002); DANIEL ROTHENBERG, WITH THESE HANDS: THE HIDDEN WORLD OF MIGRANT FARMWORKERS TODAY 50–54 (1998) (discussing "one of the most severe incidents of pesticide exposure in recent history," including the exposure of a pregnant woman); MARGARET REEVES ET AL., FIELDS OF POISON 13–20 (1999) (exploring reported pesticide exposure among California farmworkers); HUMAN RIGHTS WATCH, FINGERS TO THE BONE, CALIFORNIA FOR PESTICIDE REFORM, Summary (2000), *available at* http://www.hrw.org/ reports/2000/frmwrkr/frmwrk006.htm.

177. See NAT'L CTR. FOR FARMWORKER HEALTH, OVERVIEW OF AMERICA'S FARMWORKERS, at http://www.ncfh.org/aaf\_04.shtml (last visited Nov. 12, 2002) ("Even when children do not work, they may be at risk. Because child care facilities are rarely available, many farmworker children are present in the fields and thus are exposed to pesticides on plants and in the dirt."); Gen. Accounting Office, Report to Congressional Requesters, Pesticides, Improvements Needed to Ensure the Safety of Farmworkers and Their Children 6 (2000) [hereinafter GAO Report] (finding that "7 percent of farmworkers with children 5 years of age or younger took their children with them, at least sometimes, when they worked in the fields," and that ""farmworker children [are] forced to suffer long hours in the fields with both parents working and [virtually] no day care alternatives"" (citing the Dep't of Labor's Wage and Hour Div., 1999)); NATURAL RES. DEF. COUNCIL, *supra* note 96 (stating that younger children "accompany their parents to the fields due to the lack of childcare").

178. See, e.g., Richard A. Fenske et al., Biologically Based Pesticide Dose Estimates for Children in an Agricultural Community, 108 ENVTL. HEALTH PERSP. 515 (finding "that children living in agricultural regions represent an important subpopulation for public health evaluation, and that their exposures fall within a range of regulatory concern").

179. See GAO Report, supra note 177.

180. Numerous studies demonstrate the disproportionate aggregate exposure of pesticides to farm children and its associated risks. While agri-chemical interests might argue that this information is biased, it is no more biased than the studies that agri-chemical interests submit to the EPA for their risk-assessment process. Furthermore, the statute does not call for a certain kind of unassailable information, but rather "available information." 21 U.S.C. § 346a(b)(2)(D)(vi) (2002). Presumably, the EPA may weigh the accuracy of such "available information" when considering it in the tolerance-setting process.

In the context of "variability of sensitivities," farm children are most likely not at an identifiable risk and therefore do not meet the working definition of "major identifiable subgroup." It is difficult to conceive of a reason why farm children are at greater risk to pesticide residues because of their "variability of sensitivities." While data supports the contention that children in general have a "variability of sensitivities" that places them at an identifiable risk,<sup>181</sup> data supporting the argument that farm children differ from all children in this regard is lacking.

Conversely, data does suggest that farm children are at an identifiable risk in the context of dietary exposures—available information illustrates that farm children's dietary exposures differ from other children and consumers in general so as to place them at risk from exposure to pesticide residue. Farm children often consume fresh fruits and vegetables that contain higher levels of pesticides than fruits and vegetables that reach other consumers because of the distance from farm to table.<sup>182</sup> While an extensive study of farm children's dietary exposure to pesticides has not been completed, available information suggests an identifiable risk.<sup>183</sup> Thus, farm children should be considered a "major identifiable subgroup" in the context of dietary exposure for the purpose of setting tolerances under the FQPA.

In conclusion, available information suggests that farm children are at an identifiable risk in the contexts of aggregate exposure and dietary exposure. For this reason, the FQPA requires that the EPA consider farm children to be a "major identifiable subgroup" in the tolerance-setting process.

## C. Assessing the Policy Arguments

In advancing their arguments for and against the identification of farm children as a "major identifiable subgroup," the NRDC and the agri-chemical interests relied on several policy positions. These arguments are referred to as policy positions because they do not directly address the requirements of

<sup>181.</sup> See, e.g., NAT'L RESEARCH COUNCIL, supra note 25 (arguing that "children and infants have special sensitivities to certain toxic insults").

<sup>182.</sup> See ENVTL. LAW INST., OPPORTUNITIES FOR ADVANCING ENVIRONMENTAL JUSTICE: AN ANALYSIS OF U.S. EPA STATUTORY AUTHORITIES 185–87 (2001) (stating that a residue present on a raw agricultural product will not be considered unsafe if it is processed before reaching the consumer); NATURAL RES. DEF. COUNCIL, *supra* note 96 ("Higher levels of foodborne exposure in some agricultural areas may be due to the shorter transport time from field to table, which allows less time for degradation of residues on the food."). Farm children also consume fruits and vegetables eaten directly from the field, which contain higher levels of pesticides. *See* GAO Report, *supra* note 177, at 5–6.

<sup>183.</sup> The NRDC has conceded:

There are few data about farm children's dietary exposures to pesticides, although preliminary results from the Agricultural Health Study indicate that exposures to farm children may be higher than to the general public. Anecdotal reports of farm children picking and eating foods directly from the fields are common, although no studies have attempted to measure these exposures.

NATURAL RES. DEF. COUNCIL, supra note 96.

the statute itself. Rather, they are arguments suggesting that, in the absence of a clear statutory requirement, the statute should be interpreted by the EPA in a certain manner.

1. Agri-Chemical Policy Arguments.—One major argument, and presumably the most important impetus for agri-chemical interests, is that identifying farm children as a "major identifiable subgroup" for the purposes of setting tolerances will lead to the establishment of tolerances "at levels far lower than would be needed to assure the health of the vast majority of the population."<sup>184</sup> These lower tolerance levels would further lead to the "detriment of society because the use of many safe and effective pesticides (which are critical to the production of a diverse, abundant, and wholesome food supply) would be severely restricted, if not banned altogether."<sup>185</sup> This argument implies that lower tolerance levels would lead to increased food prices for consumers. While the agri-chemical argument is correct in many respects, it fails to recognize other possible results stemming from decreasing tolerance levels. Furthermore, it neglects other policy considerations for lower tolerance levels established to protect farm children as a "major identifiable subgroup."

The agri-chemical position is correct in that considering farm children as a "major identifiable subgroup" would presumably lead to lower tolerance levels than needed to assure the health of the population in general.<sup>186</sup> However, the other conclusion-that important and necessary pesticide use would be curtailed, resulting in a disruption to the food supply and detriment to society---is not as certain. The agri-chemical interests failed to recognize other mechanisms by which a negative outcome could be avoided. Such mechanisms might include the development of even safer pesticides, new methods to reduce the presence of pesticide residue on food products, and new legislation addressing the exposure of farm children to pesticides. Of these, the last seems the most practical--though the other two appear quite attractive on their face as potential benefits to society as a whole.<sup>187</sup> Agrichemical interests have used such mechanisms before. As discussed, when the decision in Les v. Reilly threatened to suspend the registration of several important pesticides, these interest groups sought and passed compromise legislation, the FQPA. In this case, the agri-chemical interests should seek

<sup>184.</sup> WIFE COMMENTS ON NRDC PETITION, supra note 11, at 10.

<sup>185.</sup> Id.

<sup>186.</sup> If farm children are at a greater risk than consumers in general (whether due to higher dietary exposure or aggregate exposure to pesticide residue or both), a lower tolerance level would be established to ensure protection of these individuals. Indeed, this is the point of including "major identifiable subgroups" as a factor to consider in setting tolerances.

<sup>187.</sup> But see Frank B. Cross, The Consequences of Consensus: Dangerous Compromises of the Food Quality Protection Act, 75 WASH. U. L.Q. 1155, 1188 (1997) ("No uniform national regulations can rationally reduce the risks from pesticides without compromising the health benefits of pesticides.").

both the creation and the strengthening of laws that protect farm children from pesticide exposure. If the resulting laws were enforced, there would be no need for tolerances to be lowered because farm children would not constitute a group at special risk.<sup>188</sup> Consequently, all parties would benefit farmers could maintain their level of production, pesticide companies could maintain their level of sales, and farm children would be protected from the dangers of pesticides.

The first two mechanisms available to agri-chemical interests-the development of safer pesticides and the reduction of pesticide residue on food products through new methods of production-impose higher costs on consumers. First, both mechanisms will cost agri-chemical interests money, and these costs will be passed on to consumers in the form of higher food prices.<sup>189</sup> However, the distribution of costs to all consumers is not necessarily an undesirable result. This distributional result appears more attractive than placing the externalities and costs of current pesticide use, with higher tolerance levels, solely on farm children. In either case, society pays a price, whether in the form of increased prices at the store or in the form of health care for children harmed by the effects of pesticides. Of course, not all pesticides used on certain crops may be replaced with safer substitutes. Thus, even if lower tolerances resulted in the cancellation of some pesticide uses (giving agri-chemical interests an economic incentive to produce new and safer pesticides) economic incentives would cause some crops to be left without an important pesticide, possibly limiting the crop's production.<sup>190</sup> That, in turn, might lead to disruptions in the current food supply.

The agri-chemical interest groups also advanced the policy argument that lowering the tolerance levels on pesticides by considering farm children as a "major identifiable subgroup" would not serve to adequately protect farm children from pesticides anyway. They argue that

lowering the amount of pesticide residue that is allowed in food does not specifically address the possibility that children could be exposed to pesticides if they are allowed to play in fields soon after they are

<sup>188.</sup> Such laws would presumably reduce farm children's dietary and aggregate exposure to pesticide residue and thus reduce risk to these children, taking them out of the working definition of "major identifiable subgroup." If laws were passed requiring greater protection of farm children following the lowering of tolerance levels by the EPA, the same result could occur. If agri-chemical interests could demonstrate that such laws had eliminated the risks to farm children that the EPA had considered in establishing a lower tolerance, they could readily petition the EPA for a reevaluation of the tolerance under 21 U.S.C. § 346a(d) (2000).

<sup>189.</sup> See Cross, supra note 187, at 1184–87 (noting that crop yields drop when pesticides are not used and arguing that the cost of the decreased yield will be passed to consumers). Cross also notes that such increased prices will lead to a decrease in consumer consumption of fruits and vegetables that are essential to the public health. *Id.* at 1186–87.

<sup>190.</sup> Apparently, technological and economic limitations may restrict the ability to provide an alternative pesticide for a crop. Cross, *supra* note 187, at 1183–92. Certain "orphan crops" will not have a sufficient pesticide to protect them, leading to reduced production and higher costs for consumers. *Id.* 

treated. In fact, even if the relevant tolerance were reduced almost to zero, it would not prevent such potential exposures or the harm that could occur as a result.<sup>191</sup>

It is true that no food tolerance level can effectively prevent all possibilities that farm children will be exposed to pesticides. Nevertheless, the lowering of tolerance levels would greatly reduce pesticide exposure and better protect farm children. In looking at the "risk cup" of farm children, the EPA considers exposures that occur predominantly in the agricultural setting. If consideration of these exposures suggests that farm children's "risk cup is substantially full," a food tolerance would be reduced to decrease the contribution of pesticide residues on food-thus ensuring that the overall exposure to the individual did not overflow the risk cup. By preventing an overflow of the risk cup through the tolerance-setting process, the EPA reduces the dangers of pesticide exposure. If aggregate exposure were substantial enough that it in itself filled or even exceeded the risk cup entirely, food tolerances would be set at zero. In the case that these exposures still overflowed the risk cup, any reduction in food tolerance levels would be irrelevant-the individual would still be at risk from pesticide exposure. However, a food tolerance of zero would cause large-scale reductions in pesticide use and, presumably, might result in the elimination of certain pesticide uses. Such a result would protect farm children in two ways. First, this reduction in pesticide use would likely reduce aggregate exposure to farm children in all contexts. Second, agri-chemical interests, to survive financially, would be motivated to find ways to protect farm children from aggregate exposure so that pesticide use could continue. Thus, in all cases, a reduction in the food tolerance levels of pesticides will serve to protect farm children.

The final policy argument made by the agri-chemical interests is that sufficient protections already exist in laws and regulations designed to prevent or reduce farm children's exposure to pesticides. They pointed to the Worker Protection Standard<sup>192</sup> and application requirements of FIFRA, noting that these "address practically all of the potential exposure pathways identified in the NRDC Petition."<sup>193</sup> Finally, they referred to a number of initiatives that EPA is promoting to "tak[e] steps to mitigate potential exposure to pesticides."<sup>194</sup>

This argument fails in many respects. First, the argument did not recognize that, if current laws and regulations are sufficient to protect farm children from the dangers of pesticide exposure, farm children would not be a group at risk and would not meet the working definition of "major identifiable subgroup"—thus, they would have no effect whatsoever on

<sup>191.</sup> WIFE COMMENTS ON NRDC PETITION, supra note 11, at 8.

<sup>192.</sup> Worker Protection Standard, 40 C.F.R. § 170 (1998).

<sup>193.</sup> WIFE COMMENTS ON NRDC PETITION, supra note 11, at 11.

<sup>194.</sup> Id.

pesticide tolerances.<sup>195</sup> Second, available information and studies on the sufficiency of the Worker Protection Standard and other regulatory enactments to protect farm children suggest that they are either inadequate or so minimally enforced as to lack efficacy.<sup>196</sup> Finally, the information demonstrating that farm children are a population at risk because they are disproportionately exposed to pesticides refutes any argument that current laws sufficiently protect this subgroup.<sup>197</sup>

The three main policy arguments that the agri-chemical interest groups advance in arguing that farm children should not be considered as a "major identifiable subgroup" should not compel the EPA to reject the NRDC petition.

2. NRDC Policy Argument.—The main thrust of the NRDC petition was the statutory argument that the FQPA requires the EPA to consider "major identifiable subgroups" and that farm children constitute such a group. However, the petition did proffer one policy argument that supports the idea that farm children should be identified as a "major identifiable subgroup." The petition referred to Executive Order 12,898, which requires federal agencies in their actions to consider environmental justice for minority and low-income populations.<sup>198</sup> The NRDC argued that farmworkers are predominantly Hispanic and that sixty-eight percent of farmworker children live below the poverty line.<sup>199</sup> They noted that "[t]he group of farm children addressed in [the] petition includes the children of farmworkers, who fall within both the minority and low-income populations for whose benefit this Executive Order was intended."<sup>200</sup>

Executive Order 12,898 requires that "[t]o the greatest extent practicable and permitted by law... each Federal agency shall make

<sup>195.</sup> See supra subpart III(B)(1). And if farm children did not meet this working definition, they would not merit special consideration in the tolerance-setting process and would not directly affect food tolerances in any way.

<sup>196.</sup> See GAO Report, supra note 177, at 23 (finding that "The Worker Protection Standard May Not Adequately Protect Young Children, and Questions Exist About Whether the States Are Adequately Implementing the Standard for Farmworkers Generally"); REEVES ET AL., supra note 176, at 26–33 (noting that "Enforcement of Pesticide Laws Is Weak and Uneven"); DAVIS & LEONARD, supra note 176, at 33–34 (criticizing state enforcement efforts of the Worker Protection Standard and recounting the death of an adolescent farmworker exposed to pesticides who had never received pesticide training as the Worker Protection Standard requires). In 1999, I examined the Texas Department of Agriculture enforcement actions for violations of federal pesticide laws and concluded that enforcement was minimal, few actions were taken, and even fewer punitive results were imposed.

<sup>197.</sup> See supra subpart III(B)(3). In refuting this argument, I assume pesticide tolerances are enforced. Without enforcement, a pesticide tolerance that considered the special circumstances of farm children would be as ineffectual as current pesticide safety regulations.

<sup>198.</sup> See NRDC PETITION, supra note 9, at 9.

<sup>199.</sup> Id.

<sup>200.</sup> Id.

achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations.<sup>201</sup> The Executive Order further requires (1) the creation of an interagency working group on environmental justice; (2) the development of agency strategies to address environmental justice; (3) impact reports to the President; and (4) human health and environmental data collection and analysis.<sup>202</sup> While it does not refer to any specific actions to be taken by any specific agencies, the Order "establishes generally that each federal agency must make environmental justice part of its mission and address disproportionate health and environmental impacts throughout its programs, policies, and activities to the extent appropriate and permitted by law."<sup>203</sup> In 1995, in response to this Order, the EPA adopted the position that "[n]o segment of the population, regardless of race, color, national origin, or income, as a result of [the] EPA's policies, programs, and activities, suffers disproportionately from adverse human health or environmental effects, and all people live in clean, healthy and sustainable communities.",204

The President's Executive Order and the resultant EPA position strongly suggest that the EPA should identify farm children as a "major identifiable subgroup" for the purposes of setting tolerances under the FQPA. As discussed, farm children face disproportionate risks from pesticide exposure.<sup>205</sup> A large portion of these farm children are the children of agricultural workers, who are often minorities and members of low-income populations.<sup>206</sup> "The FQPA has focused attention on major identifiable subgroups, thereby giving [the] EPA a clear means of examining how pesticide residues impact communities of color and low-income communities."<sup>207</sup> By failing to take advantage of this means to protect farm children, the EPA's actions have a disproportionate and highly adverse effect on a minority and low-income group, in direct conflict with both the President's Executive Order and the EPA's own internal position.

3. Final Policy Consideration.—Perhaps the most important policy consideration is the overall focus of the FQPA: protecting the health of

<sup>201.</sup> Exec. Order No. 12,898, 59 Fed. Reg. 7629 (Feb. 11, 1994), at § 1-101.

<sup>202.</sup> See id. §§ 1-102 to -104, 3-301 to -302.

<sup>203.</sup> ENVTL. LAW INST., supra note 182, at i.

<sup>204.</sup> Id. (quoting ENVTL. PROT. AGENCY, ENVIRONMENTAL JUSTICE STRATEGY (Apr. 3, 1995)).

<sup>205.</sup> See supra subpart III(B)(3).

<sup>206.</sup> See NATURAL RES. DEF. COUNCIL, supra note 96 (stating that "[n]on-white poor children living in farm communities are the most likely to be impacted by pesticides and are the most likely to suffer from any potential health effects from this exposure").

<sup>207.</sup> ENVTL. LAW INST., supra note 182, at 187.

infants and children from the dangers of pesticide residues through the tolerance-setting process.<sup>208</sup> The NRDC intimated this consideration by arguing that the statute required the identification of farm children as a "major identifiable subgroup" because it required that pesticide residue levels be safe for all consumers. While I suggest that this argument was misdirected, it still may be that the best way to ensure that pesticide residue levels are safe for farm children is by identifying them as a "major identifiable subgroup." Only by considering available information about farm children's dietary and aggregate pesticide exposure will farm children be protected as the statute requires.

# IV. Conclusion

The Food Quality Protection Act of 1996, which emphasizes the protection of infants and children from the dangers of pesticide residues in food products, resulted from a compromise among competing interests. The statute established new standards for setting pesticide tolerances. These standards mandate consideration of many factors to ensure the safety of the population as a whole and, specifically, of infants and children. One of the statute's mandates is the identification and consideration of "major identifiable subgroups of consumers." By requiring this consideration, Congress ensured that certain segments of the population that differed from consumers in general would be protected from the dangers of pesticide residue in food products. Statutory analysis and a working definition of the term "major identifiable subgroup" suggest that farm children constitute a "major identifiable subgroup" and should be considered as such in the tolerancesetting process. Furthermore, policy considerations support this conclusion and should compel the EPA to consider farm children as a "major identifiable subgroup." Nevertheless, the EPA has failed to act.

Due to the statutory requirements of the FQPA and the policy considerations articulated in this Note, the EPA should recognize farm children as a "major identifiable subgroup" and begin considering them in the tolerance-setting process. Alternatively, if the EPA fails to do what appears to be required of it, Congress should amend the FQPA to clarify that farm children (and other similarly situated groups) constitute a "major identifiable subgroup" that must be considered in the tolerance-setting process. Whichever step is taken, farm children should be afforded the FQPA protections. Pesticide tolerance levels should be safe for all consumers, including farm children.

Scott Cook