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FROM THE AMERICAN ACADEMY OF PEDIATRICS

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

Policy Statement—Chemical-Management Policy: Prioritizing Children's Health

COUNCIL ON ENVIRONMENTAL HEALTH

KEY WORD
environmental health

ABBREVIATIONS
TSCA—Toxic Substances Control Act
EPA—Environmental Protection Agency

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abstract

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The American Academy of Pediatrics recommends that chemical-management policy in the United States be revised to protect children and pregnant women and to better protect other populations. The Toxic Substance Control Act (TSCA) was passed in 1976. It is widely recognized to have been ineffective in protecting children, pregnant women, and the general population from hazardous chemicals in the marketplace. It does not take into account the special vulnerabilities of children in attempting to protect the population from chemical hazards. Its processes are so cumbersome that in its more than 30 years of existence, the TSCA has been used to regulate only 5 chemicals or chemical classes of the tens of thousands of chemicals that are in commerce. Under the TSCA, chemical companies have no responsibility to perform premarket testing or postmarket follow-up of the products that they produce; in fact, the TSCA contains disincentives for the companies to produce such data. Voluntary programs have been inadequate in resolving problems. Therefore, chemical-management policy needs to be rewritten in the United States. Manufacturers must be responsible for developing information about chemicals before marketing. The US Environmental Protection Agency must have the authority to demand additional safety data about a chemical and to limit or stop the marketing of a chemical when there is a high degree of suspicion that the chemical might be harmful to children, pregnant women, or other populations. *Pediatrics* 2011;127:983–990

INTRODUCTION

Over the past several decades, tens of thousands of chemicals have entered commerce and the environment, often in extremely large quantities (eg, multiple millions of pounds per year). There has also been an explosion of knowledge about special vulnerabilities and differential exposures that children and pregnant women have to environmental toxicants. A growing body of research indicates potential harm to child health from a range of chemical substances.

The primary federal law that governs chemical management in the United States, the Toxic Substances Control Act (TSCA) (Pub L No. 94-469 [1976]), is not protective of the health of children and pregnant women and has not undergone any meaningful revision since its passage almost 35 years ago. Since then, of the tens of thousands of chemicals that are in commerce, the TSCA has been used to regulate only 5 chemicals or chemical classes: polychlorinated biphenyls (PCBs); fully halogenated chlorofluoroalkanes; dioxin; asbestos; and hexavalent chromium.[1] The TSCA is so ineffective that it took a separate act of

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Congress to amend the TSCA so that the US Environmental Protection Agency (EPA) could regulate asbestos, one of the most dangerous toxic substances. It is because of the inadequacies of the TSCA that parents and pediatricians have been subjected to multiple high-profile media blitzes about specific chemicals, such as phthalates in toys and bisphenol A in infant bottles,[2,3] that create anxiety without solving the problems of risky chemical exposures.

The American Academy of Pediatrics recommends that chemical-management policy in the United States be substantially revised to better protect children and pregnant women.

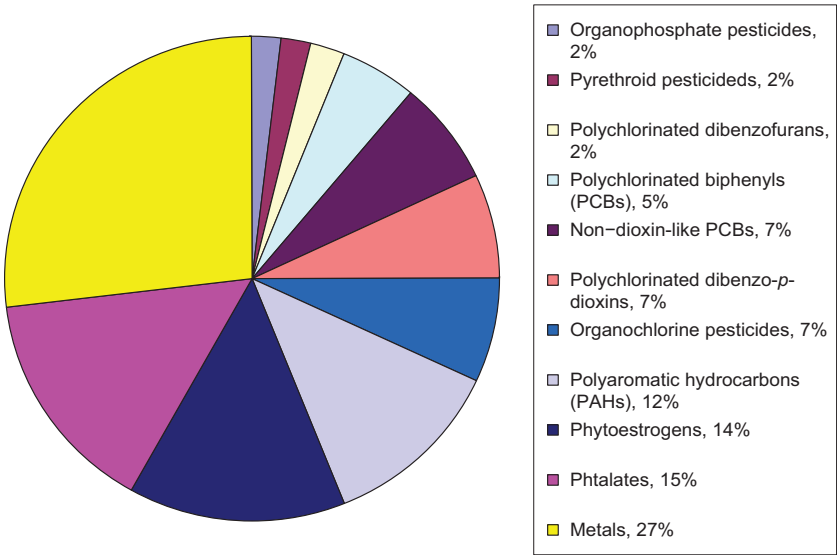

FIGURE 1
Distribution of detected chemicals in the Centers for Disease Control and Prevention biomonitoring study, 2005. (Modified with permission from Rushing R. *Reproductive Roulette: Declining Reproductive Health, Dangerous Chemicals, and a New Way Forward.* Washington, DC: Center for American Progress; 2009. Available at: www.americanprogress.org/issues/2009/07/reproductive_roulette.html.)

THE HOPE OF "BETTER LIVING THROUGH CHEMISTRY"

From the mid-19th century until today, there has been phenomenal growth in our knowledge about chemistry. Currently, there are more 80 000 chemicals in commerce in the United States, more than 3000 of which are considered to be "high-production volume" chemicals (chemicals produced in or imported into the United States in quantities of ≥1 million pounds/year). Under the EPA Inventory Update Reporting program, the chemical-manufacturing industry estimated that approximately 27 trillion pounds of chemicals were produced in or imported into the United States per year in the early part of this decade, which is the equivalent of approximately 74 billion pounds/day (nearly 250 pounds per person) and does not include fuels, pesticides, pharmaceuticals, or food products.[4] Many of these chemicals are in the environment, and some affect the health of children.

From biomonitoring data from the Centers for Disease Control and Prevention[5] and other documentation[6–11] it is known that there is widespread human exposure to many of these substances (see Fig 1). These chemicals are found throughout the tissues and body fluids of children and adults alike, including blood, cord blood, and human milk.

Few of the chemicals that are supposed to be controlled by the TSCA were intended for human consumption. Because the TSCA does not require premarket testing of these chemicals, scientific studies of their effects on the human body may be scarce or nonexistent. Food additives, pesticides, and pharmaceuticals, all of which are intended for human consumption (although at low levels in the case of pesticides), do require premarket testing and, depending on the product, some postmarket follow-up. However, the paradigm established for food additives, pesticides, and pharmaceuticals should not be taken as a model for chemical management. There are too many chemicals and too many tests that would need to be performed to use individual chemical testing as a means of ensuring safe chemical management.

CHILDREN ARE NOT LITTLE ADULTS

Children have unique physiologic, developmental, and behavioral differences that influence their environmental exposures. Because children are smaller than adults, their surface area–to–body mass ratio is greater. Children eat more food and drink more water per unit of body weight than do adults.[12] The respiratory minute ventilation—inspired air per unit time adjusting for weight—is greater in young children than in adults.[13]

Children's behavior changes with age, and with it, the routes of exposure to chemicals change.[14] Infants are incapable of independent locomotion, which makes it impossible for them to remove themselves from environmental hazards such as heat and cold. Children of all ages spend more time on the floor or ground than do adults. Therefore, children will come into more contact with contaminants on these surfaces.

Exposure of people to environmental toxicants may affect fertility. A recent

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study of blood levels of polybrominated diphenyl ether (PBDE) flame retardants in women found that it took significantly longer for women with higher PBDE levels to get pregnant.[15] Exposure of the fetus in utero to at least 1 pharmaceutical, diethyl stilbestrol (DES), is recognized to produce adverse health effects on the children and even the grandchildren of that fetus.[16] Further research may reveal that there may be such a concern with chemicals in the environment as well.

As children grow and mature, their bodies may be especially vulnerable to certain chemical exposures during critical windows of development. Neurologic and endocrine systems have demonstrated particular sensitivity to environmental toxicants at certain stages of growth. These differences in biological susceptibility and exposures in children versus adults support the need for strong consideration of children in chemicals policies. This principle must underpin all chemical-management legislation and regulation.

TABLE 1 US Legislation Concerning Chemicals

Act	Year Passed	Subject
Federal Food, Drug, and Cosmetics Act (FFDCA)	1938	Gives authority to the US Food and Drug Administration to oversee the safety of food, drugs, and cosmetics
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	1972	Pesticides
Toxic Substances Control Act (TSCA)	1976	Chemicals 1988 and 1990: asbestos and radon 1992: lead-based paint 2002: healthy and high-performance schools
Food Quality Protection Act (FQPA)	1996	Pesticides

THE TSCA FAILS TO PROTECT CHILDREN AND PREGNANT WOMEN

A number of federal laws govern the safety of food additives, cosmetics, pharmaceuticals, and pesticides (Table 1). The TSCA, which was passed in 1976, with subsequent modifications, sets out the current federal framework for the regulation of most chemicals. Congress established the following as the original goals of the TSCA:

1. to develop adequate data about the effects of chemical substances and mixtures on health and the environment and to ensure that the manufacturers and processors of such chemical substances and mixtures be responsible for the development of such data;
2. to provide adequate authority to regulate chemical substances and mixtures that present an unreasonable risk of injury to health or the environment and to take action with respect to chemical substances and mixtures that are imminent hazards; and
3. to ensure that authority over chemical substances and mixtures does not impede unduly or create unnecessary economic barriers to technologic innovation while ensuring that the innovation and commerce of chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.[17]

Unfortunately, the TSCA has not met its goals. The law suffers from a number of defects that render it ineffective in assessing the risk posed by chemicals. Without sufficient information on the safety or health effects of chemicals, it is impossible for the EPA to engage in appropriate regulation. Key weaknesses of the TSCA include the following.

- Costs of TSCA safety testing are often borne by the public sector. Manufacturers of chemicals are not required to test chemicals before they are marketed or to collect data from tests that may have been performed by others. The TSCA places the burden of obtaining information about the potential toxicity of a chemical on the public rather than the manufacturer. The EPA is charged with developing information on toxicity, but the agency has neither the technical nor the financial resources to perform extensive research on even a fraction of the tens of thousands of chemicals in commerce.
- The TSCA has created a non–evidence-based system for chemical management. Manufacturers are required to notify the EPA of their intent to market a new chemical; however, they are not required to perform any safety testing before notifying the EPA. The EPA estimates that most such notifications do not include test data of any type, and only approximately 15% include health or safety test data.[18] It is ironic that companies may harm themselves by performing premanufacture testing, because they must disclose any health or safety data they obtain. This system discourages manufacturer safety testing and also results in chemicals for which there are less data seeming to be safer than chemicals for which there are more data.
- Concerns about chemicals are permitted to be kept from the public. In their notifications to the EPA, chemical companies may declare large amounts of information to be "confidential business information." This broad exemption has effectively prevented the EPA from sharing information about potentially hazardous chemicals with community groups, local and state governments, and foreign governments or international organizations.

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- Chemicals introduced before 1976 have little oversight. The TSCA distinguished between chemicals in existence in 1976 and those introduced after passage of the law. Those on the market in 1976 were assumed to be relatively safe and in need of less testing than "new" chemicals. To pursue regulation of these "grandfathered" chemicals, the EPA must demonstrate that a chemical has a high likelihood of causing harm before it can order testing to determine if there is a health risk. Between 1979 and 2005, the EPA used its authority to require testing on fewer than 200 chemicals in commerce.[1]
- Implementation of TSCA regulatory action is unwieldy. Rule-making under the TSCA is extremely time-consuming and labor intensive. After a nearly decade-long effort to ban asbestos, the EPA found its initiative struck down by the courts on the basis that the agency had overstepped its authority under the TSCA. Since passage of the TSCA, the EPA has issued regulations to ban or limit only 5 existing chemicals or chemical classes.[18]
- The TSCA does not allow review of chemicals by group. The TSCA requires regulation on a chemical-by-chemical basis. With tens of thousands of chemicals in need of review and the multiyear process for each such undertaking, it would require many decades to review just the high-production chemicals. For example, the finding of toxicity of a radioactive substance such as plutonium would not allow another similar substance such as uranium to be defined as toxic. The TSCA would require that testing on the second compound be conducted completely anew.

THE EPA HAS ATTEMPTED TO IMPLEMENT THE TSCA THROUGH VOLUNTARY ACTION

The EPA has implemented several voluntary programs in attempts to compensate for inadequacies of the TSCA. These programs include the Endocrine Disruptor Screening Program, the Voluntary Children's Chemical Evaluation Program, and the Chemical Assessment and Management Program. Because these programs are voluntary, the EPA cannot require companies to produce information about the health and safety risks of these chemicals. Each of these programs has produced few data over long periods of time, and none has led to any significant regulatory changes.[1,19] For example, the Endocrine Disruptor Screening Program was called for in legislation passed in 1996, but the EPA only issued its first test orders, the first step in a multistep process, in October 2009.[20] The Voluntary Children's Chemical Evaluation Program was launched by the EPA at the end of 2000. It had the meager goal of gathering information on health effects, exposure, risk, and data needs for 23 chemicals to which children have a high likelihood of exposure. More than a decade later, for various reasons, complete data are not available for any of those chemicals.[21] Because of its inadequacies, in September 2009 the EPA replaced the Chemical Assessment and Management Program with what it hopes will be a "more comprehensive approach to chemicals management."[22]

CALLS TO REFORM THE TSCA

The American Medical Association,[23] the American Public Health Association,[24] and the American Nurses Association[25] have all endorsed the need for changes to the TSCA. Recognizing that "[t]he science of testing chemicals and understanding their health or environmental effects has evolved considerably since TSCA was enacted," the American Chemistry Council has also called for the modernization of the TSCA to ". . . help assure that we protect . . . our children . . ."[26]

TABLE 2 Six Essential Principles for Reform of Chemical-Management Legislation (EPA[36])

Chemicals should be reviewed against safety standards that are based on sound science and reflect risk-based criteria protective of human health and the environment.
Manufacturers should provide the EPA with the necessary information to conclude that new and existing chemicals are safe and do not endanger public health or the environment.
Risk-management decisions should take into account sensitive subpopulations, cost, availability of substitutes, and other relevant considerations.
Manufacturers and the EPA should assess and act on priority chemicals, both existing and new, in a timely manner.
"Green" chemistry should be encouraged, and provisions that ensure transparency and public access to information should be strengthened.
The EPA should be given a sustained source of funding for implementation.

A number of environmental health policy entities have been critical of the TSCA.[4,27–30] In addition, the US Government Accountability Office has issued a number of reports in which the TSCA was criticized.[1,18,31–33] In 2009, the Government Accountability Office added the TSCA to its high-risk list for federal legislation that needs to be updated.[34]

In 2009, the EPA established 6 essential principles for reform of chemicals management legislation (Table 2).[35] The proposed principles address many of the deficiencies of the TSCA discussed above.

STATE ATTEMPTS AT CHEMICAL-MANAGEMENT POLICY

In the absence of up-to-date federal regulatory policy, many states have attempted to fill the gap. A handful of state legislatures have undertaken measures to control individual chemicals, such as bisphenol A, or attempted the comprehensive identification, pri-

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TABLE 3 State-Proposed Principles on Reform of the TSCA[38]

Require chemical data-reporting
Demonstrate that chemicals and products are safe
Prioritize chemicals of concern
Protect the most vulnerable
Promote safer chemicals and products
Address emerging contaminants
Strengthen federal law and preserve states' rights
Fund state programs

oritization, and regulation of chemicals.[36] Some states have targeted their efforts specifically at chemicals of concern in children's products. Chemicals that have been the subject of state laws include phthalates and fire retardants. Officials from California, Connecticut, Illinois, Maine, Maryland, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Oregon, Vermont, and Washington have issued a list of principles on reform of the TSCA (Table 3).[37]

EXAMPLES OF INTERNATIONAL EFFORTS TO REGULATE CHEMICALS

Over the past decade, an increasing number of nations have attempted to exert greater control over the entrance of new chemicals into commerce and their use in various contexts. A number of treaties have addressed certain classes of pollutants (eg, the Stockholm Convention on Persistent Organic Pollutants), and more comprehensive approaches have been attempted by individual nations or international entities.

In 1999, Canada passed legislation that requires the development of a categorization and prioritization system for the Domestic Substances List, its chemicals registry. The Domestic Substances List catalogued approximately 23 000 chemicals known to be in commerce in Canada since the mid-1980s. The review, which was completed in 2006, methodically categorized the chemicals to prioritize those of greatest concern for review and possible restriction. On the basis of a screening assessment, chemicals were: designated as Canadian Environmental Protection Act (CEPA)—toxic, in which case they were subject to additional regulation and restriction; added to the priority substances list, which requires an in-depth assessment to be completed within 5 years; or set aside as not requiring further study at the time.[38] This process resulted in the designation of 85 substances as CEPA-toxic[39] and the placement of 67 on the priority substances list.[40] Although the Domestic Substances List categorization has been hailed as a model, critics have stated that Canadian law does not permit aggressive enough regulation to occur on those substances considered to be CEPA-toxic.

In early 2006, the United Nations Environment Program's Governing Council adopted the Strategic Approach to International Chemicals Management (SAICM), a strategy developed and negotiated with the participation of a wide range of stakeholders from more than 140 countries. The SAICM global plan of action sets out nearly 300 different activities that will help countries reach the plan's overall objective of achieving the sound management of chemicals throughout their life cycle so that, by 2020, they are used and produced in ways that reduce major adverse effects on health and the environment.[41,42] The SAICM includes activities in the area of policy change, research, and capacity-building, among others. It must be noted, however, that the strategy is purely voluntary for all participating nations, and each country is free to adapt and alter the approaches used. There is no formal oversight of the strategy or any enforcement of its recommendations.

In perhaps the most ambitious regulatory effort to date, the European Union (EU) established the new Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation in 2006.[43] The stated aim of REACH is to "to improve protection of human health and the environment from the risks of chemicals while enhancing the competitiveness of the EU chemicals industry."[44] This system, which began to phase in during 2007 and will continue its staged implementation over a decade, sought to develop a comprehensive regulatory regime for chemicals with the ultimate goal of restricting the use of the most toxic substances. Companies must register all chemicals that are sold in the EU market in quantities above 1 metric ton. A list of substances of very high concern is under development, which will constitute chemicals for which substitution is required whenever feasible and which will require an authorization for each individual use of a substance of very high concern. As of late 2009, 16 substances had been officially identified as substances of very high concern,[45] but nonprofit organizations were pressing for the addition of at least 350 more substances to this designation.[46] Although REACH was developed as a system that will cover all EU countries, there is some flexibility for member nations to opt out of or alter certain provisions. Many key provisions of REACH have not yet been implemented, so its full impact is, as yet, unclear.

RECOMMENDATIONS FOR GOVERNMENT AND ADVOCACY

1. Whenever a new chemicals policy is developed or existing policy is revised, the wide range of consequences of chemical use on children and their families should be a core component.
2. Federal, state, and local policies should support and enforce sound chemical management. Policies should incorporate the following principles.

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a. The regulation of chemicals must be based on evidence. However, decisions to limit or ban chemicals or classes of chemicals from commerce or to promote the substitution of demonstrably less hazardous chemicals should be based on reasonable levels of concern and not depend on demonstrated negative health effects after release.

b. "Old" and "new" chemicals must meet the same requirements for evidence.

c. Although testing of individual chemicals should not be the sine qua non for decisions to limit or ban chemicals or classes of chemicals, when testing is appropriate, those who propose to market a chemical must be mandated to provide evidence that the product has been tested in systems that provide information that is relevant to the special needs of pregnant women and children, including data on reproductive toxicity; developmental toxicity, including but not limited to neurodevelopmental toxicity; and endocrine disruption, as it relates to reproduction, neurotoxicity, and puberty.

d. Decisions should be based on information about hazards, proposed use, and potential exposures. Hazard implies intrinsic properties of chemicals or classes based on molecular structure (eg, persistence, carcinogenicity, or neurotoxicity). When appropriate for hazard determination, there must be consideration of aggregate (exposure to a single pollutant via multiple pathways) and cumulative (concurrent exposures to multiple pollutants with a common mechanism of action via multiple pathways) exposure concepts similar to those of the Food Quality Protection Act.

e. Chemicals must meet safety standards similar to those met by pharmaceuticals or pesticide residues on food, that is, "reasonable certainty of no harm." Exceptions should be available for chemical use when no safer alternatives exist. Such exemptions should require individual regulatory approval and biannual review to ascertain whether the exemption is still necessary.

f. There must be postmarketing surveillance of the effects of a chemical, and the EPA must have the authority and means to remove a chemical if postmarketing surveillance indicates that it no longer meets the standard for being released to the market.

g. Companies that propose to place a new chemical on the market must develop a means for biomonitoring of that chemical before it is marketed.

h. Companies must develop a public information document for each new chemical marketed. This document must be in lay language and approved by the EPA before the chemical is marketed. A companion document must be developed for all consumer products that contain the chemical and must be updated with each new formulation of the product or every 3 years. This document must include the results of any premarket testing and any postmarket surveillance. It must include information about risks associated with acute, high-dose exposure and chronic low-dose exposure as well as contact information for people who need additional information.

3. The EPA must have a relatively simple process to require additional testing when information suggests the need for such testing.

4. Federal biomonitoring programs, such as the Centers for Disease Control and Prevention National Biomonitoring Program, must be expanded. It is recognized that this program provides secondary prevention, but it may serve as an early warning system. Stored samples may allow look-backs when new problems develop in the future.

5. Federal funding should be provided for research to prevent, identify, and evaluate the effects of child exposures to chemicals. Development of additional chemical testing methodologies is needed to ensure that exposures to existing and new chemicals can be identified. Consensus in the scientific community is needed on methods and biomarkers to identify and evaluate chemicals for adverse effects through endocrine disruption. Funding to support studies to examine long-term and subclinical chemical effects is needed.

6. Federal policies should reward and promote developments in green chemistry that serve to replace existing chemicals of concern and their commercial applications.

RECOMMENDATIONS FOR PEDIATRICIANS

1. Pediatricians should familiarize themselves with the information about chemicals in the environment and their effects on child health. Many chemicals are reviewed in the

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American Academy of Pediatrics manual *Pediatric Environmental Health*.[47] The third edition of this book will be available in 2011.

2. Pediatricians should learn about the resources contained in the Environmental Health and Toxicology pages of the National Library of Medicine Web site. (http://sis.nlm.nih.gov/enviro.html). Those portions that will be of most use in counseling families include LactMed (http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT) (a peer-reviewed and fully referenced database of drugs to which breastfeeding mothers could be exposed) and the Household Products Database (http://householdproducts.nlm.nih.gov) (which links >8000 consumer brands to chemicals they may contain on the basis of Material Safety Data Sheets provided by the manufacturers).
3. Pediatricians with questions about acute chemical exposures and toxicity should call the Poison Control Center at 800-222-1222. For questions about long-term, low-dose exposure or other issues related to children and chemicals, pediatricians should contact their regional Pediatric Environmental Health Specialty Unit (www.pehsu.net).
4. Pediatricians should advocate for chemical policies that consider the special vulnerabilities of children and pregnant women. The American Academy of Pediatrics, through its chapters, committees, councils, sections, and staff, can provide information and support for public policy advocacy efforts. See www.aap.org/advocacy.html or contact your chapter leadership for further information.

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