

January 2010

ENVIRONMENTAL HEALTH

High-level Strategy and Leadership Needed to Continue Progress toward Protecting Children from Environmental Threats



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Highlights of [GAO-10-205](#), a report to congressional requesters

Why GAO Did This Study

Exposure to toxic chemicals or environmental pollutants may harm the health of the nation’s 74 million children and contribute to increases in asthma and developmental impairments. In 2007, 66 percent of children lived in counties exceeding allowable levels for at least one of the six principal air pollutants that cause or aggravate asthma, contributing to medical costs of \$3.2 billion per year, according to the Centers for Disease Control and Prevention.

In 1997, Executive Order 13045 mandated that agencies place a high priority on children’s risks and required that policies, programs, activities, and standards address those risks. In response, the Environmental Protection Agency (EPA) created the Office of Children’s Health Protection and convened the Children’s Health Protection Advisory Committee.

This report assesses the extent to which EPA has institutionalized consideration of children’s health through (1) strategies and priorities, (2) key offices and other child-focused resources, and (3) participation in interagency efforts. GAO reviewed numerous documents and met with EPA and other officials for this report.

What GAO Recommends

GAO recommends improvements to help EPA protect children, and EPA agreed to implement them. GAO also suggests that Congress consider reinstating a government-wide task force on children’s environmental health.

[View GAO-10-205 or key components.](#) For more information, contact John Stephenson at (202) 512-3841 or stephensonj@gao.gov.

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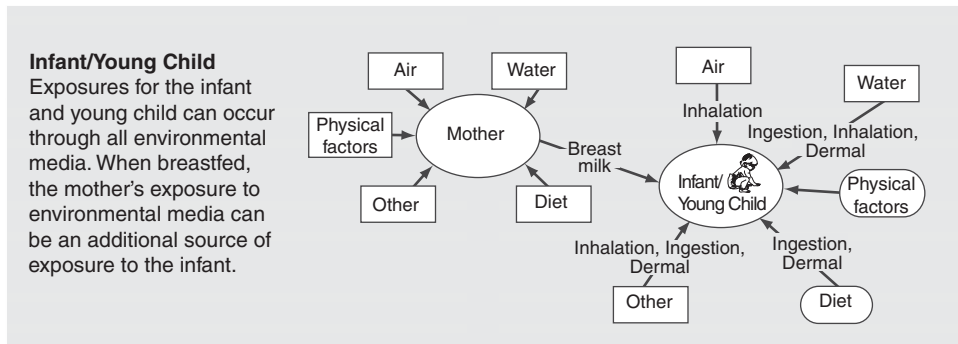
What GAO Found

EPA has developed policies and guidance to consider children, but it has not maintained attention to children through agency strategies and priorities. In 1996, EPA created a national agenda on children’s health, and its 1997 and 2000 strategic plans highlighted children’s health as a key cross-agency program. As a result, the agency’s research advanced the understanding of children’s vulnerabilities. However, EPA has not updated the agenda since 1996, and the focus on children is absent from the 2003, 2006, and September 2009 draft strategic plans.

EPA has not fully used the Office of Children’s Health Protection and other child-focused resources. The active involvement of managers from the office and experts from the Children’s Health Protection Advisory Committee has been lacking, as has the involvement of key staff throughout EPA. Although EPA now has a new Director of Children’s Health, the office had not had consistent leadership since 2002, hampering its ability to support and facilitate agencywide efforts and elevate matters of importance with senior officials. For example, a previous director established workgroups to bring together officials from the program offices and the children’s health office, but a subsequent acting director eliminated these groups, effectively halting work on a key set of children’s health recommendations. In addition, the regional children’s health coordinators—who provide outreach and coordination for EPA—have no national strategy or dedicated resources. Finally, the advisory committee has provided hundreds of recommendations, but EPA has requested advice on draft regulations only three times in the last decade.

While EPA leadership is key to national efforts to protect children from environmental threats, EPA’s efforts have been hampered by the expiration in 2005 of certain provisions in the executive order. For example, the Task Force on Children’s Environmental Health provided EPA with a forum for interagency leadership on important federal efforts, such as the National Children’s Study. It also provided biennial reports that helped establish federal research priorities.

Children Are Exposed to Many Sources of Potentially-harmful Environmental Pollutants



Source: EPA, A Framework For Assessing Health Risks of Environmental Exposure to Children (2006).

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Abbreviations

ACE Advisory Committee	<i>America's Children and the Environment Children's Health Protection Advisory Committee</i>
CDC	Centers for Disease Control and Prevention
EPA	Environmental Protection Agency
Executive Order	Executive Order 13045—Protection of Children from Environmental Health Risks and Safety Risks
Healthy SEAT	Healthy Schools Environments Assessment Tool
Interagency Forum	Federal Interagency Forum on Child and Family Statistics
Miami Declaration	<i>Declaration of the Environmental Leaders of the Eight on Children's Environmental Health</i>
NAAQS	National Ambient Air Quality Standards
National Agenda	<i>National Agenda to Protect Children's Health from Environmental Threats</i>
Office of Children's Health	Office of Children's Health Protection
OMB	Office of Management and Budget
RAPIDS	Rule and Policy Information Development System
Task Force	Task Force on Environmental Health Risks and Safety Risks to Children

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United States Government Accountability Office
Washington, DC 20548

January 28, 2010

The Honorable Barbara Boxer
Chairman
Committee on Environment and Public Works
United States Senate

The Honorable Amy Klobuchar
Chairman
Subcommittee on Children's Health
Committee on Environment and Public Works
United States Senate

Children face disproportionate health risks from environmental contaminants such as pollution in air, lead paint in homes, pesticide residues on food, and treatment-resistant microbes in drinking water. Such hazards contribute to asthma, cancer, neurodevelopmental disorders, and other diseases, and many of the nation's 74 million children are exposed to them daily. In 2007, for example, 66 percent of children lived in counties where air exceeded one or more of the six principal pollutants.¹ Two of them—ozone and particulate matter—are known to cause or aggravate respiratory diseases such as asthma. According to the Centers for Disease Control and Prevention (CDC), asthma is the third most common cause of hospitalizations for children, resulting in \$3.2 billion for treatment and 14 million days of school lost annually.

The environment's effect on children's health is complex, and scientists' understanding has continued to evolve. It can be challenging to assess the contribution of environmental exposures to childhood illnesses, because factors such as family history, nutrition, and socioeconomic factors also contribute. Nonetheless, scientists agree that children often are more significantly affected by environmental risks from exposure to air pollution, toxic chemicals, and the disease-transmitting vectors that are expected to increase with global warming. Research has also shown that childhood exposures to environmental contaminants may affect risk of diseases, such as cancer, later in life.

¹The Environmental Protection Agency sets National Ambient Air Quality Standards for ozone, particulate matter, sulfur dioxide, nitrogen dioxide, carbon monoxide, and lead.

In the late 1990s, the federal government took several steps to make children's environmental health a priority. In April 1997, the President signed Executive Order 13045—Protection of Children from Environmental Health Risks and Safety Risks (Executive Order), which mandated a concerted federal effort to address children's environmental health and safety risks. The Executive Order established, among other things, an interagency Task Force on Environmental Health Risks and Safety Risks to Children (Task Force) and charged it with recommending strategies to the President for protecting children's health and safety. Also in 1997, the Environmental Protection Agency (EPA) created the Office of Children's Health Protection (Office of Children's Health) to support the agency's efforts and formed the Children's Health Protection Advisory Committee (Advisory Committee) to provide advice, information, and recommendations to assist the agency in the development of regulations, guidance, and policies relevant to children's health.²

EPA's Advisory Committee and the EPA Office of Inspector General have raised concerns about whether the agency has continued to maintain its earlier focus on protecting children or capitalized on opportunities to tackle some significant and emerging environmental health challenges. For example, the Advisory Committee wrote to the EPA Administrator in April 2007 to reflect on EPA's achievements in the 10 years since the Executive Order was signed. The committee cited successes such as increased margins of safety for pesticides mandated under the Food Quality Protection Act and the creation of the National Children's Study. However, the Advisory Committee also expressed serious concerns about EPA's continued lack of focus on children's environmental health issues and the lack of progress in addressing the committee's many recommendations. The EPA Inspector General had also raised many of those concerns in 2004.³

To address concerns about EPA's focus on children, you asked that we assess the agency's consideration of children's environmental health. In September 2008, we testified on our preliminary assessment of EPA's efforts to address children's environmental health, focusing on the

²In 2005, EPA expanded the office to include environmental education and aging initiatives, renaming it the Office of Children's Health Protection and Environmental Education.

³EPA Office of Inspector General, *The Effectiveness of the Office of Children's Health Protection Cannot Yet Be Determined Quantitatively*, Report No. 2004-P-00016 (Washington, D.C., May 17, 2004).

Advisory Committee.⁴ This report completes our work for you, addressing more broadly the extent to which EPA has institutionalized the protection of children’s health from environmental risks through (1) agency priorities, strategies, and rulemakings, including implementation of Executive Order 13045; (2) the use of key offices and other child-focused resources, such as the Office of Children’s Health and the Advisory Committee; and (3) involvement in federal interagency efforts to protect children from current and emerging environmental threats.

To address those objectives, we interviewed officials from multiple EPA program offices most directly involved with children’s health issues and referred to long-established quality management criteria from the Government Performance and Results Act.⁵ To assess the extent that EPA prioritized children’s health in its agencywide strategies and goals, we reviewed key EPA children’s health-related policies, strategic and performance plans, and guidance documents. To assess the implementation of the Executive Order through EPA’s rulemaking process, we reviewed regulations subject to the regulatory requirements of the order, as well as internal workgroup documents detailing EPA’s rulemaking—National Ambient Air Quality Standards for Particulate Matter—published in October 2006. To assess EPA’s use of its Advisory Committee, we analyzed documents—including meeting agendas, letters from the Advisory Committee to the EPA Administrator, and EPA’s response letters. To examine EPA’s involvement in national children’s health efforts, we identified the accomplishments of the Task Force that EPA co-chaired, and we reviewed reports from groups such as the Federal Interagency Forum on Child and Family Statistics (Interagency Forum). Appendix I provides a more detailed description of our scope and methodology. We conducted this performance audit from November 2008 through January 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

⁴GAO, *Environmental Health: EPA Efforts to Address Children’s Health Issues Need Greater Focus, Direction, and Top-Level Commitment*, [GAO-08-1155T](#) (Washington, D.C.: Sept. 16, 2008).

⁵Pub. L. 103-62 (1993).

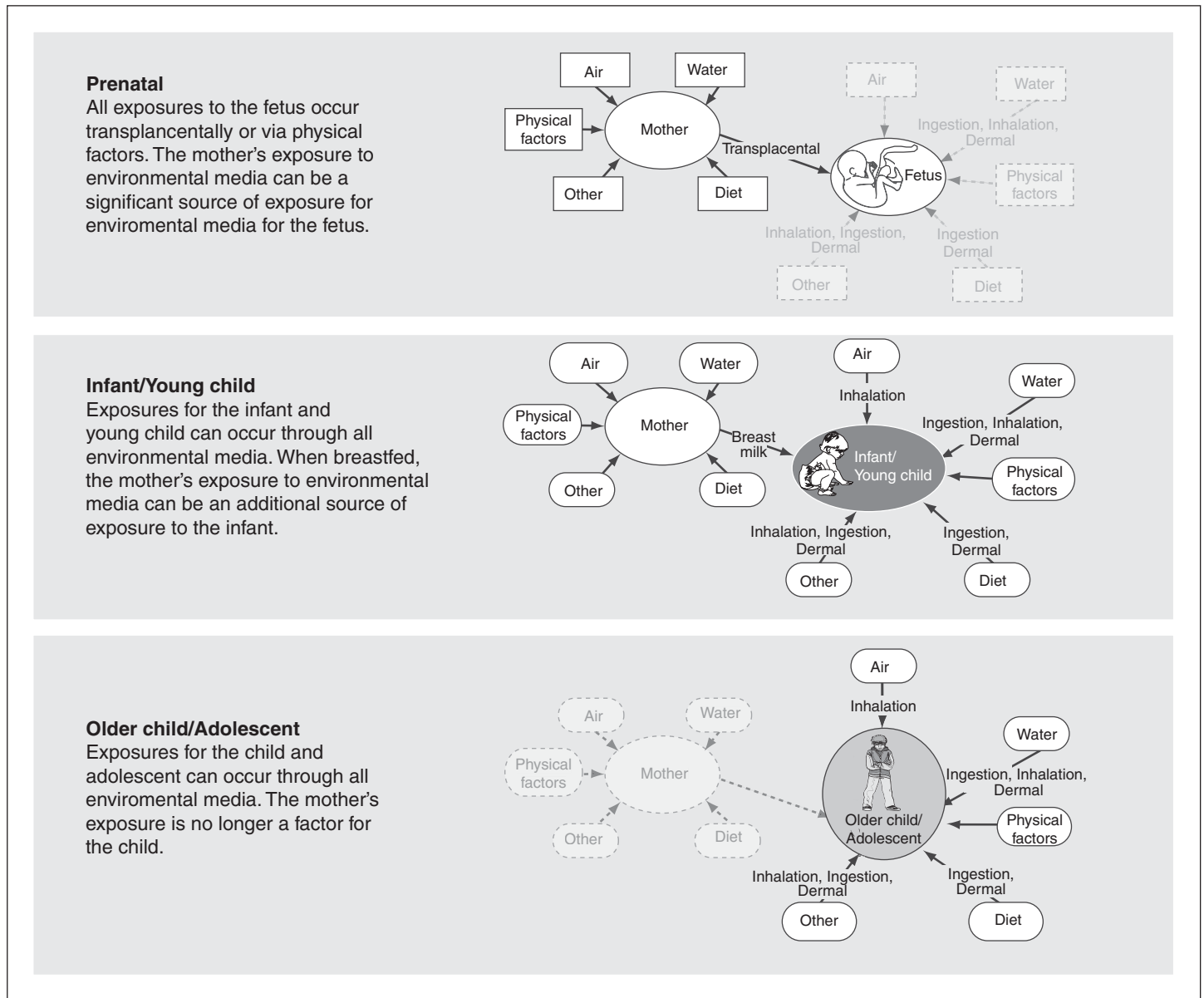
Background

The following section discusses issues related to children's environmental health risks and key actions that EPA, the President, and Congress took in the early 1990s to help address those risks.

Children's Environmental Health Risks

Children are often disproportionately affected by environmental contaminants, such as pesticides and lead, for many reasons, including greater exposure levels, unique exposure pathways, and greater vulnerability due to their still-developing bodies. For example, EPA noted that children may receive higher doses of contaminants, because they spend more time close to the ground; engage in more hand-to-mouth activities; and breathe more air, drink more water, and consume more food in proportion to their body weight than adults. Contaminants may also affect children disproportionately because of their unique exposure routes such as transplacental and breast milk. Figure 1 illustrates the relevant exposure routes during three major developmental periods of childhood.

Figure 1: Exposure Routes and Levels Change During Major Developmental Periods Of Childhood



Source: EPA, A Framework For Assessing Health Risks of Environmental Exposure to Children (2006).

Note: Arrows represent exposure routes for a given developmental period, while shaded dashed lines represent exposure routes that are not pertinent for the period.

Children also are more vulnerable than adults because of the relative immaturity of their biochemical and physiological systems. For example, air pollutants that would produce only slight breathing difficulties in adults may contribute to a more serious breathing problem in young children because of their smaller airways. Finally, EPA has noted that children have limited ability to communicate and urge action about their environment, so others must act on their behalf.

In 1993, the National Academy of Sciences summarized the state of the science concerning the effects of environmental contaminants on children's health and helped institutionalize the idea that children are not "little adults."⁶ That groundbreaking study outlined some of the profound differences between children and adults and was followed, in 1996, by congressional enactment of the Food Quality Protection Act, which mandated use of a 10-fold safety factor for children in setting pesticide residue tolerances.⁷ Since the early 1990s, scientists have expanded our understanding of environmental health consequences beyond childhood diseases and disorders and began examining how childhood exposures affect people throughout all lifestages. The term lifestage refers to a distinguishable time frame in an individual's life characterized by unique and relatively stable behavioral and physiological characteristics that are associated with development and growth. EPA now views childhood as a sequence of lifestages from conception through fetal development, infancy, and adolescence, rather than considering children as a subpopulation.⁸ In its 2005 *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants*, EPA recommended use of the following childhood age groups for assessing risk from environmental exposures:

⁶National Research Council, National Academy of Sciences, *Pesticides in the Diets of Infants and Children* (Washington, D.C., 1993).

⁷The Food Quality Protection Act provisions allowed EPA to use a different safety factor if the Administrator finds that reliable data demonstrate it would be safe for infants and children. Pub. L. No. 104-170 § 405 (1996).

⁸The term "subpopulation" is ingrained into EPA's past practice, as well as various laws that EPA administers, such as the Safe Drinking Water Act Amendments (1996). Prior to the publication of the 2005 *Guidelines for Carcinogen Risk Assessment* and the 2005 *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants*, EPA described all types of groups of individuals as "subpopulations."

-
- age groups less than 12 months old include: birth to <1 month, 1 to <3 months, 3 to <6 months, and 6 to <12 months; and
 - age groups greater than 12 months old include: 1 to <2 years, 2 to <3 years, 3 to <6 years, 6 to <11 years, 11 to <16 years, and 16 to <21 years.

According to EPA guidance, other lifestages, including pregnancy, nursing, and old age, may also be important to consider when assessing human exposure and health risk.

In addition to the growing awareness about the impact that childhood exposures may have on health risks throughout later lifestages, awareness has also grown about the linkage between children’s environmental health and environmental justice issues such as health disparities seen in affected population groups. The Interagency Forum reported that the environmental health risks that disproportionately affect children are likely to disproportionately affect minority and low-income children because of demographic trends in the United States.⁹ According to the U.S. Census Bureau, there were 73.9 million children ages 0 to 17 in the United States in 2008, 1.5 million more than in 2000. Although the number of children living in the United States has grown, the percentage of children has decreased steadily, from a peak of 36 percent at the end of the “baby boom” in the mid-1960s to a current 24 percent—where it is expected to remain through 2020. At the same time, the racial and ethnic composition of the country’s children is expected to diversify.

EPA’s Early Actions to Institutionalize Children’s Environmental Health

EPA’s mission is to protect human health and the environment and, as a result of mounting evidence about the special vulnerabilities of the developing fetus and child, the agency took actions to emphasize protection of children from environmental exposures. In 1995, EPA established an agencywide *Policy on Evaluating Health Risks to Children*, directing EPA staff to consistently and explicitly consider risks to infants and children as a part of risk assessments generated during its decision-making processes, and when setting standards to protect public health and the environment (see app. II). In 1996, EPA issued the National Agenda to Protect Children’s Health from Environmental Threats (National Agenda) and expanded the agency’s activities to specifically

⁹Interagency Forum on Child and Family Statistics, *America’s Children: Key National Indicators of Well-Being* (Washington, D.C., 2009).

address risks for children, documenting EPA's plans to achieve the following seven goals:

1. Ensure that all standards set by EPA are protective of any heightened risks faced by children.
2. Develop a scientific research strategy focused on the gaps in knowledge regarding child-specific susceptibility and exposure to environmental pollutants.
3. Develop new, comprehensive policies to address cumulative and simultaneous exposures faced by children.
4. Expand community right-to-know allowing families to make informed choices concerning environmental exposures to their children.
5. Encourage parental responsibility for protecting their children from environmental health threats by providing them with basic information.
6. Encourage and expand educational efforts with health care providers and environmental professionals so they can identify, prevent, and reduce environmental health threats to children.
7. Provide the necessary funding to address children's environmental health as a top priority among relative health risks.

In 1997, EPA also established the Office of Children's Health, within the Office of the Administrator, to support and facilitate the agency's efforts to implement the National Agenda as well as the Executive Order. The office's mission is to "make the protection of children's health a fundamental goal of public health and environmental protection in the United States and around the world." The office is not directly responsible for implementing or overseeing any EPA programs and instead carries out its mission by supporting and facilitating the work of other EPA offices, raising awareness and educating the public, participating in agency workgroups, and providing grant money that serves to assist communities in expanding awareness about children's health issues. To inform its various initiatives related to children's health, EPA also established the Advisory Committee in 1997. Through the Committee, leading researchers, academics, health care providers, nongovernmental organizations, industry representatives, as well as state and local government

representatives advise EPA on regulations, research, and communications issues important to children's health.

Executive Order 13045— Protection of Children from Environmental Health Risks and Safety Risks

The President issued the Executive Order in April 1997, which established a broad policy for a concerted federal effort to address children's environmental health risks and safety risks.¹⁰ The Executive Order required each federal agency to (1) make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children and (2) ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks (see app. III). The Executive Order has four other key provisions relating to regulatory requirements, interagency coordination and strategies, research coordination and integration, and tracking of children's health indicators. With regard to regulations, the Executive Order requires federal agencies to develop two pieces of information as part of the rulemaking process: (1) an evaluation of the environmental health or safety effects on children of the planned rule; and (2) an explanation of why the planned rule is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. The requirements of the Executive Order are among many broadly applicable regulatory requirements established by statutes and executive orders with which agencies must generally comply when issuing rulemakings. Individual rulemakings only trigger the specific analytical and procedural requirements of the Executive Order if they fall within specified conditions or impact thresholds. The requirements of the Executive Order are triggered if a rulemaking is likely to result in a rule that (1) meets the economic impact threshold, such as by having an annual impact of \$100 million or more, and (2) concerns an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children.

Statutory Requirements to Consider Children's Environmental Health

In addition to the broad mandate in the Executive Order, EPA and the Agency for Toxic Substances and Disease Registry are directed by Congress to consider children or other vulnerable populations in several environmental statutes. Table 1 lists those statutes and their express provisions related to children's health.

¹⁰62 Fed. Reg. 19,885 (Apr. 21, 1997).

Table 1: Provisions in Selected Environmental Statutes Expressly Concerning Children or Other Susceptible Subgroups

Statute	Regulated activity	Extent to which statute explicitly requires special consideration of children or susceptible subgroups in decision making
Food Quality Protection Act 21 U.S.C. §§ 321, 331, 333, 342, 346a	Pesticide residues on raw and processed food	In establishing tolerances and exemptions, EPA must consider infant and children’s exposure, susceptibility, and cumulative effect, and apply a 10-fold margin of safety (unless data support a different margin); ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and publish a specific determination of safety. ^a Also, factors to be considered include exposure and sensitivity of subgroups. ^b
Safe Drinking Water Act 42 U.S.C. §§ 300f-300j-18	Public drinking water	In selecting a maximum contaminant level, EPA must analyze the effects on groups such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk, and subject the analysis to public notice and comment. ^c In selecting unregulated contaminants for consideration of regulation, EPA must consider the effects on subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) at higher risk than the general population. ^d
Federal Insecticide, Fungicide and Rodenticide Act 7 U.S.C. §§ 136-136y	Pesticide registrations	If pesticide is for use on food, then as part of its registration and reregistration, a tolerance or exemption must be established or reviewed under FQPA; see above. ^e EPA is authorized to establish packaging standards for pesticides. ^f
Comprehensive Environmental Response, Compensation, and Liability Act 42 U.S.C. §§ 9601-9675	Hazardous waste sites	Under response authorities, health risk assessments conducted by the Agency for Toxic Substances and Disease Registry (ATSDR) are to consider susceptibility of the community. ^g ATSDR is also directed to conduct medical monitoring of subgroups at risk. ^h
Resource Conservation and Recovery Act 42 U.S.C. §§ 6901-6992k	Hazardous waste handling, treatment, storage, disposal	In the context of hazardous waste landfill permits, where ATSDR is asked to do health assessments, the agency is to consider susceptibility of the community in conducting assessments. ⁱ

Source: GAO.

Note: Statutes were reviewed as amended, and are cited to the codification

^a21 U.S.C. § 346a(b)(2)(B)(vi), (C) (tolerances), (c)(2)(B) (exemptions). There are limited exceptions (e.g., use safer than nonuse; unavoidable residues).

^b21 U.S.C. § 346a(b)(2)(D)(vi), (vii).

^c42 U.S.C. § 300g-1(b)(3)(C)(i)(V).

^d42 U.S.C. § 300g-1(b)(1)(C).

^e7 U.S.C. §§ 136(bb), 136a(c)(5), 136a-1(g)(2)(E).

^f7 U.S.C. § 136w(c)(3).

^g42 U.S.C. § 9604(i)(6)(F).

^h42 U.S.C. § 9604(i)(9)(A).

ⁱ42 U.S.C. § 6939a(f).

Other Key EPA Children's Environmental Health Protection Activities

In 1998, EPA helped establish eight Centers for Children's Environmental Health and Disease Prevention Research, with the long-range goal of understanding how environmental factors affect children's health and translating basic research findings into methods and interventions to prevent adverse health outcomes. The program is jointly funded by EPA, through its Science to Achieve Results grants program, and the National Institute of Environmental Health Sciences, with additional expertise and low-cost laboratory services provided by CDC.¹¹ The program is designed to foster research collaboration among basic, clinical, and behavioral scientists with participation from local communities.

In 1999, EPA—and the other members of the Task Force—explored the feasibility of a longitudinal cohort study of environmental effects on parents and children, and in 2000 Congress authorized the planning and implementation of the National Children's Study as part of the Children's Health Act of 2000.¹² The study is designed to examine the effects of environmental influences on the health and development of 100,000 children across the United States, following them from before birth until age 21, with the goal of improving the health and well-being of children. EPA is one of a consortium of federal partners currently leading the study that includes the U.S. Department of Health and Human Services' National Institute of Child Health and Human Development, National Institute of Environmental Health Sciences of the National Institutes of Health, and CDC.¹³

In 2000, EPA published *America's Children and the Environment* (ACE), a report that brought together quantitative information from a variety of sources to show trends in environmental risk factors related to the health and well-being of children in the United States. The ACE report provides trend information on levels of environmental contaminants in air, water, food, and soil; concentrations of contaminants measured in the bodies of mothers and children; and childhood diseases that may be influenced by environmental factors. In 2003, EPA published the second ACE report, adding data for additional years; new measures for important contaminants, exposures, and childhood illnesses; and analysis of those measures by children's race, ethnicity, and family income. Since 2006, EPA

¹¹<http://www.epa.gov/ncer/childrenscenters>.

¹²Pub. L. No. 106-310, § 1004 (2000).

¹³<http://nationalchildrensstudy.gov>.

has periodically updated the report data on its Web site.¹⁴ EPA is currently updating the ACE report's measures and developing new priority topics, and it intends to publish a new edition by the end of 2010.

EPA Strategic Plans— Goals and Performance Measures

EPA first recognized children's environmental health as a cross-agency program in its 1997 strategic plan and related annual performance plans, which are required by the Government Performance and Results Act. EPA's strategic plan defines its mission, goals, and means by which it will measure progress in addressing specific problems or challenges over the course of at least 5 years. It also describes specific results the agency aims to achieve, what actions the agency will take to realize those planned results, and how the agency will deal with current and foreseeable internal and external challenges that may hinder achieving results. An agency formulates its strategic plan with input from the Office of Management and Budget (OMB); Congress; the agency's personnel, partners, and stakeholders; and the public. EPA's strategic plan also serves a number of important management roles and functions related to achieving its mission, for example allowing agency leadership to establish and communicate priorities and direction through a strategic and unified vision. It also is the foundation of the agency's planning system, for instance providing direction for programmatic functions such as human resources and budgeting, and serves to increase leadership accountability.

EPA Action Development Process and Related Children's Guidance

EPA implements various environmental statutes in part through rulemakings, which are guided by its Action Development Process that helps the agency comply with legal requirements, executive orders, directives, agency guidance, and national policies. EPA finalized the current process in June 2004 to ensure that it uses quality information to support its actions and that scientific, economic, and policy issues are adequately addressed at the right stages in action development.¹⁵ The process has five major stages, each of which involves multiple steps. In the first stage, EPA assigns the rulemaking to one of three tiers based on the required level of cross-agency interactions and the nature of the anticipated issues, including complexity, environmental and economic

¹⁴EPA, *America's Children and the Environment*, <http://www.epa.gov/economics/children> (accessed Jan. 15, 2010).

¹⁵EPA, *EPA's Action Development Process: Guidance for EPA Staff on Developing Quality Actions* (Washington, D.C., 2004).

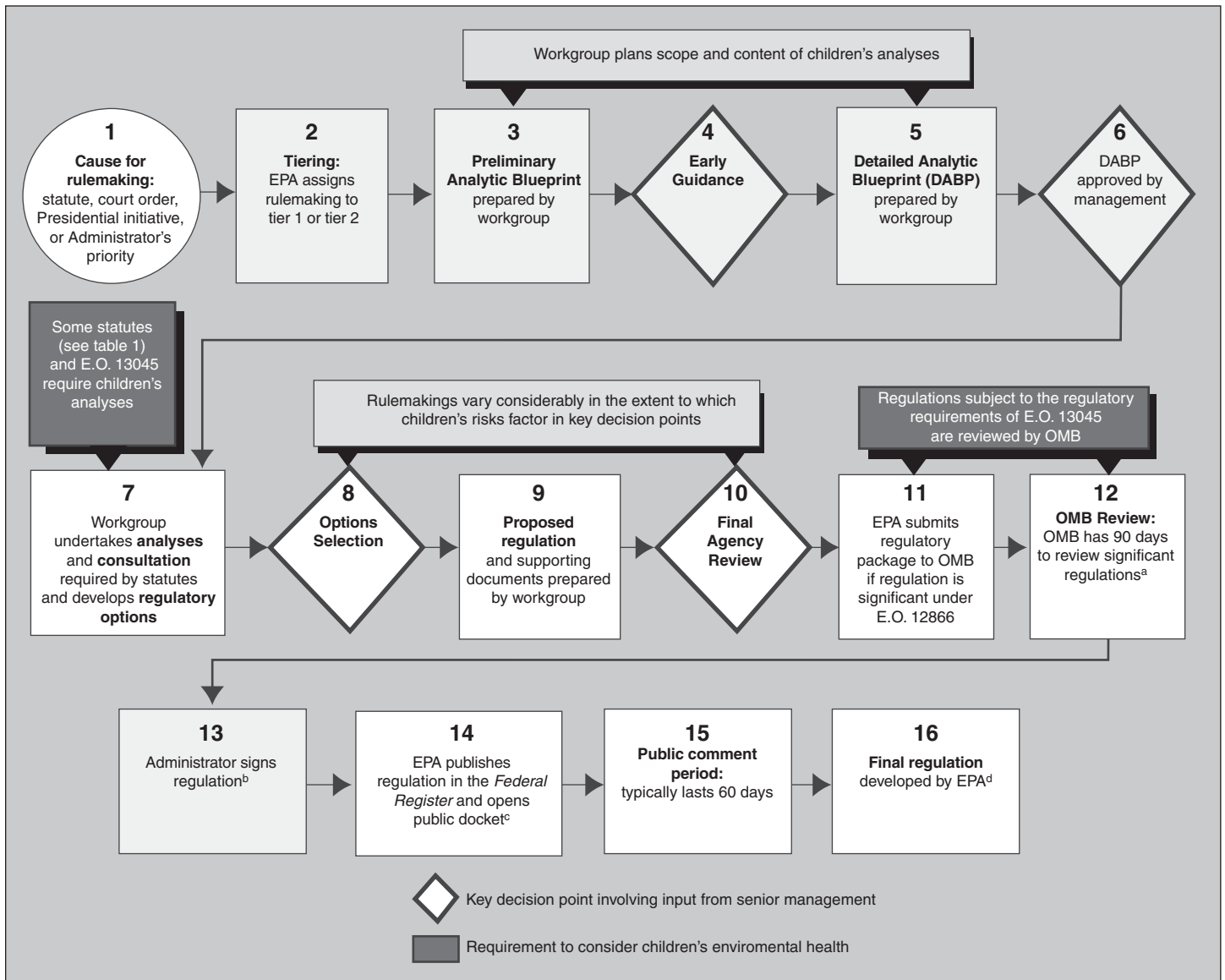
significance, and external interest. According to agency guidance, EPA assigns rulemakings that are based on a human risk assessment—including assessments of environmental health risks to children—to tier 1 or tier 2. In the second stage, EPA uses a standard process to develop the proposed regulation and supporting analyses. In the third stage, EPA submits a regulatory package to OMB and addresses OMB comments, when required to do so under Executive Order 12866.¹⁶ In the fourth stage, EPA requests the Administrator’s signature and publishes the draft regulation in the *Federal Register*. In the fifth stage, EPA develops the final action and facilitates Congressional review. In developing the final regulation, EPA repeats many of the steps it followed to develop the draft regulation. The final step in the process is to submit the final regulation to Congress and GAO.

In October 2006, EPA’s Office of Policy Economics and Innovation issued additional guidance to assist agency staff in integrating children’s health considerations into the process.¹⁷ The children’s guidance describes provisions of the Executive Order and EPA’s Policy on Evaluating Health Risks to Children. Figure 2 illustrates key steps in EPA’s Action Development Process where children are to be considered by the agency.

¹⁶Executive Order 12866 directs most agencies, including EPA, to, among other things, assess costs and benefits of available regulatory alternatives and to submit significant rules to OMB’s Office of Information and Regulatory Affairs for review before they are published. 58 Fed. Reg. 51,735 (1993). For a summary of agencies’ responsibilities for rulemakings under broadly applicable requirements, see app. I of GAO, *Federal Rulemaking: Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB’s Regulatory Reviews*, GAO-09-205 (Washington, D.C.: Apr. 20, 2009).

¹⁷EPA, *EPA’s Action Development Process: Guide to Considering Children’s Health When Developing EPA Actions: Implementing Executive Order 13045 and EPA’s Policy on Evaluating Health Risks to Children* (Washington, D.C., 2006).

Figure 2: Steps Where Children Are Considered in the EPA Rulemaking Process



Source: GAO analysis of EPA's Action Development Process.

^aEPA may request a one-time 30-day extension.

^bThe Administrator may delegate signature authority to an Assistant or Associate Administrator or Regional Administrator.

^cA docket can be established at any time during the rulemaking process, but should open no later than the date of publication in the *Federal Register*. A docket should contain all information relied upon by EPA in developing an action.

⁴Developing the final regulation involves reconvening the workgroup to evaluate comments received on the proposal and determine the appropriate next steps for preparing the final action, which could range from repeating all of the steps as outlined in the process for preparing the proposal to only doing a subset of those steps.

EPA Has Not Focused Attention on Children’s Health in Agencywide Priorities, Strategies, and Rulemakings

EPA has not updated the National Agenda since it issued the priority-setting document in 1996. EPA’s 1997 and 2000 strategic plans included children as an explicit goal or program, but the agency’s subsequent two plans showed a reduced emphasis on children. EPA has not systematically evaluated or tracked how its rulemakings addressed children’s environmental health risks, and regulatory requirements in the Executive Order have had minimal impact on EPA rulemakings.

EPA Has Not Updated the National Agenda in More than a Decade

EPA has not updated the *National Agenda to Protect Children’s Health from Environmental Threats* in more than 10 years. Issued in 1996, the National Agenda established children’s environmental health as a top priority and a central focus of all agency efforts. In it, EPA articulated the agency’s commitment to children’s health by identifying an array of environmental threats to children and specifying a multifaceted approach to accomplishing its children’s health goals. The National Agenda also was the impetus for the creation of EPA’s Office of Children’s Health, which was formed to support the agency’s implementation of the National Agenda. These actions are consistent with our prior work on implementing change in the federal government, which has shown that top leadership must provide a clear, consistent rationale for change and develop a framework that helps create a new culture. Moreover, the National Agenda also helped to institutionalize the agency’s commitment to the issue. According to current and former officials from the Office of Children’s Health, the National Agenda and Executive Order helped legitimize the office’s importance across the rest of the agency.

Several demonstrable children’s health-focused activities were initiated shortly after the EPA Administrator who founded the Office of Children’s Health issued the National Agenda (see table 2). For example, in 1999 the agency explored—through the Task Force—the feasibility of a longitudinal cohort study of environmental effects on parents and children, which Congress later established as the National Children’s

Study.¹⁸ In 2000, EPA issued a strategy for research on environmental risks to children that established EPA's long-term program goals and documented its rationale.¹⁹ The National Agenda also asserted EPA's leadership across the federal government and called on partners in Congress, industry, health professions, and interest groups to adopt and help EPA implement these children's health priorities.

Table 2: Priorities From EPA's National Agenda and Examples of Related Actions

National Agenda priority	Children's environmental health action
1. Ensuring that EPA standards are protective of potentially heightened risks faced by children	<ul style="list-style-type: none"> • In 1997, EPA asked its Advisory Committee to recommend five existing standards that may merit re-evaluation. In 1999, EPA identified eight regulations and regulatory areas for review, including pesticide tolerances and farm worker protection standards. • In 1997, EPA set air standards for particulate matter and ozone to provide additional health protection to 35 million children and set standards for fine particulate matter for the first time. • In 1998, EPA published a final Guidance for Rule Writers to risk assessors and managers who are developing regulatory standards that are specifically targeted at pregnant women, infants, and children.
2. Identifying and expanding scientific research on child-specific susceptibility to environmental pollutants	<ul style="list-style-type: none"> • In 1998, EPA partnered with the National Institute of Environmental Health Sciences (NIEHS) to establish children's health research centers to promote research and intervention and prevention methods in order to better understand how environmental factors affect children's health. • In 1999, EPA helped to initiate what became the National Children's Study (see text above).
3. Developing policies addressing cumulative and simultaneous exposures	In 1997, EPA published cumulative risk assessment guidance that recommended the integration of multiple sources, effects, pathways, stressors, and populations in risk assessments for which relevant data are available, with emphasis on sensitive subgroups such as infants and children.
4. Expanding community right-to-know efforts	EPA expanded public access to agency information on pollution, particularly through the Internet, to help people prevent pollution in their neighborhoods and protect the health of a community's children. For instance, EPA developed a national listing of state fish consumption advisories to make the advisories more accessible.
5. Providing information to parents on environmental threats in homes, schools, and communities	In 1998, EPA began publication of a Children's Environmental Health Yearbook to be a resource guide of EPA activities for the public.

¹⁸P.L. 106-310.

¹⁹The research strategy has not been updated since its publication. Instead, EPA integrated children's environmental health into its Office of Research and Development multiyear human health research plans.

National Agenda priority	Children's environmental health action
6. Educating health and environmental professionals to prevent and reduce threats to children	In 1998, EPA, in conjunction with the Agency for Toxic Substances and Disease Registry, established Pediatric Environmental Health Specialty Units to provide critical expertise to health care professionals, parents, schools, and community groups on protecting children from environmental hazards, as well as to work with federal, state, and local agencies to address children's environmental health issues in homes, schools, and communities.
7. Funding to address children's environmental health as a top priority among relative health risks	Since 1998, EPA and NIEHS share responsibility for funding the children's health research centers, with EPA providing half the funding through its Science to Achieve Results program.

Source: GAO analysis of EPA documents.

EPA officials with whom we spoke recognized the importance of the National Agenda for helping to institutionalize children's health as a priority across EPA, noting that it gave children's health more traction and consideration in EPA programs and activities. In its 2004 report, EPA's Inspector General stated that while EPA has taken steps toward meeting the goals outlined in the agenda, with programs and regional offices carrying out projects focused on children's environmental health, there was no overall, coordinated strategy to integrate the agency's efforts on behalf of children.²⁰ Moreover, as we have previously reported and testified, EPA took actions that directly contradicted a National Agenda priority in December 2006.²¹ Specifically, the agency finalized a rulemaking that significantly reduced the amount of publicly available information reported to the Toxics Release Inventory about toxic chemicals released into air, water, and land. Ultimately, Congress acted to overturn EPA's actions.²²

In the first few months of 2009, EPA's newly appointed Administrator recommitted the agency to helping ensure protection of children's environmental health, stating in a speech that children are a driving force behind the agency's priorities.²³ In July 2009, she appointed a new Director of the Office of Children's Health and said that the director will also serve as a key advisor in the Administrator's office. In order to develop concrete

²⁰EPA Office of Inspector General, Report No. 2004-P-00016.

²¹GAO, *Environmental Information: EPA Actions Could Reduce the Availability of Environmental Information to the Public*, [GAO-07-464T](#) (Washington, D.C.: Feb. 6, 2007), and *Toxic Chemical Releases: EPA Actions Could Reduce Environmental Information Available to Many Communities*, [GAO-08-128](#) (Washington, D.C.: Nov. 30, 2007).

²²Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 425 (2009).

²³Administrator Lisa P. Jackson, Remarks at the Columbia University Center for Children's Environmental Health, March 30, 2009.

ways to implement the new commitment, the Administrator tasked the new director with developing recommendations to improve regulatory and nonregulatory consideration of children's environmental health across EPA. In September 2009, the new director outlined the following five-part approach to ensure protection of children's environmental health:

- *Regulatory and policy development:* EPA will work to ensure that regulations—for example, National Ambient Air Quality Standards (NAAQS)—provide for protection of children's environmental health. It will also ensure that policies focus on health disparities among different demographic groups of children, and their causes.
- *Safe chemicals management:* EPA will ensure that children, and other susceptible populations such as the elderly, are considered in the context of chemicals management programs and implementation and potential reform of the Toxic Substances Control Act.²⁴
- *Implementation of community-based children's health programs:* EPA will re-establish a pivotal and influential role in working with tribes, states, and local governments to design and implement policies that improve the environment and protect children.
- *Research and science policy:* EPA will work with internal and external researchers to fill critical gaps in the understanding of children's vulnerabilities, unique exposures, and health effects, and will apply science policies that appropriately reflect uncertainties in children's vulnerabilities in EPA risk assessments.
- *Measuring effectiveness of EPA programs:* EPA will update its report *America's Children and the Environment*, which brings together quantitative information from a variety of sources to show trends in levels of environmental contaminants and concentrations of contaminants in the bodies of mothers and children, among other things.

The director told us about some specific steps he plans to take within the Office of Children's Health as part of the approach, including shifting resources so that the office has more public health expertise and realigning the office's focus to support the development of regulations and child-specific programs. In addition, he said he was confident the Administrator would begin to make other changes related to children's

²⁴Pub. L. 94-469 (1976); codified as amended at 15 U.S.C. §§ 2601 et seq.

health strategy, although he could not provide a time frame or specific actions the agency had planned to implement such changes. Nonetheless, the EPA Administrator has yet to formalize new priorities in a visible and public way that contains specific actions EPA intends to take, as it did in the National Agenda. In contrast, EPA has publicly committed to improvements in other areas, such as chemicals management for which the agency released in September 2009 a comprehensive approach to enhance the agency's chemical program.²⁵

EPA Recent Strategic Plans Indicate a Reduced Emphasis on Children's Health

EPA identified children's health as a cross-agency program in its 1997 and 2000 strategic plans.²⁶ However, EPA's 2003 and 2006 (current) plans did not include children's health as an explicit goal or program, indicating that the agency has placed less emphasis on protecting children's health.²⁷ The plans' goals and measures are meant to make the key components of an organization's mission explicit, thereby guiding officials in how to carry out the mission. In keeping with the requirements of the Government Performance and Results Act, EPA issued strategic plans setting forth goals that reflected top Administrator priorities; the plans also discuss cross-agency programs that cut across traditional media and organizational boundaries to consider, with a more comprehensive view, the risks posed to particular or vulnerable populations. EPA officials said that the agency removed this cross-agency goal when it streamlined its strategic plan from a 10-goal to a 5-goal structure, which was done as a result of EPA and OMB priorities.²⁸ According to EPA officials, children are considered as part of the plans' Goal 4, Healthy Communities and Ecosystems. The staff from the Office of Children's Health told us they

²⁵In September 2009, the EPA Administrator announced a five-part comprehensive approach to enhance chemical management under existing laws. This approach includes developing chemical action plans, which should target the agency's risk management efforts on chemicals of concern, and increasing public access to information about chemicals.

²⁶The Government Performance and Results Act requires that each agency prepare a strategic plan that defines its missions, goals, and the means by which it will measure its progress over a 5-year period and update them every 3 years. For example, EPA's 1997 plan covered years 1997 through 2001.

²⁷EPA has issued four strategic plans since 1997, and is currently in the process of issuing its 2009-2014 plan.

²⁸EPA's 2003 and 2006 strategic plans include five goals: (1) Clean Air and Global Climate Change, (2) Clean and Safe Water, (3) Land Preservation and Restoration, (4) Healthy Communities and Ecosystems, and (5) Compliance and Environmental Stewardship.

were not pleased with the change to a 5-goal structure, because the subsequent strategic plans no longer emphasized children's environmental health. In addition, the office had previously developed its own draft strategic plan that included a range of children's health performance measures and demonstrated how such measures fit within EPA's overall strategic plan. However, that work was not incorporated into, or referenced by, the agencywide strategic plan, in part, because the office had limited involvement in EPA's strategic planning process.

To help develop EPA's 2009 strategic plan, the agency held meetings in 2008 and 2009 to identify target areas for improvement. In the latest draft of that plan that EPA provided to us, the agency identified target areas for improvement—significant changes in strategy or performance measurement that are critical for helping the agency achieve and measure environmental and human health outcomes.²⁹ We found that children's health was not included as a target area in the draft strategic plan, and it is not yet clear to what extent children's health will be addressed in the final plan, which is subject to revision before the Administrator finalizes it in the coming months. We also found that the Office of Children's Health was not a lead office for developing the plan's goal for Healthy Communities and Ecosystems. Development of this goal has been co-led by EPA's Office of Prevention, Pesticides and Toxic Substances; Office of Research and Development; and Office of Water. EPA planning officials told us that staff from the Office of Children's Health attended at least one development meeting for the healthy community goal. However, the office staff said their input was not given much weight, since three other offices were assigned the leadership role for coordinating the goal's team. EPA officials said that a possible reason the Office of Children's Health did not become central to the process was that it is not directly responsible for implementing or overseeing any of the programs and subobjectives under the Healthy Communities and Ecosystems goal.

We recognize that EPA's strategic plan addresses five high-level goals and related objectives that generally relate to major media goals such as improving water quality or reducing chemical risks. Therefore, the strategic plans contain subobjectives and strategic targets that provide a higher degree of specificity and allow EPA to more clearly express

²⁹The draft September 2009 strategic plan includes target areas for improvement, such as impacts of sustainable agriculture, global climate change, import safety, and environmental indicators.

priorities. However, our analysis of EPA's last two strategic plans found few subobjectives or strategic targets that explicitly related to children's health.³⁰ We have previously reported on the need for a strategic planning framework to contain critical elements such as performance goals that are indicative of agency priorities and also are objective, quantifiable, and measurable; an estimate of resources needed to meet performance goals; and an evaluation plan that monitors the goals.³¹ EPA stated in its 2006 strategic plan that the agency directs its efforts toward the greatest threats in communities and the most sensitive populations, including children, who may be disproportionately exposed to environmental hazards. We found that only 2 of the 45 subobjectives relate specifically to children's environmental health: (1) asthma and (2) indoor air quality at schools.³² We also found that, of the plan's 126 strategic targets, only 3 explicitly reference children or related issues: (1) reducing the percentage of women of childbearing age exposed to mercury, (2) eliminating lead poisoning, and (3) reducing blood lead levels.

With regard to the draft 2009 strategic plan that EPA planning officials provided us, 5 subobjectives (out of a total of 62) specifically address children's environmental health—reducing (1) exposure to asthma triggers, (2) indoor air contaminants at schools, (3) the percentage of women of childbearing age with mercury blood levels above safe thresholds, (4) blood lead levels in children, and (5) pregnant women's exposure to persistent organic pollutants.

Furthermore, regarding EPA's draft 2009 strategic plan, we found that the performance measures do not clearly measure children's health progress or are not explicitly linked to children's health objectives. Performance measures are indicators, statistics, or metrics used to gauge program performance. Reliable and comprehensive performance measures allow the agency to judge whether its performance targets are reasonable and

³⁰OMB defines strategic targets as quantifiable or otherwise measurable characteristics that tell how well or at what level a program aspires to perform. Each subobjective typically has between one and four strategic targets.

³¹GAO, *Depot Maintenance: Improved Strategic Planning Needed to Ensure That Army and Marine Corps Depots Can Meet Future Maintenance Requirements*, [GAO-09-865](#) (Washington, D.C.: Sept. 17, 2009).

³²OMB defines objectives and subobjectives as statements of aim or purpose included in a strategic plan, required under the Government Performance and Results Act. EPA's current strategic plan has 9 subobjectives under goal 1, 5 subobjectives under goals 2 and 3, 20 subobjectives under goal 4, and 6 subobjectives under goal 5.

whether it is meeting them. Moreover, as we have previously reported, strategic plans need to demonstrate that crosscutting programs—such as those for protecting children’s environmental health—use the same performance measures across the offices implementing the programs. Our analysis indicates that 4 of the 12 performance measures (associated with the five subobjectives EPA identified) explicitly consider children, and only one of them measures a health outcome—the number of children ages 1 to 5 with elevated blood lead levels. The other 11 measures either did not directly measure children’s health outcomes or were indirect proxy measures. We also found that for half of the 12 performance measures, the data or the data sources had inherent limitations. For example, the data source supporting the measure for “taking all essential actions to reduce exposure to indoor environmental asthma triggers” does not cover half of EPA’s target population—children from birth to 3 years old—the age group most susceptible to health effects from secondhand tobacco smoke, a key asthma trigger according to CDC. EPA officials acknowledged that the data gaps for some performance measures are due a variety of reasons, including funding limitations. They added that EPA cannot necessarily guarantee availability of all the data used to support its performance measures, some of which are provided by other agencies.

In contrast to the EPA’s agencywide strategic plans, its Office of Research and Development has consistently addressed children’s environmental health in its research plans. For example, working with other program offices, the office has addressed children’s health in some of its multiyear research plans, which guide the direction of research over 5 or more years. The office develops separate multiyear plans on a variety of issues, including clean air, endocrine disruptors, human health risk assessments,³³ and human health research. The Office of Research and Development uses these multiyear plans to link its Annual Performance Plan, required under the Government Performance and Results Act, to longer-range objectives contained in EPA’s strategic plan. In addition to these regular planning efforts, the Office of Research and Development has also developed strategies for addressing complex, cross-cutting programs, such as children’s health. For example, the office published a *Human Health Research Strategy* in September 2003. Officials from the Office of Research and Development told us that the office is considering updating its August 2000 *Strategy for Research on Environmental Risks to*

³³Risk assessment is the process EPA uses to determine the nature and magnitude of health risks to humans from chemical contaminants and other stressors.

Children, and has held preliminary discussions with the Office of Children's Health.

The Office of Research and Development's *Human Health Research Program Multi-Year Plan* is EPA's primary research plan for addressing children's health, according to office officials. The plan supports the office's human health research program, which also provides methods to help reduce uncertainty in EPA's children's risk assessments, among other things. In June 2006, the office published an updated human health research plan for the years 2006 through 2013. The plan is organized according to the program's four long-term goals and explicitly addresses children's health in two of them. For example, children's health is addressed in the goal to ensure that "risk assessors and risk managers use the office's methods, models, and data to characterize and provide adequate protection for susceptible subpopulations." The plan considers children's health in all three of the research tracks supporting that goal—lifestages, methods for longitudinal research, and research on asthma.³⁴ In fact, a generally positive review of the research plan by EPA's Board of Scientific Counselors—which the agency established to provide advice, information, and recommendations about its research program—found that EPA may be overemphasizing children in its research on susceptible subpopulations. The board recommended in its December 2009 report that EPA redress research program imbalances within the lifestage arm to match the strengths of its childhood susceptibility research thrust with an expanded research program addressing subgroups across the entire age range, including the elderly.³⁵

EPA Has Not Evaluated or Consistently Documented How Its Rulemakings Address Risks to Children

EPA's 1995 policy directs the agency to consider the risks to infants and children consistently and explicitly as part of risk assessments—including those used to support rulemakings—or state clearly why it did not. EPA cannot be assured that it has thoroughly addressed risks to children, because it lacks a system for evaluating and documenting how the agency has considered them in rulemakings. We identified three examples. First, EPA implements the Executive Order, in part, through its efforts to

³⁴EPA's Web site explains its lifestages research (see <http://www.epa.gov/nerl/goals/health/lifestage.html>).

³⁵EPA, Board of Scientific Counselors, *Review of the Office of Research and Development's Human Health Research Program at the U.S. Environmental Protection Agency* (Washington, D.C., 2009).

institutionalize its 1995 policy. However, EPA has not evaluated the extent to which its risk assessments conform to this policy.³⁶ Officials from the Office of Children’s Health told us that significant information gaps remain concerning children’s risks. Second, EPA does not require rule writers to thoroughly document consideration of children in the agency’s Rule and Policy Information Development System (RAPIDS). EPA uses RAPIDS to track, approve, and report on agency actions, including rulemakings. RAPIDS allows EPA staff to document milestones in all phases of the rulemaking process and archives key information, according to EPA. However, RAPIDS captures limited information about human health or children’s environmental health considerations. It does not, for example, capture whether a risk assessment is conducted as part of a rulemaking. Furthermore, in January 2008, EPA eliminated a check-box in RAPIDS that indicated whether a rulemaking involved environmental health risks or safety risks that may pose disproportionate risks to children. EPA added three questions about human health impacts to RAPIDS, but those do not directly address disproportionate risks to children. In addition, the human health data maintained in RAPIDS can be inaccurate or incomplete because they are gathered early in the rulemaking process and are rarely updated later in the process, according to officials with whom we spoke. Finally, EPA does not require rule writers to document consideration of children in preambles of all published regulations, even though the Office of Children’s Health has urged EPA to require this.

EPA has taken steps to comply with the Executive Order’s requirements by, for example, publishing updated guidance to assist rule writers in addressing children’s risks in October 2006.³⁷ The guidance identifies key steps where rule writers should consider children in the rulemaking process. For example, it advises workgroups that are developing a regulation to describe proposed children’s analyses in their plans for data collection and analyses. The guidance also advises rule writers to work with risk assessors early in the rulemaking process to begin accumulating information about potential children’s risks. EPA has also developed a

³⁶EPA’s Office of Pesticide Programs noted that, as a result of the Food Quality Protection Act of 1996, its risk assessments routinely discuss the risks to infants and children resulting from use of pesticides.

³⁷EPA, Office of Policy, Economics, and Innovation, *EPA’s Action Development Process: Guide to Considering Children’s Health When Developing EPA Actions: Implementing Executive Order 13045 and EPA’s Policy on Evaluating Health Risks to Children* (Washington, D.C., 2006). This guide superseded *EPA’s Rule Writer’s Guide to Executive Order 13045* (Washington, D.C., 1998).

variety of guidance to assist risk assessors in addressing risks to children, including 2005 guidance on assessing susceptibility from early life exposure to carcinogens and 2008 guidance on assessing children's exposures to environmental contaminants.³⁸ EPA's first use of the cancer guidance is its draft risk assessment for ethylene oxide—used to make antifreeze, detergents, and polyester, and as a fumigant pesticide. The draft assessment also includes EPA's first use—apart from pesticide tolerances—of an additional safety factor for children and proposes reducing the agency's 1985 standard of 3.6 parts per billion for protecting against cancer risks to a much stricter limit of 0.6 parts per trillion.

According to staff from the Office of Children's Health, some EPA staff are more aware than others of the need to consider children's risks in rulemakings, in part because of the guidance they helped develop. However, officials from the office told us that EPA has not taken additional steps that would help institutionalize the use of the applicable guidance. For example, EPA does not provide rule writers with specific training on the guidance, according to officials. Rule writers are required to attend a 3-day comprehensive training course organized by EPA's Office of Policy, Economics, and Innovation, but the course includes only a limited discussion of children's environmental health because of competing demands. The Office of Children's Health has instructed part of this course in the past, but has not done so since 2006, according to office officials. In addition, EPA has been slow to implement at least one guidance document aimed at improving consideration of children in risk assessments and economic analyses used to support rulemakings. Specifically, in 2005 EPA issued guidance on selecting age groups for monitoring and assessing childhood exposures to environmental contaminants, but did not use the guidance in developing a risk assessment until 2008.³⁹ In another example, EPA's Office of Policy, Economics, and Innovation issued guidance on assessing the economic value of children's health benefits in October 2003, but the Director of the

³⁸EPA, Risk Assessment Forum, *Supplemental Guidance for Assessing Susceptibility from Early Life Exposure to Carcinogens* (Washington, D.C., 2005). EPA, Office of Research and Development, *Child-Specific Exposure Factors Handbook* (Washington, D.C., 2008).

³⁹EPA, Risk Assessment Forum, *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* (Washington, D.C., 2005).

Office of Children's Health told us the agency could expand efforts to ensure that children are adequately considered in economic assessments.⁴⁰

Although the Office of Children's Health can advocate that EPA address disproportionate risks to children, we found that it has had a limited role in rulemakings for a number of reasons. Because the office is not a regulatory office like the Office of Air and Radiation, it does not initiate rulemakings. Instead, the Office of Children's Health participates on regulatory workgroups as staff resources permit. Regulatory workgroups, which develop regulations, consist of members from EPA's program offices and regional offices. EPA does not maintain reliable information on the number of regulatory workgroups that have included a representative from the Office of Children's Health, but the office has participated on only a small number of regulatory workgroups because of its limited resources, according to office officials. They told us that from 2007 through 2008, the office participated in final review for seven rulemakings, including reviews of the NAAQS for ozone and lead.⁴¹ The Office of Children's Health's limited resources may also have limited its participation on the regulatory workgroup responsible for EPA's most recently completed review of *National Ambient Air Quality Standards for Particulate Matter*, published in October 2006. The office's representative on the workgroup was not designated an official workgroup member who would receive all chapters of the draft regulation, according to internal documents that we reviewed. Furthermore, the office did not send a representative to two key meetings, according to the workgroup chairman. The office's current director told us that he views this as a critical part of the office's work, and he will increase its participation in EPA rulemakings.

EPA's rulemaking for particulate matter standards provides an illustration of a rulemaking in which EPA documented its efforts to comply with the Executive Order. For its air quality standards for particulate matter, EPA addressed children's risks throughout the rulemaking process, according to documents and EPA officials who served on the regulatory workgroup. For example, it considered children in quantitative and qualitative risk assessments and its analysis of the scientific bases for alternative policy

⁴⁰EPA, Office of Children's Health Protection and Office of Policy, Economics, and Innovation, *Children's Health Valuation Handbook* (Washington, D.C., 2003).

⁴¹According to the Office of Policy, Economics, and Innovation, the agency conducted final review for 58 tier 1 or tier 2 regulations from 2007 through 2008.

options.⁴² In addition, EPA addressed children's risks in internal documents, including briefing slides and documents for the rulemaking that we reviewed. The Administrator eventually selected standards that were less stringent than those recommended by the Office of Children's Health and by EPA advisory committees. EPA documented its analyses in the notices of the proposed and final regulations as well as in the public docket, and the United States Court of Appeals for the District of Columbia used these analyses, in part, to support its February 2009 decision to remand a key standard to EPA for review.⁴³ The court stated that EPA had failed to explain why it believed the standard would provide an adequate margin of safety against illness in children and other vulnerable subpopulations, as required by the Clean Air Act.⁴⁴ In its opinion, the court cited analyses by EPA staff and determined that the Administrator had apparently too hastily discounted studies of the effect of particulate matter on children.

Regulatory Requirements in the Executive Order Have Had Minimal Impact on EPA Rulemakings

The Executive Order requires EPA to evaluate the environmental health or safety effects on children of each of the covered regulations. However, the requirements had a minimal impact on rulemakings conducted between 1998 and 2008⁴⁵ for three reasons: (1) the order applied to a narrow subset of rulemakings, (2) EPA was already considering risks to children in the rulemaking process when the order took effect, and (3) EPA does not interpret the order as requiring any particular analyses on children's environmental health. Furthermore, we reviewed the preambles of all proposed and final regulations that EPA determined to be subject to the requirements, and found that EPA varied in how explicitly it addressed the requirements of the Executive Order therein.

⁴²EPA's Office of Research and Development was responsible for supporting much of the relevant research on particulate matter. More than 40 percent of the research citations in the Criteria Document and the Staff Paper, key documents prepared during the action development process then in effect, were supported by the office, according to EPA (see fig. 2).

⁴³*American Farm Bureau Federation v. EPA*, 559 F. 3d 512, 519 (2009).

⁴⁴Codified as amended at 42 U.S.C. Ch. 85 (2009).

⁴⁵The Executive Order applies to rulemakings that are initiated after April 21, 1997, or for which a Notice of Proposed Rulemaking is published after April 21, 1998. EPA did not determine that any proposed or final regulations published before 1998 were subject to the order.

First, the Executive Order only applies to a narrow subset of regulations. We determined that just 17 EPA rulemakings were subject to the order since it took effect. On average, EPA applied the order to fewer than 2 of the approximately 450 rulemakings it completed each year, even though some of those rulemakings were especially important to children’s health. One reason for the low number is that the order extends only to situations in which analysis of the regulation’s effects on children has the potential to influence the regulation, according to EPA’s interpretation. Thus, EPA does not apply the order to regulations that are based solely on technology performance, since health-based information cannot influence such regulations. EPA guidance states that the agency may be statutorily precluded from considering health or safety risks when setting certain technology-based standards. For example, under the Clean Air Act, EPA is required to base certain initial performance standards on emissions levels that are already being achieved by better-controlled and lower-emitting sources in an industry, and not on human health outcomes. On this basis, EPA determined that a proposed technology-based regulation on mercury emissions from cement plants, issued in May 2009, was not subject to the order, even though the regulation addressed an environmental health risk that disproportionately affects children’s health.⁴⁶

Another reason the Executive Order only applies to a narrow subset of regulations is that it applies only to rulemakings that are considered economically significant under a separate executive order—Executive Order 12866. As a result, individual EPA rulemakings only trigger the Executive Order’s analytical and procedural requirements if they have an annual impact of \$100 million or more, or will have certain material adverse economic effects, a criterion that excludes most of EPA’s regulations. This is consistent with our 2009 report that stated most major rulemakings triggered the analytical requirements of the Regulatory Flexibility Act, Executive Order 12866, and the Paperwork Reduction Act but few other commonly applicable rulemaking requirements such as Executive Order 13045.⁴⁷ Between 1998 and 2008, EPA issued only 54 final regulations that were determined to be economically significant.⁴⁸

⁴⁶*National Emission Standards for Hazardous Air Pollutants from the Portland Cement Manufacturing Industry Proposed Rule*, 74 Fed. Reg. 21,136, 21,170 (May 6, 2009).

⁴⁷[GAO-09-205](#).

⁴⁸Executive Order 12866 also applies to “significant” rulemakings that meet criteria other than economic significance; however, Executive Order 13045’s regulatory requirements are triggered only by economic significance.

According to a 2008 study—authored by staff from the Office of Children’s Health—at least 65 regulations involving disproportionate risks to children were not subject to the Executive Order because they were not considered economically significant.⁴⁹ Fifty of those 65 regulations concerned the amount of pesticides that may remain in or on food. However, for those 50 rulemakings and the others that were not subject to the Executive Order, EPA must still comply with provisions in environmental statutes, such as the Food Quality Protection Act of 1996,⁵⁰ that expressly concern children (see table 1). Although the scope of the Executive Order’s regulatory requirement is limited, EPA did apply it to some regulations that the agency estimated to significantly impact children’s environmental health. For example, it applied to three rulemakings that established the NAAQS. According to the Director of EPA’s Office of Children’s Health, those standards are among the most important decisions EPA made regarding children’s health.

A second reason that the Executive Order had a minimal impact on rulemakings is because EPA was already considering risks to children in its rulemaking process when the order took effect. For example, EPA’s 1995 *Policy on Evaluating Health Risks to Children* directs agency staff to consider the risks to infants and children consistently and explicitly in all risk assessments, including those that support rulemakings. Another reason is that federal agencies were already required to perform some of the analyses that the order calls for. For example, both the children’s executive order and Executive Order 12866, issued in 1993, require agencies to explain why a planned regulation is preferable to other “potentially effective and reasonably feasible alternatives” considered by the agency.⁵¹ According to EPA officials, the agency does not provide additional documents to the Office of Information and Regulatory Affairs if a proposed regulation is subject to both the children’s executive order and Executive Order 12866, rather than Executive Order 12866 alone. Nor has the Office of Information and Regulatory Affairs requested additional

⁴⁹D. Payne-Sturges and D. Kemp, “Ten Years of Addressing Children’s Health through Regulatory Policy at the U.S. Environmental Protection Agency.” *Environmental Health Perspectives*, vol. 116, no. 12 (2008). The study covered the period from April 1998 to December 2006.

⁵⁰Pub. L. No. 104-170, § 405 amended the standard-setting provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

⁵¹Executive Order 12866 of September 30, 1993, was amended by Executive Order 13258 of February 26, 2002, and Executive Order 13422 of January 18, 2007, and is still in effect.

information about children's environmental health in these situations, according to officials from that office.

Third, EPA does not require any particular analyses to comply with the Executive Order's mandate that agencies evaluate the effects of any planned regulation on children. EPA has guidance to assist staff in complying with this requirement, but it gives staff considerable discretion. Furthermore, past guidance has been inconsistent. For example, the agency's 2003 Children's Health Valuation Handbook notes that one way to address the requirement is to analyze the costs, benefits, or other economic impacts of a policy on a specific subpopulation. EPA's 2000 *Guidelines for Preparing Economic Analyses*, however, states that the Executive Order primarily addresses risks rather than economic analyses.

Furthermore, we found that EPA varied in how explicitly it addressed the requirements of the Executive Order in publication of regulations. Every EPA *Federal Register* notice of a regulation subject to the order has a section in the preamble specifically addressing the order. We reviewed this section of all relevant notices from 1998 through 2008, and EPA did not always provide information on how it complied with the Executive Order or on what it found in conducting the required analyses.⁵² We found that EPA has not consistently documented in this section how it considered children's environmental health risks. Specifically, we found that EPA either quantified the effects on children or explained why it did not, or could not do so, for only 4 of the 17 of the rulemakings. We also found variation in the extent to which EPA provided information in the *Federal Register* notice about how the agency addressed the Executive Order's requirement to evaluate the environmental health or safety effects on children, with some notices providing minimal information. For example, the notices of the final regulations establishing the NAAQS for lead, ozone, and particulate matter merely stated that the standards may be especially important for children because the contaminants in question may disproportionately affect children's health. While EPA had conducted analyses of children's health in developing those regulations, this section of the notice did not provide the public with a summary of EPA's analyses,

⁵²Unless otherwise noted, when we refer to *Federal Register* notices in this section, we are referring to the preamble section on Executive Order 13045. The Executive Order requires that, for covered actions, the agency conduct and submit these analyses to OMB. The analyses must also be made part of the administrative record or otherwise made available to the public, to the extent permitted by law. The Executive Order does not require that the *Federal Register* notices for such regulations explain the agency's analyses.

making it difficult for the public to understand the basis upon which EPA made its decision. Finally, EPA did not include, in the section on the Executive Order, any explanation of why a planned regulation is preferable to other “potentially effective and reasonably feasible alternatives” in 9 of 17 rulemakings. Appendix IV provides details of our analysis of EPA *Federal Register* notices for the 17 rulemakings that we determined to be subject to the Executive Order’s regulatory requirements.

In some cases, EPA’s preamble discussion of its compliance with the Executive Order went beyond identifying its requirements, while at least one other agency responsible for rules potentially concerning risks to children does not routinely address the order in its *Federal Register* notices of regulations. For example, some EPA notices included information on data gaps that limited EPA’s ability to more fully address the order’s requirements. In the notice for the *National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment* rule, EPA stated that data were not adequate to conduct a quantitative risk assessment specifically for children and that EPA assumed the same risk for children as for the population as a whole when evaluating regulatory alternatives. In contrast, the Food and Drug Administration does not appear to have discussed the Executive Order in its notices. This includes its notice on the final regulation—*Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation*—issued in July 2009, even though the regulation was economically significant and concerned a risk that disproportionately affects children.

In Recent Years, EPA Has Not Fully Utilized Its Office of Children’s Health and Other Child-Focused Resources

EPA’s Office of Children’s Health has recently had inconsistent leadership and direction, and the agency has not fully utilized other child-focused resources, such as its regional children’s health coordinators and its Advisory Committee.

EPA's Children's Health Protection Office Has Lacked Committed and Consistent Leadership

EPA's Office of Children's Health experienced multiple changes in leadership over the last several years, impairing its ability to fulfill its priorities and commitments. From 2002 to 2008, the office had four acting directors and no permanent director.⁵³ EPA staff told us the Office of Children's Health had difficulty maintaining focus because of the varied priorities and initiatives of each director. For example, in 2007, the acting director tasked office staff to form workgroups and collaborate with senior program office staff across the agency in response to a set of recommendations from the Advisory Committee. The committee had recommended expanding research and committing additional EPA infrastructure to children's health, among other things, and the Administrator and acting director had committed to addressing the recommendations. The office's subsequent acting director eliminated the workgroups, and the office has yet to meaningfully address the Advisory Committee's recommendations. The committee has previously noted leadership challenges in the office, writing in a December 2002 memo to the Administrator that the office could not continue to play a key role within EPA and across the nation without permanent leadership. In May 2004, EPA's Inspector General reported that the lack of a permanent director may have a negative impact on the longevity and importance of the children's environmental health program within EPA.⁵⁴

We have previously reported that career government officials in leadership positions can help provide the long-term focus needed to institutionalize reforms that political appointees' often more limited tenure does not permit.⁵⁵ Committed and consistent leadership is particularly important to the Office of Children's Health. Its mission is broad and far reaching, requiring continuous integration and communication with other EPA offices. For example, the office participates frequently in agencywide workgroups such as the Science Policy Council and the Risk Assessment Forum. The office also contributes expertise on science issues within EPA. For instance, it works with agency scientists on how to consider age-

⁵³The first Director of the Office of Children's Health served almost 5 years, from 1997 through 2002. The four subsequent acting directors, from 2002 to 2008, served an average of 2 years.

⁵⁴EPA Office of Inspector General, *The Effectiveness of the Office of Children's Health Protection Cannot Yet Be Determined Quantitatively*, Report No. 2004-P-00016 (Washington, D.C.: May 17, 2004).

⁵⁵GAO, *Management Reform: Elements of Successful Improvement Initiatives*, GAO/T-GGD-00-26 (Washington, D.C.: Oct. 15, 1999).

specific biological differences when conducting exposure and quantitative risk assessments. Leadership is also important because the office is supported by few resources and has a small number of staff, and because responsibility for implementing agencywide children's health priorities ultimately resides with EPA's program and regional offices. These conditions necessitate a proactive leader who can secure commitments from other parts of EPA to develop children-focused cross-agency activities.

We also found that the effectiveness of the Office of Children's Health has declined in the absence of direct and meaningful support from EPA's Administrator. In our report, we wrote that sustained top leadership commitment is the single most important element in successfully implementing organizational change and that this commitment is most prominently shown through personal involvement of top leaders in developing and directing reform efforts.⁵⁶ In 1997, EPA's then-Administrator provided the first director of the Office of Children's Health with the necessary support to pursue initiatives by, for example, endorsing the director's decision to review the extent to which children's environmental health was considered in EPA's research budget and regulatory and science policies. EPA staff told us that the Administrator also endorsed the office's work with the Office of Research and Development to incorporate children's health concerns into the agency's exposure assessment guidelines, cancer guidelines, and its database on chemical risks. In carrying out these initiatives, the former director had frequent contact with the Administrator, and was invited to all Administrator staff meetings, usually attending two each week. At these meetings, the director had the opportunity to speak directly with the Administrator's chief of staff and other EPA political appointees on children's health issues. Between 2001 and 2003, EPA's subsequent Administrator maintained a similar level of support for the director of the Office of Children's Health. For example, the Administrator gave the director significant responsibility for representing EPA at international children's health conferences. According to three former directors of the office, from 2003 until the 2009 installation of the new permanent director of the Office of Children's Health, the office directors have not been given high-profile responsibility for representing the agency. Furthermore, they have not had the same level of access to the Administrator, having no longer been invited to the Administrator's staff meetings. The

⁵⁶GAO, *Diversity Management: Expert-Identified Leading Practices and Agency Examples*, GAO-05-90 (Washington, D.C.: Jan. 14, 2005).

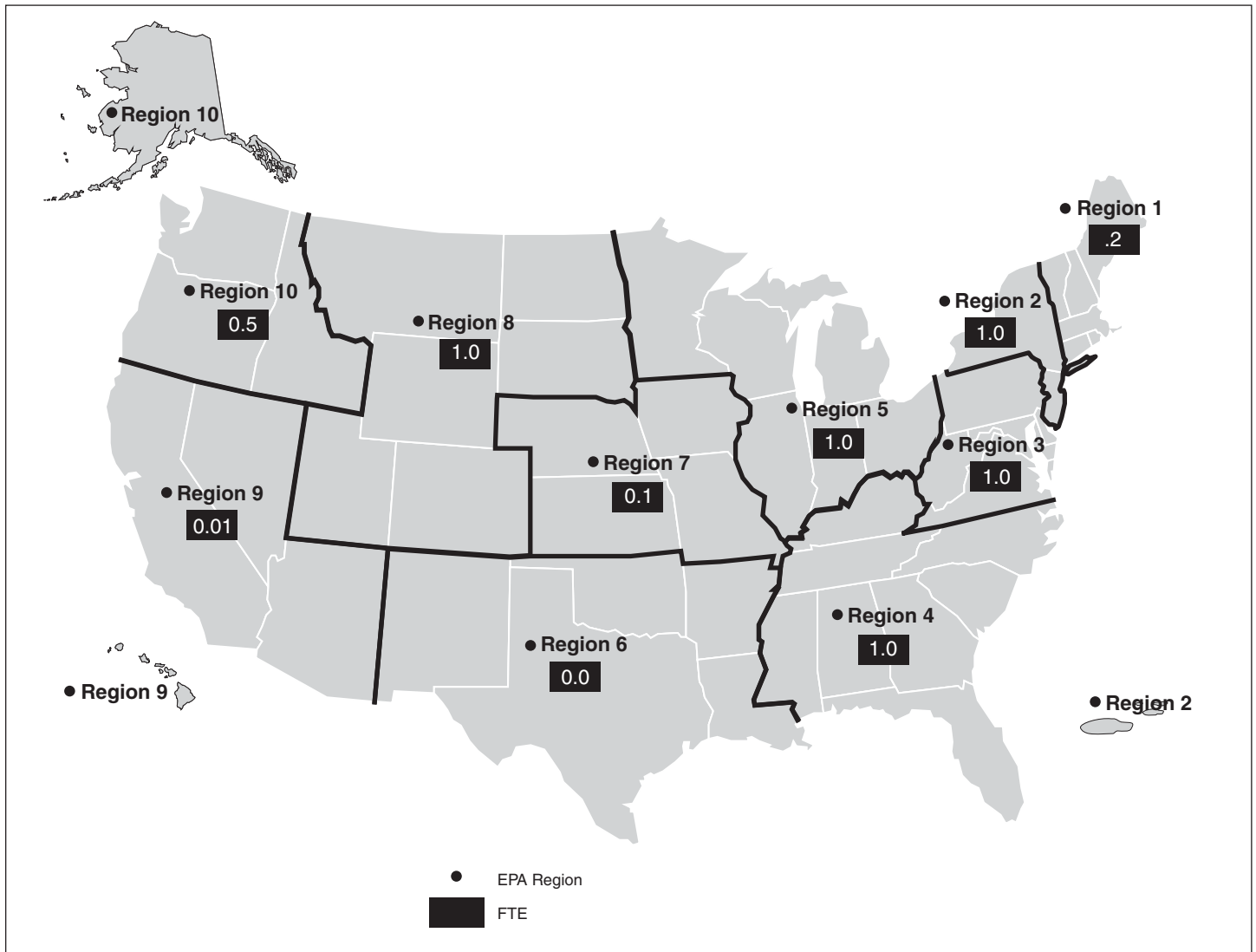
current director recently told us that, while he does not attend the Administrator's regular senior-level meetings (i.e., with the assistant and regional administrators), he believes he has had the level of access to the Administrator that he needs.

EPA's Regions Have Widely Differing Staff Resources for Children's Health and Lack Leadership from Headquarters

EPA's 10 regional offices have widely differing staff resources dedicated to children's environmental health, because the regional administrators make that determination. As shown in figure 3, each region has a designated children's environmental health coordinator, but not every region has a full-time coordinator. Four regions have one-fifth of a staff position or less dedicated to children's health work.⁵⁷ Moreover, Region 6 and Region 9— together covering the states along the U.S. southern border—have one-hundredths of a staff position for children's environmental health. EPA's regional children's environmental health coordinators told us they believe they are often understaffed, and even the full-time coordinators are increasingly being asked to perform additional work not related specifically to children's health. As a result, they are not able to fully dedicate themselves to children's health.

⁵⁷Staff positions are measured in full-time-equivalents (FTE), which generally consists of one or more employed individuals who collectively complete 2,080 work hours in a given year. For example, one FTE can represent either one full-time employee or two half-time employees.

Figure 3: EPA Regional Children’s Environmental Health Coordinator Staffing Levels by Region, in FTEs



Source: EPA.

Note: Region 2 includes Puerto Rico and the U.S. Virgin Islands, Region 9 includes Hawaii, and Region 10 includes Alaska.

In addition, EPA’s regional children’s health coordinators told us their roles are neither set by the Office of Children’s Health nor set to directly support agencywide, children-specific goals or strategies. Although the office facilitates information sharing among regional coordinators, primarily through monthly conference calls and an annual meeting, the 10

regional administrators determine the responsibilities, resources, and organizational placement of the children’s environmental health coordinators within their respective region. For example, one EPA deputy regional administrator identified, as priority areas, three contaminants that pose risks to children—diesel, lead, and radon. The children’s environmental health coordinator in that region subsequently sought resources from the program office to determine how to address these priorities and collaborate with ongoing projects in the region. In another region, priority setting was done from the “bottom up,” driven largely by the availability of external (non-EPA) funding from sources such as nonprofit organizations. In addition, the Office of the Administrator has a lead coordinator who serves as a liaison between the regional offices and the eight suboffices within the Office of the Administrator (including the Office of Children’s Health), but the lead also has a limited role determining EPA’s children’s health activities, with approximately one-eighth of their time working with the Office of Children’s Health.

According to Office of Children’s Health officials, most EPA regions do not have a dedicated budget to support the children’s health coordinators. Often, coordinators must take the initiative to obtain assistance, or get logistical support, from other staff from the EPA branch or division in which they are located. As shown in table 3, the organizational placement of the children’s coordinators also varies widely across the regions. That regional structure has led to differing priorities across regions, which may be appropriate in some circumstances when coordinators need to respond to unique regional children’s health challenges, but does not provide a consistent organizational mechanism that integrates the Office of Children’s Health or institutionalizes the Administrator’s top children’s health priorities across the regions.

Table 3: Placement of EPA’s Regional Children’s Health Coordinators within the Offices of the Regional Administrator

EPA region	Organizational placement
1	Office of Public Affairs
2	Office of Strategic Programs
3	Environmental Assessment and Innovation Division Office of Environmental Innovation
4	Air, Pesticides and Toxics Management Division Pesticides and Toxics Substances Branch Children’s Health, Lead and Asbestos Section

EPA region	Organizational placement
5	Land and Chemicals Division Chemical Management Branch
6	Multimedia Planning and Permitting Division Toxics Branch
7	Office of Public Affairs
8	Office of Partnerships And Regulatory Assistance State Partnerships and Sustainable Practices Program
9	Office of Public Affairs
10	Office of Ecosystems, Tribal, and Public Affairs Ecosystems, Community Health, and Environmental Justice Branch

Source: GAO based on EPA information.

According to EPA officials, a key factor in ensuring effective regional children’s health coordinators is strong leadership and direction from the EPA Administrator and other top EPA officials. While regional administrators and other managers were involved in agencywide strategy and priority setting exercises related to children’s health issues starting in early 2001, such efforts have not taken place since 2003. At present, there is no formal, agencywide effort in which EPA’s regional or deputy administrators involve themselves in children’s health issues. Instead, EPA staff told us that many EPA regions react to children’s health crises, rather than proactively supporting programs to prevent children’s health problems before they arise. Furthermore, regional administrators may or may not take direction from the Office of Children’s Health, and several EPA officials stated that the office has rarely communicated its priorities to the EPA regional administrators or deputy regional administrators.⁵⁸ The office recently told us that the new director has discussed his five-point approach in a call with the deputy regional administrators and visited four regional offices to discuss children’s health with regional staff and managers.

⁵⁸EPA’s Inspector General recommended in his 2004 report that coordination be reflected in EPA’s strategic plan objectives and in relevant output and outcome performance indicators.

EPA Has Made Little Use of Its Children’s Health Protection Advisory Committee

In September 2008, we testified that EPA had not proactively used its Children’s Health Protection Advisory Committee to maintain a focus on protecting children’s environmental health.⁵⁹ As we said earlier, the Advisory Committee was established to provide advice, consultation, and recommendations to EPA in the areas of research, community outreach, and the development of regulations, guidance, and policies. EPA rarely sought out the Advisory Committee’s advice in those areas, despite convening the committee 33 times between 1998 and 2008 for presentations and discussions with EPA and non-EPA officials. We identified only four instances where EPA specifically asked for the committee’s advice on research, three instances on outreach, four instances on regulations, and two instances on guidance. We did not identify any instances where EPA sought out the committee’s advice on policies, including the Policy on Evaluating Health Risks to Children, which has not been updated since it was established in 1995.

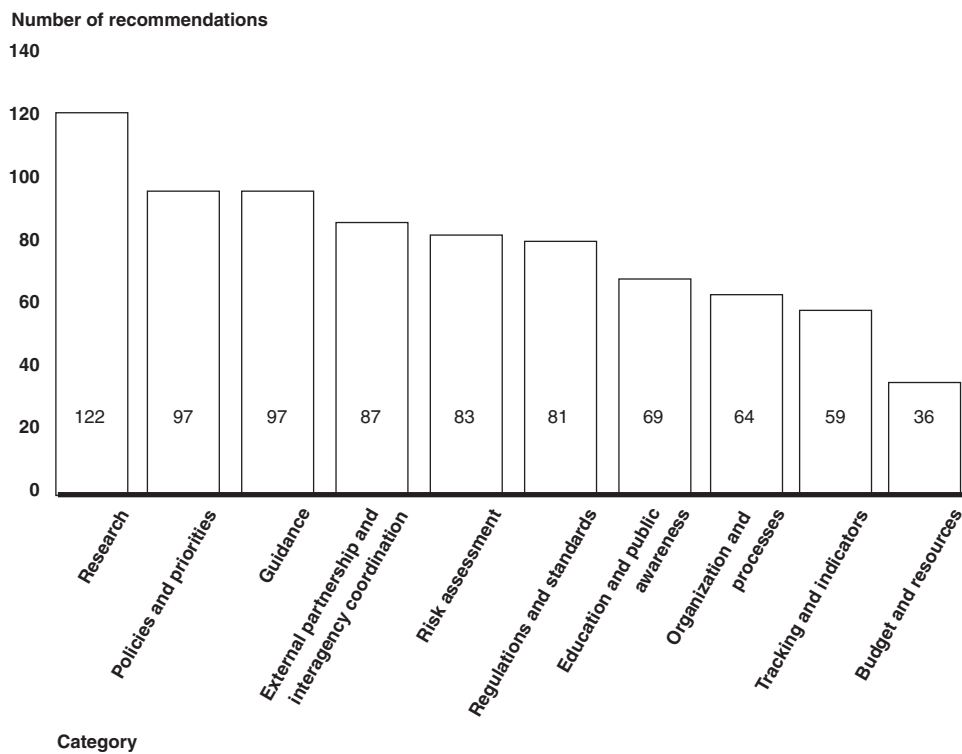
Nonetheless, the members of the Advisory Committee drafted and approved 74 letters to the Administrator between 1998 and 2008, to which EPA responded 53 times (about 73 percent). Those letters contained a range of information, advice, and recommendations. The Advisory Committee’s letters offered EPA hundreds of recommendations about a variety of topics related to reducing environmental health risks to children. We identified 607 recommendations during our review of the Advisory Committee’s letters. A small number of letters contained recommendations relating to multiple children’s environmental health issues, such as a May 2008 letter with recommendations about mercury regulation, farm worker protection standards, organophosphate pesticides, and air quality. However, most letters contained recommendations on a single issue. The number of recommendations varied from year to year, ranging from 120 in 2000 to 20 in 2001. We placed the 607 recommendations into 10 categories that demonstrate the breadth and depth of the Advisory Committee’s concerns. Figure 4 shows the number of recommendations in each category. Some recommendations were placed into multiple categories when, for example, a recommendation was related to “research” and “policy and procedures.”⁶⁰

⁵⁹GAO-08-1155T.

⁶⁰For example, we placed the following June 2008 Advisory Committee recommendation into both the research and the policy and procedure categories: “Additional research on children’s vulnerabilities to health impacts of climate change should also be a priority for the agency as a whole in the future.”

The largest category of recommendations concerned how EPA conducts, prioritizes, and utilizes research on children’s environmental health. The next largest categories involved the agency’s policies and priorities and the development and use of guidance documents.

Figure 4: Number of Children’s Health Protection Advisory Committee Recommendations by Category



Source: GAO analysis of Advisory Committee letters.

Note: Because recommendations may appear in multiple categories, the number of recommendations shown in the figure exceeds the total number of recommendations.

In our September 2008 testimony, we also stated that EPA had not substantially addressed key Advisory Committee recommendations. For example, EPA had not specifically acknowledged 11 of the Advisory Committee’s 23 recommendations concerning proposed revisions to the NAAQS for particulate matter, ozone, and lead. EPA did provide the Advisory Committee with official response letters to six of its seven NAAQS-related letters, but generally did not acknowledge or was noncommittal to the Advisory Committee’s recommendations. Instead, it provided a generic statement about considering the recommendations with all other public comments. We also testified that EPA had not fulfilled

its commitment to address key recommendations submitted to EPA by the Advisory Committee on the 10th anniversary of the Executive Order. The Advisory Committee's April 10, 2007, letter provided recommendations in seven areas for renewing EPA's vision on children's environmental health and its commitment to the principles outlined in the order. EPA's June 13, 2007, response letter directed the Office of Children's Health to work collaboratively with program offices across the agency and committed the agency to working with the Advisory Committee to review these recommendations. However, while the office established workgroups within its Children's Health Advisory Management Partners group to address each of the seven areas outlined by the Advisory Committee, a new acting director stopped the process in late 2007.

In our September 2008 testimony, we recommended that the Administrator examine ways to more proactively use the Advisory Committee to reinvigorate the agency's focus on protecting children's health. Since that time, EPA's Administrator and the Director of EPA's Office of Children's Health have met with the Advisory Committee in March and July 2009, respectively. In his remarks to the Advisory Committee, the Director expressed his commitment to more proactively use the Advisory Committee to support EPA's efforts to protect children's health. Specifically, he said that EPA could more effectively use the Advisory Committee for advice in developing regulations, and he asked for input on how to engage the Advisory Committee early and often in rulemakings. He also said that the committee could provide leadership in the area of science policy at EPA. He told the committee that it could advise EPA on developing policies for conducting research and making decisions in instances where EPA lacks conclusive information about children's vulnerabilities. For example, the Director recently asked the committee to provide EPA with advice on its draft school siting guidelines.

Opportunities Exist for EPA to Lead and Coordinate National Efforts to Protect Children from Environmental Threats

The Executive Order provides EPA with opportunities for leadership and coordination across the federal government. Key provisions of the Executive Order, specifically an interagency task force that reports to the President on federal research priorities—were allowed to lapse in 2005. There are other federal opportunities to set national goals and indicators related to children's environmental health, such as the Interagency Forum on Child and Family Statistics and Healthy People 2020.

Task Force Provided High-level Opportunities for Strategy Development and Interagency Coordination until It Expired in 2005

The President's Task Force on Children's Environmental Health Risks and Safety Risks was authorized by the Executive Order in April 1997 for a period of 4 years to provide high-level leadership and interagency coordination on children's environmental health. It comprised nine cabinet officials and seven White House office directors and was co-chaired by the Administrator of EPA and the Secretary of the Department of Health and Human Services. The Task Force convened five times for meetings in October 1997, April 1998, January 1999, September 1999, and October 2001. As part of National Children's Health Month in October 2001, the President extended the Task Force for 2 years. According to EPA officials, the Administrator urged the President to continue the Task Force; in April 2003, the President extended it for a final 2 years. However, the final order eliminated the provision for reassessing the need for continuance of the Task Force, which was not convened after the October 2001 meeting. According to EPA officials involved on the steering committee, the agency was not able to convene the Task Force thereafter, for reasons related to new priorities following the September 11, 2001, terrorist attacks. Nonetheless, a senior career-level staff steering committee continued to meet until 2005 to coordinate and implement the strategies that the Task Force developed to address the threats to children's health.

The Task Force contributed to eight areas which related to children's health, including the establishment of the National Children's Study, the largest long-term study of environmental influences on children's health and development. The study was proposed and developed through the cooperation of four agencies, including EPA, to examine the effects of environmental influences on the health and development of more than 100,000 children across the nation, following them from before birth until age 21. It was initiated as part of the Children's Health Act of 2000.

The Task Force also identified four major environmental and safety threats to children—asthma, developmental disabilities (including lead poisoning), cancer, and unintentional injuries—and created national strategies for each of them. In its strategy documents, the Task Force recognized that an integrated solution was needed across the federal government to address the complex interaction between a child's biology, behavior, and the physical, chemical, biological, and social environment. According to the children's health experts with whom we spoke—including EPA's first senior advisor for children's health and the first director of the office—the Task Force provided critical leadership on several important initiatives such as the National Children's Study and the Healthy School Environments Assessment Tool (HealthySEAT). These national programs focus heavily on the environmental influences on

children's health, with the National Children's Study examining the role of environmental factors on health and disease and Healthy SEAT offering school districts a self-assessment tool for identifying and evaluating environmental, safety, and health hazards.

In addition, the departments and agencies that made up the Task Force partnered to prepare a fiscal year 2001 interagency budget initiative to fund the Task Force's initiatives in the four priority areas. The Secretary of Health and Human Services and the Administrator of EPA submitted the request to OMB with the recommendation that it be included as part of the President's budget request that year. EPA officials told us that OMB's involvement helped ensure that adequate funds were available to these agencies to address children's health. This interagency budgeting effort did not continue past the last meeting of the Task Force in 2001.

Since the Task Force's expiration, EPA and the Department of Health and Human Services no longer have a high-level infrastructure or mandate to coordinate federal strategies for children's environmental health and safety. According to the EPA staff and children's health experts with whom we spoke, had the Task Force continued, it could have helped the federal government respond to the health and safety concerns that prompted the 2007 recall of 45 million toys and children's products. Furthermore, since the Task Force provision of the Executive Order expired in 2005, the Task Force's reports are no longer generated. Those reports collected and detailed the interagency research, data, and other information "necessary to enhance the country's ability to understand, analyze, and respond to environmental health risks to children."

The Task Force was also charged with preparing reports on research, data, and other information that would enhance the federal government's ability to understand, analyze, and respond to environmental health risks to children. In the 2003 order to extend the Task Force, the President also directed that each report detail the accomplishments of the Task Force from the date of the preceding report. Through the biennial reporting process, each agency on the Task Force identified and described key data needs related to environmental health risks to children that had arisen in the course of the agency's programs and activities. The reports were made available to the public and intended for use by the Office of Science and Technology Policy and the National Science and Technology Council to establish national research priorities.

EPA Has Had Varied Involvement in Federal Interagency Forum on Child and Family and Children Statistics

The Executive Order also formally established the Interagency Forum on Child and Family Statistics, made up of representatives from federal statistics and research agencies and convened by the Director of OMB.⁶¹ The order required the forum to publish an annual report on the most important indicators of the well-being of the country's children. As a result, the forum has published America's Children: Key National Indicators of Well-Being each year since 1997. The 2003 amendments to the Executive Order required the forum to begin publishing the report biennially. Accordingly, the forum issued a brief report in 2004 to highlight selected indicators, and it publishes the full report on alternate years. The Interagency Forum also updates all indicators and background data each year on its Web site.⁶²

According to the forum's 2009 report:

One important measure of children's environmental health is the percentage of children living in areas in which air pollution levels are higher than the allowable levels of the Primary National Ambient Air Quality Standards. These standards, established by the U.S. Environmental Protection Agency under the Clean Air Act, are designed to protect public health, including the health of susceptible populations such as children and individuals with asthma. Ozone, particulate matter, sulfur dioxide, and nitrogen dioxide are air pollutants associated with increased asthma episodes and other respiratory illnesses. Lead can affect the development of the central nervous system in young children, and exposure to carbon monoxide can reduce the capacity of blood to carry oxygen.

Table 4 shows the key national indicators for physical environment and safety from the 2009 report.

⁶¹The forum was founded in 1994 to foster the coordination and integration of the collection and reporting of data on children and families.

⁶²<http://childstats.gov>.

Table 4: Key Physical Environment and Safety Indicators of Children’s Well-Being, 2009

Indicator	Measure	Previous value (year)	Most recent value (year)	Change between years
Outdoor and indoor air quality	Children ages 0-17 living in counties in which levels of one or more air pollutants were above allowable levels	66% (2006)	66% (2007)	NS
Drinking water quality	Children served by community water systems that did not meet all applicable health-based drinking water standards	9% (2006)	8% (2007)	NS
Lead in the blood of children	Children ages 1-5 with blood lead level greater than or equal to 10 µg/dL	2% (1999-2002)	* (2003-2006)	NS
Housing problems	Households with children ages 0-17 reporting shelter cost burden, crowding, and/or physically inadequate housing	40% (2005)	43% (2007)	NS
Youth victims of serious violent crimes	Serious violent crime victimization of youth ages 12-17	14 per 1,000 (2005)	10 per 1,000 (2006)	NS
Child injury and mortality	Injury deaths of children, ages 1-4	13 per 100,000 (2005)	12 per 100,000 (2006)	NS
	Injury deaths of children, ages 5-14	8 per 100,000 (2005)	7 per 100,000 (2006)	↓
	Injury deaths of adolescents, ages 15-19	50 per 100,000 (2005)	50 per 100,000 (2006)	NS

Source: Forum on Child and Family Statistics, America’s Children: Key National Indicators of Well-Being, 2009.

Notes:

* = Percentage is not shown because sample is too small to provide a statistically reliable estimate.

NS = No statistically significant change.

↑ = Statistically significant increase.

↓ = Statistically significant decrease.

The forum’s reports provide substantial detail about each indicator, including its relationship to children’s health, and identify important areas where indicators are needed. For example, the 2009 report identified the need for a broader set of indicators on (1) body burden measurements (i.e., levels of contaminants in blood and urine) to characterize children’s exposures, and (2) environmental quality to assess indoor air contaminants other than environmental tobacco smoke (e.g., pesticides) in homes, schools, and day care settings and for cumulative exposures to multiple environmental contaminants that children encounter daily.

Our analysis of EPA’s involvement in the forum showed that the agency has not been consistently involved over the years. EPA had nearly no involvement in the first three reports—1997, 1998, and 1999—and, not surprisingly, those reports contained no indicators related to children’s environmental health. Beginning with the 2000 report, the Director of the

Office of Children's Health helped lead the establishment of an indicator on air pollution (i.e., the NAAQS). That report identified the need for indicators to describe children's potential exposure to contaminants in drinking water and food. Subsequent reports began including an expanded set of indicators, including one for drinking water. Beginning in 2003, EPA's newly created Office of Environmental Information led EPA's involvement. In 2008, EPA's Office of Children's Health was again made the lead office for the agency. The official contact for the office is its Director of the Child and Aging Health Protection Division, who recently told us that the office again is participating and coordinating with other offices such as the EPA's Office of Policy, Economics, and Innovation.

Additional Federal Efforts to Address Children's Environmental Health Risks

In addition to the provisions of the Executive Order, there are other federal opportunities to address children's environmental health, including Healthy People 2010 and Healthy People 2020 and the international commitments to environmental health through the G8 (Group of Eight) countries. Healthy People is led by the Department of Health and Human Services and is composed of 28 focus areas with a total of 467 objectives and targets, including 17 on environmental quality. Within each area, Healthy People selected a few leading indicators. The Healthy People 2010 leading indicators for environmental quality are:

- reduce the proportion of children, adolescents, and adults that are exposed to ozone above the EPA standard from 43 percent (in 1997) to 0 percent (by the year 2010), and
- reduce the proportion of nonsmokers exposed to environmental tobacco smoke (i.e., secondhand smoke) from 65 percent (in 1988-1994) to 45 percent (in 2010).

According to Healthy People 2010, these indicators were selected because poor air quality contributes to respiratory illness, cardiovascular disease, and cancer. For example, asthma can be triggered or worsened by exposure to ozone, and while the overall death rate from asthma increased 57 percent from 1980 to 1993, for children it increased 67 percent. Healthy People 2010 is national in scope and includes identifying health indicators, collecting data, and reporting on progress toward meeting a range of health goals. In fact, the data sources for tracking most environmental indicators come from EPA.

EPA's environmental regulations and standards are key to achieving national environmental health objectives. EPA was not a lead federal

agency in efforts to develop the Healthy People 2010 goals and indicators for environmental quality or the Federal Interagency Workgroup for Healthy People 2020. The agencies involved in Healthy People 2010 and 2020 are the Agency for Toxic Substances and Disease Registry, CDC, and the National Institutes of Health—each within the Department of Health and Human Services, the department that formerly co-chaired the Task Force with EPA.

With regard to international agreements, while the United States reiterated its commitment to protect children from environmental threats at the most recent meeting of the G8 environmental ministers, EPA has not undertaken an evaluation of its progress since 2002 or considered opportunities for a broader leadership role. The environmental ministers of the G8 countries declared that children’s environmental health was a shared priority among the eight countries at their meeting in Miami, Florida, in May 1997.⁶³ They developed *the Declaration of the Environmental Leaders of the Eight on Children’s Environmental Health* (Miami Declaration) that provided a framework for domestic, bilateral, and international actions by member nations to improve protection of children’s health from seven environmental threats. In 2002, the Government of Canada published a status report on the implementation of the Miami Declaration. Table 5 lists the seven issues and key commitments, along with a brief progress summary from Canada’s report. Notably, the status update for U.S. commitments on lead and air quality refer to two of the national strategies developed by the now-defunct President’s Task Force.

⁶³The G8 countries are Canada, France, Germany, Italy, Japan, Russia, the United Kingdom, the United States, as well as the European Commission. The most recent meeting of the G8 took place in Italy in April 2009.

Table 5: Summary of Commitments and U.S. Implementation of the 1997 Miami Declaration, as of 2002

Children’s environmental health issue	Key commitment	Status update
Risk assessment and standard setting	“We pledge to establish national policies that take into account the specific exposure pathways and dose-response characteristics of children when conducting environmental risk assessments and setting protective standards.”	Implementation of the Food Quality Protection Act requires an additional 10-fold margin of safety for threshold effects
Lead	“We call for further actions that will result in reducing blood lead levels in children to below 10 micrograms per deciliter. Where this blood lead level is exceeded, further action is required.”	Implementation of the federal Strategy to Eliminate Childhood Lead Poisoning by 2010
Microbiologically safe drinking water	“We agree to focus increased attention on drinking water disinfection, source water protection and sanitation....”	There are new final rules for Cryptosporidium and disinfection by-products
Air quality	“We undertake to reduce air pollution in our respective countries. We agree to exchange information on indoor air health threats and remedial measures.”	Implementation of Asthma and the Environment: An Action Plan to Protect Children
Environmental tobacco smoke (ETS)	“We agree to cooperate on education and public awareness efforts aimed at reducing children’s exposure to environmental tobacco smoke.”	A new national public information campaign focuses on reducing at-risk children’s exposure to ETS and other indoor and outdoor asthma triggers
Endocrine disrupting chemicals (EDC)	“We encourage continuing efforts to compile an international inventory of research activities, develop an international science assessment...identify and prioritize research needs and data gaps, and develop a mechanism for coordinating and cooperating on filling research needs. We pledge to develop cooperatively risk management or pollution prevention strategies, as major sources and environmental fates of endocrine disrupting chemicals are identified and will continue to inform the public as new knowledge is gained.”	The United States has a research program on EDCs and a screening program
Climate change	The declaration does not contain any specific commitments on this issue but recognized that “action must be taken to confront the problem of global warming” given that “children and future generations face serious threats to their health and welfare from changes in the Earth’s climate.”	Global Change Research Program includes human health assessments

Source: Excerpts from Government of Canada, *Status Report on the Implementation of the 1997 Declaration of the Environment Leaders of the Eight on Children’s Environmental Health* (2002).

EPA has not undertaken an evaluation of its progress toward the country’s international commitments for children’s environmental health. Nor has the United States taken a leadership role in updating or reissuing specific new commitments since the 1997 declaration. At the April 2009 meeting of the G8, the EPA Administrator cited the declaration, highlighted

subsequent U.S. activities, and provided examples of other countries' actions—including Europe's new chemicals policy and the World Health Organization's Children's Environment and Health Action Plan.⁶⁴ The Administrator closed her remarks to the environmental ministers by stating,

We have learned much in the last 12 years about the ways that environmental exposures uniquely affect children. With that increased knowledge, our sense of urgency for further action on children has also increased....The U.S. government, under this new administration, will keep faith with the promise we've made to future generations. I hope we can continue the work we started in 1997, renewing our commitment to protect children from environmental threats where they live, learn, work and play.

Conclusions

Since the President signed Executive Order 13045 in 1997, every EPA Administrator has stated that children's environmental health is a priority at the agency. However, the momentum seen in the goals, strategies, and accomplishments for children's health that resulted from that initiative more than a decade ago has not been sustained through succeeding EPA administrators. Instead, we have seen diminished leadership, planning, and coordination at EPA and across the federal government with regard to children's environmental health. In the intervening years, research has only further substantiated the importance that environmental exposures have during development—from before birth, through early childhood and adolescence, and into adulthood. The possibility that exposure to environmental contaminants may have lifelong health consequences for an individual person—and subsequent generations—is a paradigm shift in sophistication from the idea that “children are not just little adults,” an idea that was groundbreaking in the early 1990s. In order to continue making progress toward protecting children from environmental health threats, we believe EPA needs to reinvigorate its leadership and focus on children's environmental health in concrete and actionable ways.

Notwithstanding the actions that EPA can take on its own, leadership from outside the agency will likely be needed for sustained progress toward protecting children from current and emerging environmental threats. As we stated in our testimony, the Children's Health Protection Advisory Committee and the President's Task Force on Children's Environmental

⁶⁴Administrator Lisa P. Jackson, Remarks at the G8 Environmental Minister's Meeting Children's Health Event, April 24, 2009.

Health Risks and Safety Risks have served as two such entities. The Advisory Committee has provided strategic, specific, and often unsolicited advice to EPA over the past decade. We continue to believe that EPA could do more to fully utilize that body of experts to inform EPA's developing regulations and generally support the agency's efforts to protect children's health.⁶⁵ Engaging the committee early and often in rulemakings and providing leadership in the area of science policy and other areas where EPA may lack conclusive information about children's vulnerabilities would take advantage of the Advisory Committee's expertise and reinvigorate its original purpose. The President's Task Force that expired in 2005 provided high-level infrastructure to coordinate federal strategies for children's environmental health and safety problems such as asthma, as well as data needs. Furthermore, the Task Force documented its accomplishments to the President in reports that detailed its members' efforts to enhance the nation's ability to understand, analyze, and respond to environmental health risks to children. EPA staff and children's health experts told us the Task Force could help the federal government respond to national health and safety concerns, such as recalls of toys and other children's products. Because the Task Force included nine cabinet officials and seven White House office directors and was co-chaired by the Administrator of EPA and the Secretary of Health and Human Services, it provided the leadership and authority needed to address children's environmental health issues of national scope. We see opportunity for EPA to take a leadership role and identify, assess, and address the environmental health challenges of the 21st century such as low levels of toxic chemicals that may cause cancer and induce reproductive or developmental changes in the nation's children.

Recommendations for Executive Action

To help ensure that EPA assumes high-level leadership and develops strategies and structures for coordinating efforts addressing children's environmental health both within the agency and throughout the federal government, we are making eight recommendations for executive action.

To maximize opportunities to institutionalize children's health throughout the agency, we recommend that the EPA Administrator take the following actions:

⁶⁵ [GAO-08-1155T](#).

-
- update and reissue a child-focused strategy, such as the 1996 National Agenda, to articulate current national environmental health priorities and emerging issues;
 - strengthen the data system that identifies and tracks development of rulemakings and other actions to ensure they comply with the 1995 policy on evaluating health risks to children;
 - re-evaluate the 1995 policy to ensure its consistency with new scientific research demonstrating the risks childhood exposures can have on risks for disease in later lifestages;
 - ensure that the EPA's 2009-2014 strategic plan expressly articulates children-specific goals, objectives and targets;
 - re-evaluate the mission of the Office of Children's Health Protection and its director to make the office an agencywide champion for implementation of a reissued national children's environmental health agenda, policy, and related goals in the next EPA strategic plan;
 - establish key children's environmental health staff within each program office and regional office, with linkages to the Office of Children's Health, to improve cross-agency implementation of revised priorities and goals, and ensure coordination and communication among EPA's program offices;
 - use the Children's Health Protection Advisory Committee proactively as a mechanism for providing advice on regulations, programs, plans, or other issues; and
 - ensure participation, to the fullest extent possible, by the Office of Children's Health or other key officials on the interagency organizations identified in Executive Order 13045.

Matter for Congressional Consideration

Because EPA alone cannot address the complexities of the nation's challenges in addressing environmental health risks for children, we encourage Congress to re-establish a government-wide task force on children's environmental health risks, similar to the one previously established by Executive Order 13045 and co-chaired by the Administrator of EPA and the Secretary of Health and Human Services. We encourage Congress to charge it with identifying the principal environmental health threats to children and developing national strategies for addressing them. We further encourage Congress to establish in law the Executive Order's

requirement for periodic reports about federal research findings and research needs regarding children's environmental health.

Agency Comments and Our Evaluation

We provided EPA with a draft of this report for review and comment. EPA stated that the report accurately portrays the agency's challenges in addressing children's environmental health, and sets forth sound recommendations on steps that could be taken to better incorporate protection of children's health as an integral part of EPA's everyday business. EPA also commented that implementing the recommendations provided in this report will bring the agency a long way to achieving its goals for protecting children's health. EPA's written comments are in appendix V. In addition, EPA provided technical comments, which we incorporated into the report as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from its issuance. At that time, we will send copies of this report to interested congressional committees, the Administrator of the Environmental Protection Agency, and other interested parties. The report also will be available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VI.



John B. Stephenson
Director, Natural Resources
and Environment

Appendix I: Scope and Methodology

Our report objectives were to examine (1) the extent to which the Environmental Protection Agency's (EPA) policies, plans, and guidance have served to institutionalize the agency's consideration of children's environmental health; (2) the extent to which EPA has utilized its children's health office and other child-focused resources; and (3) what opportunities exist for EPA to provide national leadership in addressing current and emerging environmental risks to children's health.

To address our first objective, we obtained and analyzed key EPA children's health-related policies, strategic and performance plans, guidance documents, and selected children's indicator reports, and referred to long-established quality management criteria from the Government Performance Results Act. We considered EPA's "2006-2011 Strategic Plan: Charting Our Course," "2003-2008 Strategic Plan: Direction for the Future," "EPA Strategic Plan: 2000-2005," "EPA Strategic Plan: 1997-2003," as well as EPA's forthcoming strategic plan, "2009-2014 Strategic Plan: Change Document," which was in draft form at the time of our review. We analyzed the goals, objectives, and strategic targets of these documents in order to determine the extent that they address children's health. We reviewed EPA's performance and accountability reports to identify performance measures associated with identified children's health objectives and strategic targets. We discussed the plans and reports with officials from EPA's Office of the Chief Financial Officer, including staff from the Office of Planning, Analysis, and Accountability. We also reviewed OMB Circular No. A-11 on guidance to agencies preparing materials required for strategic plans and annual program performance reports. We reviewed EPA *Federal Register* notices for regulations subject to the regulatory requirements of the order as well as documents detailing EPA's rulemaking for its National Ambient Air Quality Standards for Particulate Matter published in October 2006. We also reviewed children's health data that EPA maintains in its regulatory tracking database.

To address our second objective, we used NVivo, a content analysis software package, to analyze 35 Advisory Committee meeting agendas and related summaries derived from meetings held bi- or tri-annually between December 1997 and July 2009. Content analysis is a methodology for structuring and analyzing written material. We also used the software to analyze 74 Children's Health Protection Advisory Committee (Advisory Committee) letters sent to EPA and 53 EPA response letters, issued between May 1998 and December 2008. Our internal team of subject matter and methodological experts developed a coding scheme for identifying (1) recommendations, which we defined as any and all

statements made in Advisory Committee letters that advise, ask, request, suggest, or urge EPA to take action; and (2) EPA requests of the Advisory Committee, which we defined as formal or incidental requests for advice or input by EPA to its Advisory Committee. Recommendations were identified in Advisory Committee letters sent to EPA. In some cases, a single sentence contained multiple recommendations. For example, the Advisory Committee wrote “EPA should show leadership in applying stringent mercury controls in our own coal-fired power plants and involve the U.S. in technology transfer to improve emissions in other parts of the world,” which we coded as two recommendations. EPA requests of the Advisory Committee were identified in meeting summaries, which represent the official and complete record of proceedings. Other requests—for example, individually from an EPA official to an individual Advisory Committee member—were not considered requests as the entire Advisory Committee must be informed and consensus must be reached by the Advisory Committee on all matters, as specified in its charter.

To characterize the range of issues recommended to EPA by its Advisory Committee, we developed content analysis categories based on a review of the Advisory Committee’s charter and an initial review of the letters. We then coded each recommendation into one or more of the following 10 categories:

- budget and resources (financing, funding, or the need to change resource levels for a program or issue),
- education and public awareness (providing information to the public through different media outlets),
- organization and processes (how EPA is organized, including how it operates, the form or function of EPA management, and its internal processes and procedures),
- policies and priorities (advising EPA to amend, go forward with, or cease a particular policy or prioritization that directly or indirectly may impact children’s health),
- external partnership and inter-agency coordination (how EPA coordinates or collaborates with other agencies or entities),
- guidance (developing, updating and using guidance documents and related information resources),

- regulations and standards (EPA regulations and its work setting or influencing EPA or government-wide standards),
- research (conducting, funding, utilizing, or prioritizing research that would benefit children’s health),
- risk assessment (development of risk assessment protocols, and selecting assumptions, risk factors, and margins of error), and
- tracking and indicators (tracking environmental pollutants, as well as monitoring such pollutants and/or observing human health outcomes over time).

The content analysis was conducted by two analysts, and discrepancies in coding were discussed and agreement reached between the analysts, or resolved through a third analyst review. Our analysis produced an inventory of Advisory Committee recommendations and EPA requests of the Advisory Committee.

We also interviewed officials from EPA program offices most directly involved with children’s health issues: the Office of Children’s Health Protection, including current and former office directors; the Office of Research and Development; the Office of Pesticide Programs; and the Office of Policy, Economics and Innovation. We interviewed EPA’s regional children’s environmental health coordinators and lead regional coordinator within the Office of the Administrator. To gain further perspective on EPA’s use of its children’s health-focused resources, we interviewed leading children’s health research and policy experts at nonprofit organizations and academic institutions, including those associated with EPA’s Advisory Committee.

To address our third objective, we reviewed the annual reports from the Federal Interagency Forum on Child and Family Statistics to determine the extent of EPA’s involvement in their development. We also interviewed staff involved with the children’s task force and reviewed documents from the Task Force on Environmental Health Risks and Safety Risks to Children, including the strategy documents that were developed. We also reviewed documents related to the G8 Miami Declaration on Children’s Environmental Health, including the 2002 *Status Report on Implementation of the 1997 Declaration of the Environmental Leaders of the Eight on Children’s Environmental Health*.

We conducted this performance audit from November 2008 through January 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: EPA Policy on Evaluating Health Risks to Children



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
THE ADMINISTRATOR

OCT 20 1995

MEMORANDUM

SUBJECT: New Policy on Evaluating Health Risks to Children

TO: Assistant Administrators
General Counsel
Inspector General
Associate Administrators
Regional Administrators

We are establishing a new Agency-wide policy (attached) that will, for the first time, ensure that we consistently and explicitly evaluate environmental health risks of infants and children in all of the risk assessments, risk characterizations, and environmental and public health standards that we set for the nation.

This is not a new idea to the many programs throughout the Agency that currently consider children's health issues in assessing overall risk. This is, however, a major step forward in establishing a consistent nationwide children's environmental health policy. We know that children have a greater potential for exposure to environmental hazards and our assessments of health risks do not always fully take into account the potential effects on this vulnerable population. The National Academy of Sciences has called for policy changes to reflect children's health factors in evaluating environmental risks.

Our new policy answers that call for change and, in doing so, will allow us to make better public health decisions that reflect not just data on adults, but on children whenever possible. By making children a health priority, we expect that this policy will encourage new, much-needed research to provide the child-specific data we will need to thoroughly evaluate the health risks children and infants face from pollution in our air, land, and water. In the long run, healthier children mean healthier adults - a great benefit for the nation.

The policy set forth in this memorandum takes effect November 1, 1995, and is sponsored by the Agency's Science Policy Council, which is charged with evaluating science policy issues of Agency-wide importance. We are confident that each of your offices will work with the Council to ensure a smooth transition to this new policy that is so important to our nation's future.

/s/
Carol M. Browner
Administrator

/s/
Fred Hansen
Deputy Administrator

Attachment

Policy on Evaluating Health Risks to Children

POLICY

It is the policy¹ of the U.S. Environmental Protection Agency (EPA) to consider the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision making process, including the setting of standards to protect public health and the environment. To the degree permitted by available data in each case, the Agency will develop a separate assessment of risks to infants and children or state clearly why this is not done - for example, a demonstration that infants and children are not expected to be exposed to the stressor under examination.

BACKGROUND

When it comes to their health and development, children are not little adults. This maxim has long been understood in the medical community. Documentation of the similarities and differences between children and adults is an integral part of assessing the effects and efficacy of drugs, for example. The National Academy of Sciences has pointed out on more than one occasion^{2,3} that the maxim should hold true with respect to exposure to environmental pollutants, as well.

Children may be more or less sensitive than adults when confronted with an equivalent level of exposure to an environmental pollutant. In many cases, their responses are substantially different - qualitatively and quantitatively - from those exhibited by adults. These age-related variations in susceptibility are due to many factors, including differences in pharmacokinetics, pharmacodynamics, body composition, and maturity of biochemical and physiological functions (for example, metabolic rates and pathways).

In addition, there are often age-related differences in types and levels of exposure. For example, it is known that infants and children differ from adults both qualitatively and quantitatively in their exposures to pesticides in foods. Children eat more food and drink more water per unit of body weight, and the variety of the food they consume is more limited than adults. Children also breathe more rapidly than adults and can inhale more of an air pollutant per pound of body weight than adults. Children's skin and other body tissues may absorb some harmful substances more easily. Children's bodies are not yet fully developed, so exposure to toxic substances may affect their growth and development. Infants' immune systems are not as strong as those of healthy adults, so they are less able to fight off emerging microbial threats such as Cryptosporidium in drinking water.

The Agency is particularly concerned about safeguarding the health of infants and children, who are among the nation's most fragile and vulnerable populations. Therefore, it is important that there be a clear articulation of policy in this regard.

IMPLEMENTATION

¹ This document is a statement of Agency policy and does not constitute a rule. It is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States.

² National Research Council. 1993. Pesticides in the Diets of Infants and Children. National Academy of Sciences Press, Washington, DC.

³ National Research Council. 1994. Science and Judgment in Risk Assessment. National Academy of Sciences Press, Washington, DC.

Appendix II: EPA Policy on Evaluating Health Risks to Children

The policy already is currently being followed in many Programs and regions. The entire Agency will expand implementation activities during the Fall of 1995 as part of the overall implementation of the Administrator's policy on risk characterization. Other related activities and sources of information include the presentation of relevant data in the revised draft Exposure Factors Handbook, and current EPA solicitations of grant proposals for independent studies on risk to children from exposure to a wide range of substances. EPA's 1991 Guidelines for Developmental Toxicity Risk Assessment are also relevant.

This policy is not retroactive; it will apply only to those assessments started or revised on or after November 1, 1995. Any questions relating to the policy and its implementation should be referred to Dr. Dorothy Patton, Executive Director of the Agency's Science Policy Council. She can be reached at 202-260-6600.

Appendix III: Executive Order 13045 and Amendments

19885

Federal Register

Vol. 62, No. 78

Wednesday, April 23, 1997

Presidential Documents

Title 3—

Executive Order 13045 of April 21, 1997

The President

Protection of Children From Environmental Health Risks and Safety Risks

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy.

1-101. A growing body of scientific knowledge demonstrates that children may suffer disproportionately from environmental health risks and safety risks. These risks arise because: children's neurological, immunological, digestive, and other bodily systems are still developing; children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; children's size and weight may diminish their protection from standard safety features; and children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves. Therefore, to the extent permitted by law and appropriate, and consistent with the agency's mission, each Federal agency:

(a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and

(b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.

1-102. Each independent regulatory agency is encouraged to participate in the implementation of this order and comply with its provisions.

Sec. 2. *Definitions.* The following definitions shall apply to this order.

2-201. "Federal agency" means any authority of the United States that is an agency under 44 U.S.C. 3502(1) other than those considered to be independent regulatory agencies under 44 U.S.C. 3502(5). For purposes of this order, "military departments," as defined in 5 U.S.C. 102, are covered under the auspices of the Department of Defense.

2-202. "Covered regulatory action" means any substantive action in a rule-making, initiated after the date of this order or for which a Notice of Proposed Rulemaking is published 1 year after the date of this order, that is likely to result in a rule that may:

(a) be "economically significant" under Executive Order 12866 (a rule-making that has an annual effect on the economy of \$100 million or more or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities); and

(b) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children.

2-203. "Environmental health risks and safety risks" mean risks to health or to safety that are attributable to products or substances that the child is likely to come in contact with or ingest (such as the air we breathe, the food we eat, the water we drink or use for recreation, the soil we live on, and the products we use or are exposed to).

Sec. 3. *Task Force on Environmental Health Risks and Safety Risks to Children.*

Appendix III: Executive Order 13045 and
Amendments

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3-301. There is hereby established the Task Force on Environmental Health Risks and Safety Risks to Children ("Task Force").

3-302. The Task Force will report to the President in consultation with the Domestic Policy Council, the National Science and Technology Council, the Council on Environmental Quality, and the Office of Management and Budget (OMB).

3-303. *Membership.* The Task Force shall be composed of the:

(a) Secretary of Health and Human Services, who shall serve as a Co-Chair of the Council;

(b) Administrator of the Environmental Protection Agency, who shall serve as a Co-Chair of the Council;

(c) Secretary of Education;

(d) Secretary of Labor;

(e) Attorney General;

(f) Secretary of Energy;

(g) Secretary of Housing and Urban Development;

(h) Secretary of Agriculture;

(i) Secretary of Transportation;

(j) Director of the Office of Management and Budget;

(k) Chair of the Council on Environmental Quality;

(l) Chair of the Consumer Product Safety Commission;

(m) Assistant to the President for Economic Policy;

(n) Assistant to the President for Domestic Policy;

(o) Assistant to the President and Director of the Office of Science and Technology Policy;

(p) Chair of the Council of Economic Advisers; and

(q) Such other officials of executive departments and agencies as the President may, from time to time, designate.

Members of the Task Force may delegate their responsibilities under this order to subordinates.

3-304. *Functions.* The Task Force shall recommend to the President Federal strategies for children's environmental health and safety, within the limits of the Administration's budget, to include the following elements:

(a) statements of principles, general policy, and targeted annual priorities to guide the Federal approach to achieving the goals of this order;

(b) a coordinated research agenda for the Federal Government, including steps to implement the review of research databases described in section 4 of this order;

(c) recommendations for appropriate partnerships among Federal, State, local, and tribal governments and the private, academic, and nonprofit sectors;

(d) proposals to enhance public outreach and communication to assist families in evaluating risks to children and in making informed consumer choices;

(e) an identification of high-priority initiatives that the Federal Government has undertaken or will undertake in advancing protection of children's environmental health and safety; and

(f) a statement regarding the desirability of new legislation to fulfill or promote the purposes of this order.

3-305. The Task Force shall prepare a biennial report on research, data, or other information that would enhance our ability to understand, analyze,

and respond to environmental health risks and safety risks to children. For purposes of this report, cabinet agencies and other agencies identified by the Task Force shall identify and specifically describe for the Task Force key data needs related to environmental health risks and safety risks to children that have arisen in the course of the agency's programs and activities. The Task Force shall incorporate agency submissions into its report and ensure that this report is publicly available and widely disseminated. The Office of Science and Technology Policy and the National Science and Technology Council shall ensure that this report is fully considered in establishing research priorities.

3-306. The Task Force shall exist for a period of 4 years from the first meeting. At least 6 months prior to the expiration of that period, the member agencies shall assess the need for continuation of the Task Force or its functions, and make appropriate recommendations to the President.

Sec. 4. Research Coordination and Integration.

4-401. Within 6 months of the date of this order, the Task Force shall develop or direct to be developed a review of existing and planned data resources and a proposed plan for ensuring that researchers and Federal research agencies have access to information on all research conducted or funded by the Federal Government that is related to adverse health risks in children resulting from exposure to environmental health risks or safety risks. The National Science and Technology Council shall review the plan.

4-402. The plan shall promote the sharing of information on academic and private research. It shall include recommendations to encourage that such data, to the extent permitted by law, is available to the public, the scientific and academic communities, and all Federal agencies.

Sec. 5. Agency Environmental Health Risk or Safety Risk Regulations.

5-501. For each covered regulatory action submitted to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to Executive Order 12866, the issuing agency shall provide to OIRA the following information developed as part of the agency's decisionmaking process, unless prohibited by law:

(a) an evaluation of the environmental health or safety effects of the planned regulation on children; and

(b) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency.

5-502. In emergency situations, or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall comply with the provisions of this section to the extent practicable. For those covered regulatory actions that are governed by a court-imposed or statutory deadline, the agency shall, to the extent practicable, schedule any rulemaking proceedings so as to permit sufficient time for completing the analysis required by this section.

5-503. The analysis required by this section may be included as part of any other required analysis, and shall be made part of the administrative record for the covered regulatory action or otherwise made available to the public, to the extent permitted by law.

Sec. 6. Interagency Forum on Child and Family Statistics.

6-601. The Director of the OMB ("Director") shall convene an Interagency Forum on Child and Family Statistics ("Forum"), which will include representatives from the appropriate Federal statistics and research agencies. The Forum shall produce an annual compendium ("Report") of the most important indicators of the well-being of the Nation's children.

6-602. The Forum shall determine the indicators to be included in each Report and identify the sources of data to be used for each indicator. The

**Appendix III: Executive Order 13045 and
Amendments**

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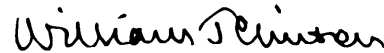
Forum shall provide an ongoing review of Federal collection and dissemination of data on children and families, and shall make recommendations to improve the coverage and coordination of data collection and to reduce duplication and overlap.

6-603. The Report shall be published by the Forum in collaboration with the National Institute of Child Health and Human Development. The Forum shall present the first annual Report to the President, through the Director, by July 31, 1997. The Report shall be submitted annually thereafter, using the most recently available data.

Sec. 7. General Provisions.

7-701. This order is intended only for internal management of the executive branch. This order is not intended, and should not be construed to create, any right, benefit, or trust responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or its employees. This order shall not be construed to create any right to judicial review involving the compliance or noncompliance with this order by the United States, its agencies, its officers, or any other person.

7-702. Executive Order 12606 of September 2, 1987 is revoked.



THE WHITE HOUSE,
April 21, 1997.

[FR Doc. 97-10695
Filed 4-22-97; 8:49 am]
Billing code 3195-01-P

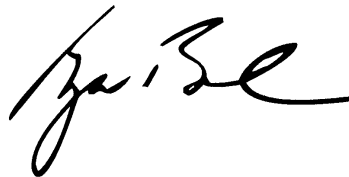
Federal Register / Vol. 66, No. 197 / Thursday, October 11, 2001 / Presidential Documents 52013

Presidential Documents

Executive Order 13229 of October 9, 2001

**Amendment to Executive Order 13045, Extending the Task
Force on Environmental Health Risks and Safety Risks to
Children**

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to extend the Task Force on Environmental Health Risks and Safety Risks to Children, it is hereby ordered that Executive Order 13045 of April 21, 1997, is amended by deleting in section 3-306 of that order "for a period of 4 years from the first meeting" and inserting in lieu thereof "for 6 years from the date of this order".



THE WHITE HOUSE,
October 9, 2001.

[FR Doc. 01-25788
Filed 10-10-01; 8:54 am]
Billing code 3195-01-P

19931

Federal Register
Vol. 68, No. 78
Wednesday, April 23, 2003

Presidential Documents

Title 3--

Executive Order 13296 of April 18, 2003

The President

Amendments to Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to extend the Task Force on Environmental Health Risks and Safety Risks to Children, and for other purposes, it is hereby ordered that Executive Order 13045 of April 21, 1997, as amended, is further amended as follows:

Section 1. Subsection 3-303(o) is amended by striking "Assistant to the President and".

Sec. 2. Section 3-305 is amended by:

(a) striking "cabinet agencies and other agencies identified" and inserting in lieu thereof "executive departments, the Environmental Protection Agency, and other agencies identified"; and

(b) inserting the following new language after the second sentence: "Each report shall also detail the accomplishments of the Task Force from the date of the preceding report."

Sec. 3. Section 3-306 is amended by:

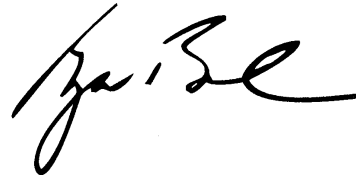
(a) striking "6 years" and inserting in lieu thereof "8 years"; and

(b) striking the second sentence.

Sec. 4. Section 6-601, the second sentence, is amended by deleting "an annual" and inserting "a biennial" in lieu thereof.

Sec. 5. Section 6-603, the third sentence, is amended by deleting "submitted annually" and inserting "published biennially" in lieu thereof.

Sec. 6. Section 7 is amended by adding new section 7-703 as follows: "7-703. Nothing in this order shall be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals."



THE WHITE HOUSE,
April 18, 2003.

[FR Doc. 03-10194
Filed 4-22-03; 8:45 am]
Billing code 3195-01-P

Appendix IV: EPA Regulations Subject to Executive Order 13045

Executive Order 13045—Protection of Children from Environmental Health Risks and Safety Risks (Executive Order)—requires that federal agencies provide, to the Office of Management and Budget (OMB) and in the public record, (1) an evaluation of the environmental health or safety effects of the planned regulation on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency.¹ Table 6 summarizes the *Federal Register* notice preamble section pertaining to the Executive Order for each of the EPA regulations subject to the Executive Order. The table's columns show (1) the office that initiated the rulemaking; (2) whether a given regulation was final or proposed, and its *Federal Register* citation; (3) the children's environmental health concern(s) EPA identified; and (4 and 5) summaries of how EPA described, in the preamble, its analyses pursuant to the two regulatory requirements of the Executive Order. The table indicates with an arrow (→) when EPA explicitly directed readers to additional information in the body of the rulemaking or the public docket. The table also indicates with a star (★) when EPA either quantified the effects on children of the regulation or other regulatory options, or explained why it did not do so.

We identified 17 rulemakings since 1998 that EPA determined were subject to the Executive Order's requirements. For each of those regulations, we analyzed whether and how EPA discussed how it met the order's requirements in the notice's preamble. We found that EPA has not consistently documented therein how its rulemakings considered children's environmental health risks. Specifically, we found that, for only 4 of the rulemakings did EPA either quantify the effects of the rulemaking on children or explain why it did not, or could not, do so. For 8 of the rulemakings, EPA explicitly directed the reader—with varying degrees of specificity—to additional information about the regulation's effect on children.

¹These requirements are provided in Executive Order 13045 section 501(a) and 501(b), respectively.

Appendix IV: EPA Regulations Subject to Executive Order 13045

Table 6: EPA Regulations Subject to Executive Order 13045

EPA office	Type of regulation (date)	Children’s environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
1 National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule				
Water	Final 71 Fed. Reg. 654 (Jan. 5, 2006).	Cryptosporidiosis from exposure to Cryptosporidium in drinking water. Common symptoms include diarrhea and vomiting. EPA described studies on children’s unique susceptibilities and exposures to Cryptosporidium and analyzed data on the number of Cryptosporidium cases in 1999, by age.	EPA stated that the planned regulation will reduce the risk of illness for the entire population, including children. Because children may be disproportionately affected, the regulation may result in greater risk reduction for children. Existing data are not adequate to assess children’s risks.	EPA briefly described other regulatory options it considered and stated that the planned regulation was selected because it was deemed feasible and provided significant public health benefits in terms of avoided illnesses and deaths. EPA’s analysis indicated that the planned regulation ranks highly among those evaluated with respect to maximizing net benefits.
		→	→ ★	→
	Proposed 68 Fed. Reg. 47,640 (Aug. 11, 2003).	Same	Same	Same
		→	→ ★	→
2 National Pollutant Discharge Elimination System Permit Regulation and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFO)				
Water	Final 68 Fed. Reg. 7,176 (Feb. 12, 2003).	Infants under 6 months may be at risk of methemoglobinemia from exposure to nitrates in private drinking-water wells.	EPA estimated that 112,000 households would have their nitrate levels brought to levels that are safe for infants. EPA did not have information on the number of infants living in those households.	EPA estimated that more stringent options would provide only small changes in pollutant loadings to groundwater, such that more stringent options would not provide meaningful protection of children’s health risks from methemoglobinemia.
		→	→ ★	→

Appendix IV: EPA Regulations Subject to Executive Order 13045

EPA office	Type of regulation (date)	Children’s environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
	Proposed 66 Fed. Reg. 2,960 (Jan. 12, 2001).	Same In addition, EPA stated that information was not available on the actual number of cases of methemoglobinemia. Furthermore, EPA noted that the following pollutants may also have a disproportionate risk to children: pathogens; trace metals such as zinc, arsenic, copper, and selenium; pesticides; hormones; and endocrine disruptors. However, EPA did not have adequate information to assess the risks to children.	EPA estimated the number of households that would have their nitrate levels brought to levels that are safe for infants at 166,000 households under the two-tier structure; and 161,000 households under the three-tier structure.	Same
		→	→ ★	→
3 National Ambient Air Quality Standards for Lead				
Air and Radiation	Final 73 Fed. Reg. 66,964 (Nov. 12, 2008).	Neurological effects from childhood exposure to lead.	EPA stated that the standards were designed to protect public health with an adequate margin of safety, as required by the Clean Air Act, and that the protection offered by the standards may be especially important for children.	Not explicitly addressed
		→		
	Proposed 73 Fed. Reg. 29,184 (May 20, 2008).	Same	Same	Same
		→		
4 Control of Emissions of Air Pollution From Locomotive Engines and Marine Compression-Ignition Engines Less Than 30 Liters per Cylinder^a				
Air and Radiation	Final 73 Fed. Reg. 25,098 (May 6, 2008).	Not specified EPA stated that children appeared to be overrepresented for some individual facilities, based on initial screening conducted by the agency and described in this section.	EPA stated that the rulemaking would achieve significant reductions of various emissions from locomotive and marine diesel engines, and that the regulation would benefit children.	EPA stated that it had evaluated several regulatory strategies and selected the most stringent and effective control reasonably feasible, in light of the technology and cost requirements of the Clean Air Act.
		→	→	

Appendix IV: EPA Regulations Subject to Executive Order 13045

EPA office	Type of regulation (date)	Children's environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
5 National Ambient Air Quality Standards for Ozone				
Air and Radiation	Final 73 Fed. Reg. 16,436 (Mar. 27, 2008).	Not specified	Not explicitly addressed	Not explicitly addressed
		→		
	Proposed 72 Fed. Reg. 37,818 (Jul. 11, 2007).	Same	EPA stated that the standards were designed to protect public health with an adequate margin of safety, as required by the Clean Air Act, and that the protection offered by the standards may be especially important for children.	Same
		→		
6 Control of Hazardous Air Pollutants From Mobile Sources				
Air and Radiation	Final 72 Fed. Reg. 8,428 (Feb. 26, 2007).	Cancer and respiratory problems from exposure to hazardous air pollutants from mobile sources, including particulate matter.	Not explicitly addressed	Not explicitly addressed
		→		
	Proposed 71 Fed. Reg. 15,804 (Mar. 29, 2006).	Same	EPA stated that the regulation may have a disproportionately beneficial effect on children.	Same
		→		
7 Clean Air Fine Particle Implementation Rule^b				
Air and Radiation	Final 72 Fed. Reg. 20,586 (Apr. 25, 2007).	Not specified	EPA stated that the standards implemented the previously promulgated National Ambient Air Quality Standards (NAAQS) for fine particulate matter, which were designed to protect public health with an adequate margin of safety, as required by the Clean Air Act, and that the protections offered by the standards may be especially important for children.	Not explicitly addressed
		→		

Appendix IV: EPA Regulations Subject to Executive Order 13045

EPA office	Type of regulation (date)	Children’s environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
8 National Ambient Air Quality Standards for Particulate Matter				
Air and Radiation	Final 71 Fed. Reg. 61,144 (Oct. 17, 2006).	Not specified	EPA stated that the standards were designed to protect public health with an adequate margin of safety, as required by the Clean Air Act, and that the protection offered by the standards may be especially important for children.	Not explicitly addressed
		→		
	Proposed 71 Fed. Reg. 2,620 (Jan. 17, 2006).	Same	Same	Same
		→		
9 Standards of Performance for New and Existing Stationary Sources: Electric Utility Steam Generating Units				
Air and Radiation	Final 70 Fed. Reg. 28,606 (May 18, 2005).	Neurodevelopmental effects to developing fetuses from exposure to methylmercury.	EPA stated that the regulation would help reduce exposure of women of childbearing age to methylmercury, and estimated the number of children who will be exposed to methylmercury in 2020. EPA estimated how IQ decrements would be reduced as a result of the regulation. EPA also discussed limitations of the regulation to affect human health.	EPA stated the selected option delivered about the same amount of benefits as other regulatory alternatives it considered, but at a lower cost.
		→	→ ★	
	Proposed 69 Fed. Reg. 4,652 (Jan. 30, 2004).	Not specified	EPA stated that the strategies proposed in this rulemaking would improve air quality and children’s health.	Not explicitly addressed
		→		
10 Revision of December 2000 Clean Air Act Section 112(n) Finding Regarding Electric Utility Steam Generating Units; and Standards of Performance for New and Existing Electric Utility Steam Generating Units: Reconsideration^e				
Air and Radiation	Final 71 Fed. Reg. 33,388 (Jun. 9, 2006).	Not specified	EPA explained that it had evaluated the environmental health or safety effects to children of its Clean Air Mercury Rule.	Not explicitly addressed
		→		

Appendix IV: EPA Regulations Subject to Executive Order 13045

EPA office	Type of regulation (date)	Children’s environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
11 Control of Air Pollution from New Motor Vehicles: Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements				
Air and Radiation	Final 66 Fed. Reg. 5,002 (Jan. 18, 2001).	Not specified EPA noted that some of pollutants addressed in the regulation may disproportionately affect children’s health, such as ozone, particulate matter and certain toxic air pollutants.	EPA stated that the rulemaking would reduce air toxics and the related impacts on children’s health. Explained that EPA had addressed the effect on children of exposure to ozone and particulate matter in its rulemakings to establish the NAAQS for those pollutants, and that it was not revisiting those here.	EPA stated that, consistent with the Clean Air Act, the planned regulation was designed to achieve the greatest degree of reduction of emissions achievable through available technology, taking cost and other factors into consideration.
		→	→	→
	Proposed 65 Fed. Reg. 35,430 (June 2, 2000).	Same	Same	Same
		→	→	→
12 Control of Emissions of Air Pollution from 2004 and Later Model Year Heavy-Duty Highway Engines and Vehicles; Revision of Light-Duty On-Board Diagnostics Requirements				
Air and Radiation	Final 65 Fed. Reg. 59,896 (Oct. 6, 2000).	Not specified EPA noted that some pollutants addressed in the regulation may disproportionately affect children’s health, such as ozone, particulate matter and certain toxic air pollutants.	EPA stated that the rulemaking would reduce air toxics and the related impacts on children’s health. Explained that EPA had addressed the effect on children of exposure to ozone and particulate matter in its rulemakings to establish the NAAQS for those pollutants, and that it was not revisiting those here.	EPA stated that, consistent with the Clean Air Act, the planned regulation was designed to achieve the greatest degree of reduction of emissions achievable through available technology, taking cost and other factors into consideration.
		→	→	→
	Proposed 64 Fed. Reg. 58,472 (Oct. 29, 1999).	Same	Same	Same
		→	→	→

Appendix IV: EPA Regulations Subject to Executive Order 13045

EPA office	Type of regulation (date)	Children’s environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
13 Control of Air Pollution From New Motor Vehicles: Tier 2 Motor Vehicle Emissions Standards and Gasoline Sulfur Control Requirements				
Air and Radiation	Final 65 Fed. Reg. 6,698 (Feb. 10, 2000).	Not specified EPA noted that some of pollutants addressed in the regulation may disproportionately affect children’s health, such as ozone, particulate matter and certain toxic air pollutants.	EPA stated that the rulemaking would reduce air toxics and the related impacts on children’s health. Explained that EPA had addressed the effect on children of exposure to ozone and particulate matter in its rulemakings to establish the NAAQS for those pollutants, and that it was not revisiting those here.	EPA stated that the planned regulation was the most stringent and effective control reasonably feasible at the time, in light of the technology and cost requirements of the Clean Air Act.
	Proposed 64 Fed. Reg. 26,004 (May 13, 1999).	Same	Same	Same
		→	→	→
		→	→	→
14 Lead; Renovation, Repair, and Painting Program				
Prevention, Pesticides, and Toxic Substances	Final 73 Fed. Reg. 21,692 (Apr. 22, 2008).	Not specified	EPA stated that the primary purpose of the regulation was to minimize exposure in children under age 6 to lead-based paint hazards created during renovation, repair, and painting activities in housing or other buildings. Estimated that the regulation would affect 1.4 million children under age 6, providing considerable benefits to those children.	Not explicitly addressed
	Proposed 71 Fed. Reg. 1,588 (Jan. 10, 2006).	Same	EPA stated that one purpose of the proposed regulation was to prevent the creation of new lead-based paint hazards from housing where children under age 6 reside. Estimated that the regulation would affect 1.1 million children under age 6, providing considerable benefits to those children.	Same
		→	★	
		→	★	

Appendix IV: EPA Regulations Subject to Executive Order 13045

EPA office	Type of regulation (date)	Children’s environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
15 Lead and Lead Compounds; Lowering of Reporting Thresholds; Community Right-to-Know Toxic Chemical Release Reporting				
Prevention, Pesticides, and Toxic Substances	Final 66 Fed. Reg. 4,500 (Jan. 17, 2001).	Not specified EPA stated that it identified and assessed the environmental health risks and safety risks that may disproportionately affect children.	EPA described how the informational benefits of the planned regulation could positively impact children and other populations.	Not explicitly addressed
	Proposed 64 Fed. Reg. 42,222 (Aug. 3, 1999).	Same	Same	Same
16 Lead; Identification of Dangerous Levels of Lead				
Prevention, Pesticides, and Toxic Substances	Final 66 Fed. Reg. 1,206 (Jan. 5, 2001).	Not specified	EPA stated that the selected standards were designed first and foremost to protect children from lead in residential paint, dust, and soil.	EPA stated that it could have selected numerically more stringent standards, but concluded that they would provide less protection to children because limited resources would be diluted and possibly diverted away from children at greatest risk.
	Proposed 63 Fed. Reg. 30,302 (Jun. 3, 1998).	→ Same	EPA stated that young children were the primary beneficiaries of the proposed regulation because exposure to lead, paint, and dust is mostly limited to children under the age of 6.	Not explicitly addressed
17 Persistent Bioaccumulative Toxic (PBT) Chemicals; Lowering of Reporting Thresholds for Certain PBT Chemicals; Addition of Certain PBT Chemicals; Community Right-to-Know Toxic Chemical Reporting				
Prevention, Pesticides, and Toxic Substances	Final 64 Fed. Reg. 58,666 (Oct. 29, 1999).	Not explicitly addressed	EPA described how the informational benefits of the rule could positively impact children and other populations.	Not explicitly addressed
	Proposed 64 Fed. Reg. 688 (Jan. 5, 1999).	Same	Same	Same

Source: GAO analysis of *Federal Register* notices' preamble sections.

**Appendix IV: EPA Regulations Subject to
Executive Order 13045**

Notes:

The table indicates with an arrow (→) when EPA explicitly directed readers to additional information in the body of the rulemaking or the public docket. The table also indicates with a star (★) when EPA either quantified the effects on children of the regulation or other regulatory options, or explained why it did not do so.

^aEPA determined that the proposed regulation, published April 3, 2007, was not subject to Executive Order 13045 because the agency did not have reason to believe that the environmental health risks or safety risks addressed by the regulation presented a disproportionate risk to children.

^bEPA determined that the proposed regulation, published November 1, 2005, was not subject to Executive Order 13045. EPA did not explicitly state in its *Federal Register* notice why the regulation was not subject to the order.

^cThis regulation sets forth EPA's decision after reconsidering certain aspects of the March 29, 2005, final rule entitled "Revision of December 2000 Regulatory Finding on the Emissions of Hazardous Air Pollutants From Electric Utility Steam Generating Units and the Removal of Coal- and Oil-Fired Electric Utility Steam Generating Units from the Section 112(c) List" (Section 112(n) Revision Rule). The regulation also includes EPA's final decision regarding reconsideration of certain issues in the May 18, 2005, final rule entitled "Standards of Performance for New and Existing Stationary Sources: Electric Utility Steam Generating Units" (Clean Air Mercury Rule; CAMR), which was subject to Executive Order 13045.

Appendix V: Comments from the Environmental Protection Agency



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 22 2009

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

John B. Stephenson
Director
Natural Resource & Environment
United States Government Accountability Office
441 G Street, NW, Room 2075
Washington, D.C. 20548

Dear Mr. Stephenson,

Thank you for the opportunity to review and comment on the draft report of the Government Accountability Office (GAO), entitled *Environmental Health: High-level Strategy and Leadership Needed to Continue Progress Toward Protecting Children from Environmental Threats*. Consistent with our comments on the Statement of Facts, the Environmental Protection Agency (EPA) agrees that the GAO report reflects well the early history and progress of the Agency's children's health protection efforts. The report accurately portrays the Agency's challenges in addressing children's environmental health, and sets forth sound recommendations on steps that could be taken to better incorporate protection of children's health as an integral part of EPA's everyday business.

Offices throughout the Agency continue to implement mandates, develop regulations, support programs and reach out to communities to protect children from environmental threats and help prevent illness and injury. While the Agency has taken important steps to ensure protection of children's health since the inception of the Office of Children's Health Protection in 1997, the Administrator is committed to strengthening these efforts and dedicating resources to bolster our efforts in children's health protection to bring about more tangible results in this area. She recently cited protecting children's health as central to the Agency's mission in an internal memo dated September 11, 2009. Specifically, she noted that "...several goals central to the environmental mission of this Administration need to be brought into the regulatory process as early as possible in order to give them the attention they are due; these are environmental justice, children's health, and climate change... With respect to children's health, early attention to this issue is critical to grasping the full implications of a regulatory or policy decision for children and to addressing those implications in the decision-making process." Implementing the recommendations provided in the GAO report will bring us a long way to achieving this goal.

GAO recommended that the Agency *update and reissue a child-focused strategy, such as the 1996 national agenda, to articulate current national environmental health priorities and emerging issues*. While the National Agenda has served as a valuable guide for leadership on children's environmental health, it is timely to conduct an evaluation of the National Agenda and determine if revision, reaffirmation, or reissuance is needed. The Agency's 2009 five point

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agenda for children's environmental health is a beginning for this work and is consistent with the National Agenda.

GAO recommended that the Agency *strengthen the data system that identifies and tracks development of rulemakings and other actions to ensure they comply with the 1995 policy on evaluating health risks to children*. Already, in the past six months, EPA has reviewed its Rule and Policy Information Development System (RAPIDS) and is enhancing it to collect more targeted information regarding effects on children's health. Specifically, programs are now asked to provide information on whether a rule is likely to address an adverse impact on childhood life-stages and the nature of that impact. Using this information, the Office of Children's Health Protection and Environmental Education is identifying rules on which to focus its attention. Additionally, EPA is in the process of establishing "the Rulemaking Gateway," a new, publicly accessible interface to our data system that provides more user friendly information on child health impacts resulting from our priority rulemakings.

GAO recommends that the Agency *reevaluate the 1995 policy to ensure its consistency with new scientific research demonstrating the risks childhood exposures can have on risks for disease in later lifestages*. The Agency will reevaluate the 1995 policy as part of a broader effort to implement science policies that are adequately protective of children's environmental health. Such review is critically important since, as a regulatory agency, risk assessment policies are core to how we apply science to protect human health.

GAO recommends that the Agency's *2009-2013 strategic plan expressly articulate children specific goals, objectives and targets*. The strategic plan is currently under development. We will ensure that it reflects the Administrator's priorities, including children's environmental health.

GAO recommends that the Agency *reevaluate the mission of the Office of Children's Health Protection and its director to make the office an agencywide champion for implementation of a reissued national children's environmental health agenda, policy, and related goals in the next EPA strategic plan*. The Agency is currently implementing this recommendation through the reorganization of the Office of Children's Health Protection and Environmental Education.

GAO recommends that the Agency *establish key children's environmental health staff within each program office and regional office, with linkages to the Office of Children's Health, to improve cross-agency implementation of revised priorities and goals, and ensure coordination and communication among EPA's program offices*. The report points out the efforts undertaken in the past to do this, including the establishment of regional children's health coordinators. We will build upon these efforts to broaden Agency-wide implementation of programs and policies to protect children's health.

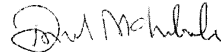
GAO recommends that EPA *use the Children's Health Protection Advisory Committee proactively as a mechanism for providing advice on regulations, programs, plans or other issues*. The Agency has recently renewed the charter of the Advisory Committee and is committed to using the CHPAC to request advice on regulations, policies and other important environmental issues.

**Appendix V: Comments from the
Environmental Protection Agency**

GAO recommends that EPA *ensure participation to the fullest extent possible, by the Office of Children's Health or other key officials on the interagency organizations identified in Executive Order 13045*. We also note with interest the GAO recommendation to Congress on the reestablishment of the interagency task force. EPA will ensure active participation from the Office of Children's Health or other key officials on interagency efforts related to children's environmental health.

Again, thank you for the opportunity to comment on this draft report. If you have further questions, please contact me, or your staff may call Bobbie Trent, the EPA GAO liaison, at (202) 566-0983.

Sincerely,



David McIntosh
Associate Administrator

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

John Stephenson, (202) 512-3841 or stephensonj@gao.gov

Staff Acknowledgments

In addition to the contact named above, Diane Raynes, Assistant Director; Elizabeth Beardsley; Timothy Bober; Mark Braza; Emily Hanawalt; Terrance Horner, Jr.; Aaron Shiffrin; Benjamin Shouse; and Kiki Theodoropoulos made key contributions to this report.

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