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A Child-Safe U.S. Chemicals Policy

Children's Environmental Health Network

Summary

Mounting scientific evidence points to widespread exposure to chemicals that can cause serious adverse impacts on human health, particularly for children and other vulnerable populations. Yet the existing legal framework for regulating commercial chemicals is effectively unable to identify these dangers and to take effective action to prevent continued threats to environmental health. As opposed to the regulation of pharmaceuticals and pesticides, the federal law governing industrial chemicals in the United States requires virtually no information on health or human exposure as a precondition for manufacture or sales. Even in cases of clear threats to public health, as in the case of asbestos, the burden of proof is so onerous that the U.S. Environmental Protection Agency (EPA) has little choice but to negotiate voluntary agreements with manufacturers.

Recent international developments including a new European law and some global treaties to eliminate toxic chemicals provide promising examples of policy reforms that provide more health protections. The U.S. government is beginning to awake to the pressing need to modernize its approach to chemicals, including recognition of the special importance of children's environmental health. This paper provides an overview of current statutes and regulations regulating chemicals and identifies some of the necessary changes to U.S. policies to help identify and eliminate chemicals that endanger children's health and the public at large.

Children's Environmental Health and Toxic Chemicals

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 nervous, reproductive, digestive, respiratory, and immune systems are developing, creating periods of enormous 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 vapor 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.

Many of the chemicals of greatest concern were only created in the last century. As a result of unprecedented industrial expansion, synthetic chemicals are ubiquitous in the environment. Traces of these compounds are found in all humans and animals, even in the most remote corners of the globe.

The Centers for Disease Control and Prevention's National Human Exposure Report demonstrates that chemicals, pesticides and other environmental pollutants are routinely detected in blood and urine samples from the U.S. population, finding dozens of compounds, many linked to potential health threats.

Frequently, these substances are found in substantially higher levels in children than in adults.

Many of these chemicals are readily passed across the placenta to the fetus or to the infant via breast milk. Laboratory tests of the umbilical cord blood of ten newborns in 2005 found that the samples contained an average of 200 chemicals that can cause cancer, brain damage, birth defects and other health ailments. The lab tests tested for 413 chemicals and detected 287 in the blood samples, with each containing between 159 and 234 chemicals. Of the chemicals detected, 180 can cause cancer in humans and animals, 217 are known to be dangerous to the nervous system and brain, and 208 can cause birth defects in animals.

According to the EPA, roughly 80,000 industrial chemicals are currently produced or imported into the United States. These materials are the building blocks of our consumer society finding their way into everyday products and countless environmental exposures. For the majority of the tens of thousands of new chemicals introduced since World War II, little is known about which chemicals children are exposed to nor their health effects on children, especially on children's developing systems. Yet environmental influences are powerful determinants of health, especially in our children.

Some categories of chemicals of concern include:

- Brominated flame retardants: Monitoring studies of chemicals used as flame retardants (versions of polybrominated diphenyl ethers, or PBDEs) find these chemicals in the breast milk of U.S. women at unexpectedly high levels, levels ten to 20 times higher than those found in European women. While flame retardants save lives, recent animal data have linked PBDEs to thyroid, liver and developmental problems and possibly higher

cancer rates. A recent study of PBDE levels in homes and in breast milk suggest that children could be exposed to levels that put them at risk of developing neurological problems.

- Phthalates are a class of chemicals widely used to make plastics soft and flexible, and are found in a broad variety of products, such as cosmetics and food packaging. Phthalate esters are generally of concern because they are endocrine disruptors in the laboratory and some have demonstrated developmental and reproductive toxicity. Di(2-ethylhexyl) phthalate (DEHP) "can reasonably be anticipated to be a human carcinogen" according to the National Toxicology Program. Both DEHP and di-n-butyl phthalate (DBP) are recognized as developmental and reproductive toxicants. Children have significantly higher levels of the metabolites for DEHP, DBP and at least two other phthalates than adults. Of concern for potential in utero exposure is that females have significantly higher concentrations of DEHP and BBP than do males.

- Polyfluorinated compounds used to protect fabric, upholstery, and other surfaces (such as Teflon and Gore-Tex). A recent EPA science advisory board concluded that PFOA (perfluorooctanoic acid) should be classified as a likely carcinogen. Levels as low as 10 parts per billion have been found to cause liver damage in laboratory animals. Polyfluorinated compounds are bioaccumulative and widely found in humans, with U.S. residents having the world's highest levels. A 2007 study of 300 newborns by the Johns Hopkins Bloomberg School of Public Health found 99% had PFOA in their umbilical cord blood.

- Persistent organic pollutants: Known as POPs, these are a class of especially dangerous chemicals that resist biological degradation, accumulate in the food chain and in humans, and are carried around the globe by wind and water. Some POPs include dioxins, pesticides such as chlordane, and polychlorinated biphenyls (PCBs). Additionally, some brominated flame retardants and perfluorinated compounds, described above, have been nominated as POPs. POPs are of special concern for children because of their persistent nature, their accumulation in breast milk, and potential injuries to the developing nervous system. Some POPs are carcinogens and others appear to disrupt endocrine function, a special concern for children.

In brief, 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. Yet emerging evidence provides growing evidence of links between environmental exposures and chronic diseases such as cancer, asthma and birth defects.

Current U.S. Policy on Chemicals

Toxic Substances Control Act (TSCA)

When enacted in 1976 the Toxic Substances Control Act (TSCA) (15 U.S.C. §2601 et seq.) was seen as a bold step in regulating chemicals introduced into commerce.

Before TSCA no laws in the United States were specifically related to the introduction of industrial chemicals into commerce and the control of hazards of existing chemicals. This is in contrast to regulation of 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).

Today the law is recognized as an outdated statute that does not give EPA the authority to protect human health from the threats of industrial chemicals.

Congress enacted TSCA to address three major policy concerns:

- 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."

The original legislation distinguished existing chemicals from chemicals that had yet to be introduced. It contained specific requirements regarding polychlorinated biphenyls (PCBs). Over the years, the core statute has never been reauthorized or amended, but new titles were added to regulate asbestos in 1986, radon in 1988, and lead in 1992.

An estimated 20,000 new chemicals have been introduced since the advent of TSCA, yet even today over 95 percent of commercial chemicals were essentially grandfathered under this weak law. Only a handful of hazardous chemicals have been banned under TSCA, while many more known toxic substances are used in everyday products and released into our environment

TSCA provides EPA with the authority to require information on chemical hazards and uses. But before a "test rule" can be written, TSCA requires either that a substance may present an unreasonable risk, or that there is substantial exposure to a substance. This has created a Catch-22 in which EPA lacks sufficient information to justify a request for information. With regard to

EPA's authority to take action on dangerous chemicals, the record is even worse. A 2005 report by the Government Accountability Office (GAO) concluded that EPA has regulated very few chemicals under TSCA, listing only five (PCBs, chlorofluorocarbons, dioxin, asbestos and hexavalent chromium), one of which was required to be regulated by statute.

For PCBs and asbestos EPA took a comprehensive regulatory approach. Because PCBs were expressly identified in TSCA, EPA was not required to first make a finding of "unreasonable risk" As a result PCB manufacture ceased, imports and exports were banned, and continued use is carefully controlled. But in the case of asbestos the rule was ultimately overturned by the courts. 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 reality, little has been accomplished under TSCA. Regulation of existing chemicals under TSCA has been weak. 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.

Health-Protective Policy Approaches

Decision-makers at all levels of government are developing and adopting chemical policy reforms that better protect human health. Some examples at the federal and international level are below, including policies that have been adopted and policy proposals.

Many concepts revolve around questions such as:

- Who bears the "burden of proof" -- is it the government seeking to regulate a chemical or the industry seeking to market the chemical?;
- What needs to be proved? Examples include whether a chemical is a hazard to human health and/or the environment and whether a chemical presents a risk to human health and/or the environment;
- Social/economic factors, such as cost-benefit criteria; and
- Whether safer alternatives are available.

What happens in the absence of adequate information about a chemical? For example, the National Academy of Sciences (NAS), when reviewing Federal pesticide regulatory policy, said "In the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children."

Enacted U.S. Statute: Food Quality Protection Act (FQPA)

TSCA's shortcomings stand in sharp contrast with the 1996 law that aimed to reduce exposures to dangerous pesticides in processed foods. The Food Quality Protection Act (FQPA) amended both the Federal Food, Drug and Cosmetics act and the national pesticide law, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). While there are important differences between the use and regulation of agricultural and industrial chemicals, comparing TSCA with FQPA's approaches highlights the serious deficiencies of TSCA.

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: 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. Under TSCA EPA is not precluded from adopting an additional safety margin to protect children, but it 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 it does not preclude the EPA from applying these same protective measures.

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 previously approved and registered. In 1988, the law required re-registration, to require updated testing data. The data submitted include both hazard and exposure data. Under TSCA, roughly 62,000 existing chemicals were grandfathered into use. To require testing, EPA must issue a test rule that contains a finding of "unreasonable risk," a heavy burden that EPA rarely meets. 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: The approval of new pesticides under FIFRA requires an extensive database of health effects testing. 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 data 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 "re-registration" 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" in this framework 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.

Proposed U.S. Legislation: The Kid-Safe Chemicals Act of 2005

In response to growing evidence of TSCA's inability to regulate chemicals and the domestic and international calls for a more health-protective approach, twin bills were introduced in the U.S. Senate and the House of Representatives. The "Child-, Worker- and Community-Safe Chemicals Act of 2005," also known as the Kid-Safe Chemicals Act was introduced by Senators Lautenberg and Jeffords on June 13, 2005 and by Rep. Waxman on November 11, 2005 in the House. The bills did not attract bipartisan support and no hearings were held in either chamber. Senator Lautenberg and other lawmakers have indicated their intention to reintroduce a version of the Kid Safe Chemicals Act in the 110th Congress.

The Kid Safe Chemicals Act proposed a "reasonable certainty of no harm" safety for industrial chemicals, similar to the regulatory standard at the heart of the FQPA. It would also have shifted the burden of proof from the EPA to chemical manufacturers. Over the course of 15 years, it would have required EPA to review industry data on chemical hazards, uses and exposure and to deny approval of chemicals that fail to meet the safety standard. EPA would also have been obliged to designate a set of chemicals for priority review on the basis of inherent health or environmental hazards, documented presence in the human body through biological monitoring, or production volume. The Kid-Safe Chemicals Act would also have required biological monitoring to detect the presence of chemicals in human blood, breast milk and other media. It would have allowed for certain narrow exceptions, including for national security reasons. However these exemptions were conditioned on the lack of safer alternatives. The bill also proposed federal support for research and development into safer alternatives to chemicals identified as priorities by EPA.

International Initiatives

The European Union's REACH Legislation

In December 2006, after many years of public debate, consultation, and political negotiation, the European Union adopted sweeping new legislation to control industrial chemicals. Known as REACH (for the Registration, Evaluation and Authorization of Chemicals), the new law will enter into force in June 1, 2007 for the 27 countries that comprise the EU. As the law is phased in over the next dozen years, manufacturers of new and existing chemicals will be obligated to provide basic safety information including physical and toxicological data as well as information on exposure and uses. Chemicals lacking basic registration data will not be permitted for sale or importation in the EU. This information will be evaluated by environmental authorities. Substances of very high concern must be specifically authorized. Authorization of chemicals whose risks are not "adequately controlled" will be denied unless social and economic benefits outweigh the risks and no suitable alternatives are available. An estimated 13,000 chemicals will be subject to registration and evaluation with approximately 2,000 destined for the authorization process.

The Stockholm Convention on Persistent Organic Pollutants (POPs)

As mentioned earlier, POPs are a class of especially dangerous chemicals. The Stockholm Convention on Persistent Organic Pollutants, or POPs treaty, requires reduction and ultimate elimination of a small number of POPs -- the worst of the worst -- that are defined in this international agreement. The treaty also contains a rigorous scientific review process for adding additional chemicals to the initial twelve POPs listed in the treaty. To date nine additional chemicals have been nominated for review, including lindane and other pesticides, two brominated flame retardants, and certain perfluorinated compounds. More than 137 nations have ratified the treaty including virtually all the major trading partners and allies of the United States.

Although the United States signed the POPs treaty under President Bush in 2001, we have yet to ratify it pending modest changes to TSCA and FIFRA. The key policy issue is how to ensure that EPA will have the necessary authority to regulate new POPs that are added to the treaty. Over the past four years Congress debated the issue, but ultimately deadlocked over changes to TSCA that would authorize EPA to take timely action on POPs. Consequently the United States remains a mere observer while the rest of the world works to implement to Stockholm Convention and expand its coverage.

Other International Activities

A number of other international agreements aim to reduce the danger of toxic chemicals by eliminating specific hazards, increasing information, and improving management especially in the industrializing countries. The 1992 Earth Summit in Rio 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), which includes the World Health Organization, the United Nations Environment Program, and other international bodies..

Among industrialized nations, the Organization for Economic Cooperation and Development (OECD) has developed a internationally harmonized guidelines for chemicals testing, good laboratory practices, and mutual acceptance of data that facilitates responsible management by all nations. There is progress toward adoption of a Globally Harmonized System (GHS) for classification and labeling of chemicals. In 2006 countries agreed on a nonbinding framework for the Strategic Approach to International Chemicals Management, with a special emphasis on assisting developing countries to adopt better practices.

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."

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