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A Child-Safe U.S. Chemicals Policy

In the United States, environmental chemicals are regulated in different ways. Pollutants, pesticides, consumer products, and industrial chemicals are each under different statutory and regulatory guidance and frameworks. Yet for each we can and must assure that children's unique vulnerabilities and susceptibilities are considered and, ultimately, that children and their health are adequately protected.

This paper provides an overview of current statutes and regulations regulating industrial chemicals and identifies potential changes to U.S. policies to help assure that these chemicals are child-safe.

Children, in our society, have unique moral standing. Children's bodies and behaviors differ from adults. In general, they are more vulnerable than adults to toxic chemicals.

- Children are growing. Pound for pound, children eat more food, drink more water and breathe more air than adults. Thus, they are likely to be more exposed to substances in their environment than are adults. Children have higher metabolic rates than adults and are different from adults in how their bodies absorb, detoxify and excrete toxicants.
- Children's systems, including their nervous, reproductive, digestive, respiratory and immune systems, are developing. This process of development creates periods of vulnerability. Exposure to toxicants at such times may result in irreversible damage when the same exposure to a mature system may result in little or no damage.
- Children behave differently than adults, leading to a different pattern of exposures to the world around them. For example, they exhibit hand-to-mouth behavior, ingesting whatever substances may be on their hands, toys, household items, and floors. Children play and live in a different space than do adults. For example, very young children spend hours close to the ground where there may be more exposure to toxicants in dust, soil, and carpets as well as low-lying vapors such as radon, mercury vapor¹ or pesticides.
- Children have a longer life expectancy than adults; thus they have more time to develop diseases with long latency periods that may be triggered by early environmental exposures, such as cancer or Parkinson's disease.

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The world in which today's children live has changed tremendously from that of previous generations. One of these changes is the phenomenal increase in substances to which children are exposed. Synthetic chemicals are ubiquitous in our environment worldwide, and traces of these compounds are found in all humans and animals. For the majority of the thousands of new chemicals introduced into children's environments since World War II, little is known about the health effects on children. According to the EPA, 75,000 industrial chemicals are currently produced or imported into the United States.ⁱⁱ The Centers for Disease Control and Prevention's National Human Exposure Report has amply demonstrated that such chemicals often are ubiquitous, appearing in the vast majority of blood and urine samples taken at random from the general population in the U.S. Many of these are readily passed across the placenta to the fetus or to the infant via breast milk.

Too many untested substances are in the indoor air in homes, daycare centers and schools, in automobiles, are treatments applied to children's clothing, are allowed in personal care items like soaps, sunscreens and toothpaste, are in or on toys that children put in their mouths, and are allowed in food packaging and containers. Relatively few have been assessed with regard to human health impacts, and even fewer for the potential for exposure and harm to children. Most hazards, unless severe and acute, are not identified.

Toxic Substances Control Act (TSCA)

The U.S. Environmental Protection Agency (EPA) regulates these thousands of industrial chemicals through the Toxic Substances Control Act (TSCA) (15 U.S.C. s/s 2601 et seq.). This statute was adopted by Congress in 1976. Over the years, the core statute has never been reauthorized or amended, but new titles have been added (to specifically regulate asbestos in 1986, radon in 1988, and lead in 1992) and the original legislation contained specific requirements regarding polychlorinated biphenyls (PCBs).

Historically in the U.S., regulation of chemicals lagged significantly behind the growth and development of the industry. Until TSCA in 1976, no laws in the United States were specifically related to the introduction of chemicals into commerce and the control of hazards of existing chemicals. Up to that point regulation of chemicals was limited to food additives, cosmetics, and pharmaceuticals by the Food and Drug Administration (FDA) and pesticides (initially by the USDA and the FDA and in 1972 by the newly-created EPA).

By 1976, it was estimated that there were 60,000 chemical substances in commerce in the U.S.; however, the government did not have an inventory of chemicals manufactured and imported into the country.

In 1976, Congress enacted the TSCA to address three major policy concernsⁱⁱⁱ:

- Those who manufacture and process chemical substances and mixtures should develop adequate data with respect to the effect of chemical substances and mixtures on health and the environment;
- The government should have adequate authority to regulate chemical substances and mixtures which present "an unreasonable risk of injury to health or the environment, and to

take action with respect to chemical substances and mixtures which are imminent hazards”;
and

- Government’s authority over chemical substances and mixtures should be exercised “in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation” while assuring that such substances and mixtures do not present “an unreasonable risk of injury to health or the environment.”

Under TSCA, according to EPA, the agency “repeatedly screens these chemicals and can require reporting or testing of those that may pose an environmental or human-health hazard. EPA can ban the manufacture and import of those chemicals that pose an unreasonable risk.”

“Also, EPA has mechanisms in place to track the thousands of new chemicals that industry develops each year with either unknown or dangerous characteristics. EPA then can control these chemicals as necessary to protect human health and the environment.”^{iv}

In reality, little has been accomplished under TSCA. Regulation of existing chemicals under TSCA has been modest. Not only have there been fundamental problems with an outdated statute that provides inadequate authority to the EPA, but also, successive administrations have failed to provide the EPA with sufficient staffing and resources to address the risks of older chemicals on the market.

Before a test rule can be written, TSCA has two alternative requirements, one of which needs be met: either that a substance may present an unreasonable risk, or that there is substantial exposure to a substance. Yet, an estimated 85% of the 3,000 chemicals most commonly found in commerce lack basic publicly-available data on potential health and environmental impacts.

In 1994, the then-General Accounting Office (GAO) concluded that EPA regulates few chemicals under TSCA, listing only five (PCBs, chlorofluorocarbons, dioxin, asbestos and hexavalent chromium), one of which was required to be regulated by statute.

In only two cases (PCBs and asbestos) has the EPA taken a comprehensive approach to the regulation of chemicals. In one of these cases -- asbestos -- the rule was essentially overturned by the courts.^v If the EPA, after 10 years of building its case, cannot make a supportable finding under TSCA for regulating asbestos -- a known human carcinogen which has caused at least 200,000 deaths in the U.S. -- restricting other agents under TSCA would also be impossible.

In contrast, for PCBs, EPA was not required to first make a finding of “unreasonable risk,” since Congress specified in statute that, for this class of chemicals, manufacture shall cease, imports and exports banned, and continued use be carefully controlled. As a result, more protective actions were taken regarding PCBs.

Key challenges to TSCA’s effectiveness in assuring that chemicals are safe for children can be illustrated by a comparison with two statutes governing pesticide regulation: the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Food Quality Protection Act (FQPA), which was legislation amending FIFRA enacted in 1996.

Risk standard: FQPA uses “a reasonable certainty of no harm” for food-use pesticides. TSCA uses a lesser standard: to avoid “unreasonable risk to health or the environment.”

Child-specific safety factor: Reflecting the National Academy of Sciences’ 1993 recommendation that “in the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children,” the FQPA statute imposes an additional ten-fold safety margin to protect children, in the absence of adequate data on children. This safety margin is to be removed only if “reliable data” show that the additional protection is not needed to adequately protect children.

TSCA does not take the approach that, in the absence of information, we must act with caution to protect children. EPA is not precluded from using an additional safety margin to protect children (which would be an incentive to generate the necessary safety data) outside of FQPA, but has not done so.

Protection of sensitive populations: FQPA includes additional specific provisions regarding examination of toxicity and exposure to children, requires an assessment of “aggregate” risks from multiple uses of a pesticide and an assessment of cumulative risks from multiple pesticides with same mode of action. TSCA does not include such specific provisions. But the statute also does not preclude the EPA from applying these same protective measures.

Role of other considerations such as costs versus benefits: Under FQPA, costs and benefits are a consideration for nonfood pesticide uses, but for food use, only public health can be considered. The burden is on the manufacturer to prove safety before a pesticide can be marketed or re-registered. Under TSCA, the standard is cost-benefit balancing, not public health-based, and is the same for all circumstances. The burden is on EPA to prove the cost-benefit standard is met.

Assessment of risks of existing chemicals: Under FIFRA, all pesticides on the market were approved and registered at some point. In 1988, the law required reregistration, to require updated testing data. The data submitted include both hazard and exposure data. Under TSCA, 70,000 existing chemicals were grandfathered into use and placed on the “inventory,” which has numerous inaccuracies and is only partially updated. To require testing, EPA must write a test rule that contains a finding of “unreasonable risk.” As mentioned above, this is a heavy if not impossible burden to meet. In this regulatory regime, the generation of data is not rewarded. Voluntary testing programs for some chemicals are underway, but have limitations. TSCA does not require routine exposure monitoring; EPA can ask for use and exposure information on a chemical by chemical basis but such requests are reviewed by OMB and rarely have been issued. Without hazard and exposure data there can be no “risk assessment.”

Approval of new chemicals: Approval of new pesticides requires an extensive database of health effects testing (under FIFRA). Though the data required fall short of what is necessary for assuring adequate protection of children (for example, developmental neurotoxicity data are not yet routinely required), this testing battery is far more extensive than the information required under TSCA. Under TSCA, only chemical structure and physical characteristics are required on a routine basis, and the EPA uses Structure Activity Relationships and physicochemical

properties for most decisions. EPA has the authority to require pre-manufacture testing; when using this authority, this testing requirement is not triggered unless a minimum volume of the chemical is produced.

Management of existing chemical hazards: For pesticides, this occurs through FQPA's pesticide "reregistration" processes, involving hundreds of individual actions every year. TSCA has almost no regulatory actions in a year. As mentioned above, the rejection of the 1989 asbestos ban and phase out set a precedent for a very high bar for EPA. TSCA is unable to encourage the use of safer substitutes or pollution prevention approaches.

Managing risks to consumers, workers, and communities: FQPA's registration process considers all risk scenarios. For non-pesticides, responsibilities are fragmented within EPA (air, water, waste offices) and among agencies (Occupational Safety and Health Administration, Consumer Products Safety Commission). The TSCA "referral process" has been unproductive.

Right to know and access to information: Under TSCA, a high percentage of information filed was claimed as confidential business information (CBI). In 1998, more than 65% of the information filings directed to the Agency through TSCA were claimed as confidential. About 20% of facility identities were claimed as confidential. Many chemical risk management decisions in this country are done at the state and local level, yet states cannot receive CBI filings under the statute.

In brief, TSCA is an outdated statute that does not give the EPA sufficient authority in a number of areas and is not health based. The vast majority of chemicals regulated under TSCA lack basic publicly-available data on potential health and environmental impacts. After almost three decades, only a handful of hazardous chemicals have been restricted under TSCA, while many more known toxic substances are used in everyday products and released into our environment

Persistent Organic Pollutants (POPs)

Persistent organic pollutants, or POPs, are a dangerous class of chemicals that includes highly toxic dioxins, pesticides such as chlordane, and polychlorinated biphenyls (PCBs), all of which pose a global hazard. POPs are of special concern for children because of their persistent nature and because exposure to some POPs can result in serious injuries to the developing nervous system. Some are thought to be carcinogens and endocrine disruptors with potential effects on children.

Once released into the environment, POPs can cause harm to health and the environment thousands of miles away. They accumulate and magnify in the food chain; we are exposed when we eat foods near the top of the food chain (mostly animal products). Most POPs are transferred from a mother to the fetus through the placenta, and later to the infant via breast milk.

The Stockholm Convention on Persistent Organic Pollutants (known as the POPs treaty) would mandate the phase out and ultimate elimination of an agreed-upon subgroup of POPs, plus agree to phase out additional POPs in the future. The U.S. has already essentially eliminated most of the POPs on the initial list.

Although the U.S. signed the POPs treaty, the United States Senate has yet to ratify it. The key policy issue is how additional POPs will be added to the list in the future. In 2002, the White House introduced legislation that did not provide a process for EPA to add new chemicals to the list of prohibited POPs in the future.^{vi} The criteria for adding chemicals to the convention were proposed by the U.S. government and supported by U.S. industry. Unfortunately, it is not an option to ratify just a portion of a convention.

International Convention on Prior Informed Consent: The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC) will provide countries with the means to exclude from import any chemicals that have been determined by an international body to be very hazardous.

The principle of prior informed consent was initially established as a voluntary procedure to create an information exchange from chemical exporters to importers for certain highly hazardous chemicals. Exporting countries are to notify importing countries prior to shipping a chemical that is “banned or severely restricted.”

PIC, signed in 1998, requires that chemicals and pesticides that have been added to the convention because they are banned or severely restricted in at least one country in each of two regions shall not be exported unless explicitly agreed by the importing country. The Convention came into force in February 2004 and the first Conference of Parties will be held this September.

The U.S. has not ratified this convention.

Other International Activities

In other ways, internationally, a high degree of cooperation on chemical assessment and safety exists.

The Rio Conference adopted a chapter on Sound Management of Chemicals with a number of goals that are managed by nations under the Intergovernmental Forum on Chemical Safety (IFCS). Much has been done.

The OECD Chemicals Forum has developed an internationally harmonized set of guidelines for chemicals testing, an agreement on good laboratory practices, and an agreement of mutual acceptance of data that allows all nations to adopt these agreements. These have been adopted by the EPA.

The ILO (International Labor Organization) has obtained agreement by countries on a system for classification and labeling of chemicals in commerce.

In addition to POPs and PIC, the United Nations Environmental Program (UNEP) is active on mercury risk reduction efforts. At a meeting in late February 2005, the UNEP Governing Council recommended addressing the “global adverse impacts of mercury on health and the environment.” These included a request for governments to take immediate actions, including

"considering curbing primary production and the introduction into commerce of excess mercury supply." Also, over the objections of the U.S. and others, the council will consider additional action on mercury at its next meeting, "including the possibility of a legally binding instrument on mercury, partnerships, and other actions."

Unfortunately, in the last four years, the Administration has not supported either strengthening or ratification of these efforts (which are strongly supported by U.S. allies such as Canada and the European nations).

Exposure Information and Biomonitoring

Our children are exposed to hundreds, if not thousands, of substances new to human environments. We have emerging evidence of links between chronic diseases such as cancer, asthma and birth defects and environmental exposures.

Yet we have virtually no information about our children's exposures to environmental toxicants that may be linked to such diseases. Currently, we are just beginning to research how to establish national or state systems that would track and link exposures to environmental toxicants and potentially related health effects. The capability to track environmental exposures and chronic diseases and to evaluate their possible relationship is especially important for pediatric health conditions such as asthma and birth defects.

In terms of chemicals policy, finding out what is in our bodies and our children's bodies -- biomonitoring -- is also extremely important when we are faced with deciding which of the thousands of chemicals used in commerce should receive priority for testing. Scientifically sound biomonitoring data is a vital tool for assisting in such priority-setting.

The Centers for Disease Control and Prevention's National Center for Environmental Health issued its first biomonitoring report in 2001, and is working to provide additional information in each succeeding report. The 2003 *Second National Report on Human Exposure to Environmental Chemicals* presented information on the levels of 116 environmental chemicals in the U.S. population. The \$6.5 million study tested the blood and urine of 2,500 anonymous volunteers for 116 chemicals, with positive results found for 89 substances. Chemicals found included PCBs, dioxins, phthalates and pesticides.

Very little information about young children (under 6) was generated in these first two reports. The next report is expected in May 2005 and reportedly will contain more information about children. To be adequate, national biomonitoring data should include routine monitoring of umbilical cord blood, breast milk and, possibly, meconium (a neonate's first bowel movement).

ⁱ Goldman LR. Case Studies of Environmental Risks to Children. *The Future of Children: Critical Issues for Children and Youths*. Vol. 5, No. 2, Summer/Fall 1995.

ⁱⁱ U.S. EPA Web site, <http://www.epa.gov/region5/defs/html/tsca.htm>

ⁱⁱⁱ *Toxic Substances Control Act*, in U.S.C. 1976.

^{iv} U.S. EPA Web site, <http://www.epa.gov/region5/defs/html/tsca.htm>

^v *Corrosion Proof Fittings v. EPA*. 1991, 5th Circuit. p. 1201.

^{vi} “Bush Administration Blocks Progress on Toxics Treaty,” news release by national public health and environmental groups, November 1, 2002.