June 9, 2009

Peter Grevatt, Ph.D.
Senior Advisor for Children's Health
U.S. EPA
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Dear Dr. Grevatt,

As leading organizational members of the Collaborative on Health and the Environment's Learning and Developmental Disabilities Initiative (LDDI), we are engaged in efforts to help shape and support reform of the Toxic Substances Control Act (TSCA). As advocates for people with learning or developmental disabilities, we are particularly concerned with chemicals that are neurotoxicants, and with exposures during fetal development, infancy and childhood, when the developing brain is extremely vulnerable to chemical insult, even at very low exposure levels. We are part of a broad coalition which is urging policymakers to adopt a legislative framework that, in contrast to the current TSCA, provides EPA with the tools and authority it needs to identify, prioritize and assess toxic chemicals and restrict or ban their use in commerce, with an emphasis on reducing risks to children's health.

We are heartened by Administrator Jackson's recent comments in which she identified improved management of toxic chemicals and protecting children's health as top priorities for EPA. However, we are very concerned that EPA's voluntary Chemical Assessment and Management Program (ChAMP), not be considered a sufficient model or as lessening the need for a fundamental overhaul of TSCA. In our estimation, ChAMP does not adequately screen chemicals in order to protect children and future generations from exposures that can undermine their health.

Under ChAMP's current framework, EPA has committed to assessing approximately 2,750 high production volume (HPV) chemicals and 4,000 medium production volume (MPV) chemicals by 2012. Chemical manufacturers have voluntarily submitted hazard data for the HPV chemicals, as well as submitting required but limited data on use and exposure under the Inventory Update Rule. Based on this hazard and exposure data, EPA intends to quickly produce thousands of "risk-based prioritizations" of these HPV chemicals as well as "hazard-based prioritizations" for MPV chemicals.

Our most urgent concerns with this process under ChAMP include the following:

1) In assessing hazard data:
- EPA assessments frequently rely on incomplete, inconsistent data sets, and do not consistently acknowledge such gaps or take steps to address them. Data gaps remain in at least one third of the "final" data submissions on HPV chemicals EPA has examined to date, even though the requested data set represents the

minimum amount of data needed to conduct an initial, screening-level hazard assessment.

- EPA routinely characterizes chemicals as low or moderate hazard, even when the minimum data set is incomplete.
- EPA's own advisory committee on protecting children's health found that the data sets submitted under ChAMP typically do not provide information on important toxicity endpoints in children, including effects on the developing nervous, immune and endocrine systems, or whether a chemical is carcinogenic.

2) In assessing exposure data:

- Under the Inventory Update Rule (IUR), which provides EPA with chemical use and exposure data, only manufacturers are required to report. EPA gets no information from downstream processors, distributors or users of the chemical even though they are typically in the best position to know and report accurate information on chemical use.
- The IUR data provided often fails to provide any information on a chemical's use in consumer products. One of the greatest potential sources of children's exposure to toxic chemicals is through the use of consumer products in the home.
- Even where other information exists suggesting uses of or exposures to chemicals beyond that reported under the IUR, EPA frequently ignores or downplays such information and instead relies primarily or exclusively on the IUR information.
- Manufacturers frequently took advantage of a major loophole EPA provided under the IUR, claiming at least 20 percent of the time that they could not readily obtain information about the commercial or consumer products in which their chemicals were used; hence, *they did not have to provide it to EPA*.
- Manufacturers claimed 40 percent of the time that they could not readily obtain information on whether the chemical is used in products intended for use by children – *so again they did not have to provide it to EPA*.

3) In determining risk:

- The above findings on the limited nature of the data submitted under ChAMP mean that EPA is forced to assess risks based on hazard and exposure data that are often incomplete or of questionable quality and reliability.
- EPA placed chemicals in the "high concern" category only if the chemical ranked high in both hazard and exposure. This means that chemicals that are highly hazardous but to which EPA asserts people are only moderately exposed, or chemicals that are moderately hazardous but to which people are highly exposed, are downgraded in priority. This failure to err on the side of caution, especially given the very limited data available to EPA, is likely to result in decisions that do not adequately protect public health.
- In numerous cases, EPA arrived at exposure rankings for children that were lower than the exposure rankings for the general public or consumers, by concluding that children are less exposed to chemicals than adults. Children, however, are typically *more highly exposed* to chemicals than adults, both in proportion to body weight and size and as a result of their physiology and their behaviors (e.g. greater contact with soil and house dust).

- Children also are at greater risk of harm from those exposures because their biological systems are developing rapidly. By neglecting these factors, ChAMP fails to take into account the full impact that chemical exposures may have on children starting *in utero* and extending throughout adolescence.

Taken together, these serious deficits in data and methodology constitute a chemical assessment program *that actually places a lower value on children's risks and exposures than adults*. We consider ChAMP a grievously flawed and unscientific approach that puts children at great risk.

The Chlorobenzenes category provides one example of EPA's failure to recognize children's greater risks of exposures as well as their greater vulnerability to harm from chemical exposures. In the risk-based prioritization document for Chlorobenzenes, dated April 2009, EPA estimates a high exposure risk to the general population and consumers for all four of the chlorobenzenes under assessment, based on their use in household products. However, EPA assumes children's potential exposure to these toxic chemicals through the use of household products as medium.

EPA should make the opposite assumption: that children are likely more highly exposed to chemicals in consumer products than adults. Children spend a lot of time on the ground, contacting soil and household dust, and put their hands and objects in their mouths. In proportion to their body weight, children consume more food, drink more water and breathe more air than adults. A 2004 study in Minneapolis of children's exposures to volatile organic compounds, including dichlorobenzenes, found that exposures to VOCs in the home had the largest influence on children's personal exposure to most compounds, and that the home and personal exposures were well above health benchmarks for several compounds, especially for p-dichlorobenzene.

Under the IUR, manufacturers provided EPA with <u>no</u> data on the use of chlorobenzenes in products, which calls into serious question the reliability of the IUR data. In estimating all of the exposure risks, both to children and the general population, EPA states it "has no information on exposures to this chemical and has made assumptions about potential exposures based on all of the information considered including available use information and physical/chemical properties."

Assessing health hazards to children seems an equally dubious task under ChAMP. For chlorobenzenes, as for many other toxic chemicals, EPA is largely forced to extrapolate from data in adult animals, finding that "the data in adult animals for all category members suggest either a moderate or high human health hazard potential."

For any of the HPV and MPV chemicals, even if all of the data requested under ChAMP were supplied, the screening assays are far from sufficient to identify developmental neurotoxicants. Again, chlorobenzenes provide a case in point.

In adult animals, acute exposure to monochlorobenzene affects the brain, liver and kidneys. Workers exposed to chlorobenzenes commonly suffer mild to severe depression

of functions of parts of the nervous system. However, we have no data on developmental neurotoxicity for the chlorobenzenes. What we do know is that exposure to chemicals that are neurotoxins during early fetal development can harm the brain at doses much lower than those affecting adult brain function. EPA fails to take this higher hazard potential into account, by assuming no greater hazard to children than to adults.

Many of these alarming shortcomings under ChAMP are reflections of structural problems with TSCA, which severely restricts EPA's ability to identify and manage toxic chemicals. Under EPA's voluntary HPV Challenge, nearly half of HPV chemicals still lack even a basic set of toxicity information, let alone sufficient information on developmental toxicity. Even fewer data are available for lower volume chemicals despite the fact that many of them are used in consumer products.

The coordinators of our coalition on chemical policy reform will be meeting with Administrator Jackson on June 11th. We would welcome any opportunity to meet with you, Administrator Jackson or others to discuss the concerns we have outlined above. We look forward to working with you and other policymakers on meaningful, comprehensive reform of TSCA that establishes a rigorous and scientifically sound framework for regulating toxic chemicals – one which enables EPA to take all needed actions to protect children's health.

Sincerely,

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