FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

August 27, 2014

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Administrator McCarthy:

I am writing to you regarding EPA's August 8, 2013, human health risk assessment for a proposed use of the herbicide 2,4-Dichlorophenoxyacetic acid (2,4-D) on herbicide-tolerant corn and soybean crops.[1] In conducting that assessment, EPA determined that there was no need to use a ten-fold safety factor to protect infants and children.[2] That safety factor is generally required under the Food Quality Protection Act (FQPA), and its application is a widespread convention in risk assessment. EPA has characterized its 2,4-D assessment as "protective and conservative" despite omitting this safety factor and has recommended that 2,4-D be registered for the proposed use.[3]

The ten-fold safety factor is a key component of the FQPA.[4] It resulted from a recommendation in a report by the National Research Council that "the 10- fold factor traditionally used by EPA and FDA for fetal developmental toxicity should also be considered when there is evidence of postnatal developmental toxicity and when data from toxicity testing

---

[1] U.S. Environmental Protection Agency, *Human Health Risk Assessment for a Proposed Use of 2,4-D Choline on Herbicide-Tolerant Com and Soybean* (Aug. 8, 2013) (online at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2014-0195-0007).

[2] *Id.* at 14.

[3] *Supra* note 1 at 7.

[4] Section 405 of the Food Quality Protection Act of 1996 (P.L. 104-170).

relative to children are incomplete."[5] The report recommended that "in the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children."[6]

The FQPA adopted that recommendation and required that "an additional tenfold margin of safety for the pesticide chemical residue … shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children."[7] The FQPA allows the Administrator to use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children."[8]

The EPA risk assessment for 2,4-D found that "the toxicology database is adequate to assess this proposed use" and that "[t]here are no residual uncertainties for pre- and/or postnatal toxicity." It therefore recommended that the "10X FQPA Safety Factor (for the protection of infants and children) be reduced to 1X."[9] I have questions about this recommendation.

Dr. Philip Landrigan was the chair of the National Research Council Committee on Pesticides in the Diets of Infants and Children that authored the National Academy of Sciences report. Because an EPA decision to authorize the registration of 2,4-D for use on corn and soybeans could lead to a three to six fold increase in use of 2,4-D in the United States, I asked Dr. Landrigan to look at EPA's justification for not using the ten-fold child-protective safety factor. After reviewing the report, he concluded that the database for assessing potentially harmful health endpoints of 2,4-D is thin and appeared to be based entirely on old studies.

He pointed out that the basis for determining whether to use a ten-fold child-protective safety factor is the adequacy of developmental toxicity data. He noted that it appeared that the developmental toxicity data relied on by EPA consisted of only two studies, a 1983 study on pregnant rats (MRID 00130407) and a 1990 study on pregnant rabbits (MRID 41747601).[10] He found that the rat study did not look for possible long term effects on the offspring of the treated rats, such as cancer or neurological problems. The rabbit study found significant adverse developmental effects on three of the 80 fetuses, but EPA concluded that they were not treatment-related. He noted, however, that EPA did not explain the basis for determining that the effects were not treatment-related. Finally, he indicated that EPA appeared to consider only risks from herbicide exposure via food and water and not from potential airborne drift of 2,4-D during its application to fields.

---

[5] National Research Council, *Pesticides in the Diets of Infants and Children* (1993) at 9 (online at http://www.nap.edu/openbook.php?isbn=0309048753).

[6] Id.

[7] *Supra* note 4.

[8] Id.

[9] *Supra* note 1 at 4.

[10] *Supra* note 1 at 61-64.

Registering 2,4-D for use on herbicide-tolerant corn and soybean crops could lead to one of the largest increases in herbicide use in the United States in the last 20 years. As EPA evaluates this important decision, protecting children from potentially dangerous exposures should be a top priority. I therefore ask that you explain why EPA is not using the additional safety factor ordinarily required by the FQPA.

If the agency's determination is based on the two developmental toxicity studies, please explain why the agency believes they are adequate. If the determination is based on other evidence, please explain what this other information is and why the agency believes it is sufficient. In addition, please explain the basis for not including potential long term effects in the rat study and the basis for concluding that the adverse developmental effects found in the three fetuses in the rabbit study were not treatment-related. Finally, please explain whether EPA included potential risks from airborne exposure in its assessment, and if not, why not.

If your staff has any questions about these requests, they should contact Eric Flamm or Jacqueline Cohen at 202-225-3641.

Sincerely,

Henry A. Waxman
Ranking Member