

Children's Health Protection Advisory Committee

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August 2, 2013

Administrator Gina McCarthy
United States Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

RE: Human Health Benchmarks for Pesticides a missed opportunity

Dear Administrator McCarthy:

The Environmental Protection Agency (EPA) is promoting new and updated drinking water values (Human Health Benchmarks for Pesticides or HHBPs¹) that are "intended to provide states, the public and other stakeholders with information to support their internal decision-making processes" such as interpreting drinking water monitoring data. One typical use of these values is to respond to inquiries from the public asking how the monitoring results compare to "safe" levels. Often these inquiries come from parents concerned about their child's exposure or a pregnant woman wanting to know about implications for her fetus.

The Children's Health Protection Advisory Committee (CHPAC) is concerned that the HHBPs fail to use current EPA guidance related to the most recent children's health and exposure data and methods as described below. This is a missed opportunity to develop advisory values that incorporate EPA methods and data into drinking water levels that are appropriately protective of communities.

CHPAC has vigorously supported 1) the use of the most current estimates of children's drinking water intake in calculating risk values, 2) the assumption that an acute health effect on the body can be at least as, if not more, harmful to children as to adults, 3) the inclusion of the Food Quality Protection Act (FQPA) safety factor that addresses concerns about children's susceptibility; and 4) the use of EPA supplemental guidance for carcinogens, which recommends age dependent adjustment factors (ADAFs) for children.² These key assumptions and considerations that protect early life are not being used to develop or apply HHBPs for drinking water. This is particularly troubling because newborns that are exclusively fed formula reconstituted with tap water have about ten-fold greater exposure to water contaminants than older children and adults.³ On a body weight basis, the formula fed infant is not only the most exposed segment of the population, but may also be uniquely sensitive due to immaturity of metabolic functions that remove toxic substances from the body and immaturity of organ systems that are targets of toxic action. Moreover, while rates of breast feeding are increasing across the entire population, African-

¹ <http://www.epa.gov/pesticides/hhbp>

² Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens, <http://www.epa.gov/cancerguidelines/guidelines-carcinogen-supplement.htm>

³ Exposure Factors Handbook, 2011 Edition, <http://www.epa.gov/ncea/efh/pdfs/efh-complete.pdf>

American infants still have the lowest prevalence of breastfeeding initiation and duration.⁴ Breastfeeding rates are also significantly lower in low-income mothers.⁵ We are concerned that the majority of children born today in this country are members of racial or economic groups that face exposure and health disparities that correlate with increased rates of formula intake.

CHPAC is concerned that HHBPs fail to use the most recent EPA guidance⁶ to use specific susceptible age categories (such as 0 to 2 years of age, or 3 to 15 years of age) for the HHBP values. As a result, the HHBPs are far less protective than the values that would be developed if EPA advice on age susceptibility for cancer and non-cancer endpoints were used.

The daily intake rate used to calculate acute HHBPs should be based on the formula-fed infant rather than a children's exposure of 100 mL/kg-day (1 Liter water per 10 kg body weight per day). The most recent data on newborns that EPA analyzed and presented in the EPA Exposure Factors Handbook⁷ show that at the 95th percentile, an infant one to three months of age is ingesting 285 mL/kg-day when the sole source of water intake is tap water. EPA's presentation of the data shows that the drinking water intake used for HHBP calculations for child exposure corresponds to the 50th percentile of exposure. The 50th percentile is not sufficiently protective and CHPAC recommends use of the 95th percentile for intake.

There are also shortcomings in the daily intake rate used to calculate chronic HHBPs. CHPAC is concerned that the rate intended to represent intake for pregnant women, 30 mL/kg-day (2 L/66 kg-day), is outdated. EPA's presentation of data shows that the 95th percentiles for tap water use by pregnant and lactating women, another very important population, are 42 and 55 L/kg-day, respectively.⁸

Similarly, the drinking water intake rates used to calculate HHBPs for lifetime exposures to carcinogens are not based on the most recent EPA recommendations. HHBPs are calculated with a water intake and cancer algorithm that CHPAC has critiqued in the past. Specifically, CHPAC^{9,10} has recommended that EPA programs, in using the EPA supplemental guidance for carcinogens, apply the ADAFs for any carcinogen unless there is sufficient information indicating that use of the default ADAFs is not appropriate. The EPA has received similar recommendations from the EPA Science Advisory Board¹¹ and the National Research Council's report *Science and Decisions*.¹² Use of the supplemental guidance for calculating cancer risk from exposures to carcinogens results in a 1.7-fold greater lifetime cancer risk, and when age specific water intake is also used in the equation, the increase is more than 3-fold.

CHPAC is concerned that the HHBP may not take into account an assumption that children are at least if not more sensitive to noncancer health effects as adults (whether these effects are caused by

⁴ Progress in Increasing Breastfeeding and Reducing Racial/Ethnic Differences — United States, 2000–2008 Births, www.cdc.gov/mmwr, 2/8/2013

⁵ Breastfeeding in the United States: Findings from the National Health and Nutrition Examination Survey, 1999–2006, www.cdc.gov/nchs/data/databriefs/db05.htm

⁶ EPA 2005, Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants, <http://www.epa.gov/raf/publications/guidance-on-selecting-age-groups.htm>

⁷ <http://www.epa.gov/ncea/efh/pdfs/efh-complete.pdf>, Table 3-19

⁸ <http://www.epa.gov/ncea/efh/pdfs/efh-complete.pdf>, Table 3-77

⁹ CHPAC letter from December 14, 2007 on Mutagenic Mode of Action, [http://yosemite.epa.gov/ochp/ochpweb.nsf/content/12142007.htm/\\$file/12142007.pdf](http://yosemite.epa.gov/ochp/ochpweb.nsf/content/12142007.htm/$file/12142007.pdf)

¹⁰ CHPAC letter from October 21, 2010 on Science and Decisions, http://yosemite.epa.gov/ochp/ochpweb.nsf/content/CHPAC_NRC_Report.htm

¹¹ SAB report March 3, 2004, on the Supplemental Guidance, [http://yosemite.epa.gov/sab/sabproduct.nsf/658FD14F8F94C7E385256F0A006C94E0/\\$File/sab04003.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/658FD14F8F94C7E385256F0A006C94E0/$File/sab04003.pdf)

¹² National Research Council. *Science and Decisions: Advancing Risk Assessment*. Washington, DC: National Academies Press, 2009

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a short or long period of exposure). Some of the effects that are typically considered to be a health effect observed in chronic studies may be initiated or even manifest over a relatively short period of time (e.g., acetylcholinesterase inhibition). When the protective dose derived from studies of exposures to adults is combined with a corresponding exposure duration that starts before or at birth, the resulting advisory level is more suitably protective of the general population. CHPAC recommends that EPA's acute advisory values for drinking water be based on or incorporate the most susceptible life stage, the formula-fed infant, and the 95th percentile of intake. CHPAC recommends that advisory values calculated for any duration of exposure give closer consideration to the minimal length of exposure that must take place to initiate a health effect, even when that effect does not manifest during the period of exposure. When a neonate or fetus may be as susceptible as an adult to developing the health effect, EPA programs should calculate the corresponding minimal exposure period starting with the first age (e.g., infant exposure at birth, mother's exposure during gestation) of susceptibility through the duration of exposure (whether it is a few days, months, or years) that appears to be necessary to induce the health effect.

HHBPs are advisory only, which offers EPA an opportunity to use the most current and recommended approaches in risk assessment practice. The EPA Office of Water applied EPA's 2005 guidance on age groupings in developing guidance for perchlorate in drinking water and included in the analysis values based on drinking water ingestion rates during the first months of life.¹³ CHPAC recommends that all EPA programs follow this precedent in developing advisories for pesticides and other contaminants in water.

CHPAC has provided reasons to apply these recommended risk assessment methods, and CHPAC's historic concerns over children's exposures to pesticides underscore the importance of developing values that are based on recommended practice. Advice and guidance such as HHBPs offer EPA an opportunity to use the best methods and data available.

We appreciate having EPA programs, represented by Drs. Behl and Doyle, present information about the HHBPs to the CHPAC at our August 1, 2013, meeting and answer questions from our members.

Thank you for your consideration of our recommendations and suggestions.

Sincerely,

/Signed/

Pamela Shubat, Ph.D.
CHPAC Co-Chair

/Signed/

Sheela Sathyanarayana, M.D., M.P.H.
CHPAC Co-Chair

cc: Betsy Behl, Director, Health and Ecological Criteria Division (HECD), Office of Water
Elizabeth Doyle, Branch Chief, Human Health Risk Assessment, HECD, Office of Water
Jacqueline Mosby, Acting Director, Office of Children's Health Protection

¹³ EPA's 2008 Drinking Water: Perchlorate Supplemental Request for Comments FR Notice (Federal Register: August 19, 2009 (Volume 74, Number 159) – EPA-HQ-OW-2009-0297; FRL-8943-9) <http://www.epa.gov/fedrgstr/EPA-WATER/2009/August/Day-19/w19507.htm>, Table 2