

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



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This document is a step-by-step guide to assist Agency staff in integrating children's health considerations into EPA's Action Development Process (ADP). It describes the provisions of Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" and EPA's "Policy on Evaluating Health Risks to Children." This guide also is designed to assist EPA staff in determining whether rules are subject to the Executive Order, whether the Agency Policy applies to an action and what should be done to address the Executive Order and/or EPA's policy in the development of a rule or Agency action. This guide was developed by the Office of Children's Health Protection in consultation with the Office of Policy Economics and Innovation and the Regulatory Steering Committee. This guide supersedes the 1998 EPA's *Rule Writer's Guide to EO 13045*.

Disclaimer: This document identifies internal Agency policies and recommended procedures for EPA employees who are participants or managers developing or reviewing an action in the Action Development Process. This document is not a rule or regulation and it may not apply to a particular situation based upon the circumstances. This Guide does not change or substitute for any law, regulation, or any other legally binding requirement and is not legally enforceable. As indicated by the use of non-mandatory language such as "guidance," "recommend," "may," "should," and "can," it identifies policies and provides recommendations and does not impose any legally binding requirements.

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ACRONYMS AND ABBREVIATIONS

AA/RA:	Assistant Administrator / Regional Administrator
ADP:	Action Development Process
DABP:	Detailed Analytic Blueprint
EA:	Economic Analysis
EO:	Executive Order
FAR:	Final Agency Review
MOA:	Mode of action
NCEE:	National Center for Environmental Economics
OCHPEE:	Office of Children’s Health Protection and Environmental Education
OGC:	Office of General Counsel
OMB:	Office of Management and Budget
OPEI:	Office of Policy, Economics, and Innovation
ORD:	Office of Research and Development
PABP:	Preliminary Analytic Blueprint
RfC:	Reference Concentration
RfD:	Reference Dose
RIA:	Regulatory Impact Analysis
RMD:	Regulatory Management Division
RSC:	Regulatory Steering Committee

Overview and Background

A. What is the Purpose of this Guide?

This Guide is designed to help Agency staff involved in developing actions determine whether Executive Order 13045 or EPA's Children's Health Policy applies to an Agency action and, if so, how to implement the Executive Order and/or EPA's Policy. This Guide uses the definition of "agency actions" provided in EPA's Action Development Process (ADP), which is available online at <http://intranet.epa.gov/adplibrary>. Agency actions include rules, policy statements, risk assessment, guidance documents, models that may be used in future rulemakings and strategies that are related to regulations. This Guide identifies key steps throughout the ADP where children's health should be considered. As a matter of policy, Agency staff should consider children's health as part of the ADP, even if it is determined that the Executive Order is not applicable to a specific action. In addition to this Guide, Agency staff may also find it useful to refer to other EPA guidance documents related to risk assessment, and economic analysis (see Attachment D).

B. Who is the Audience for this Guide?

This guide is for participants on action development workgroups and any other Agency staff involved in developing actions. Each action development workgroup member has the responsibility for being familiar with, and understanding, the various statutes and executive orders that impact EPA's ADP. In addition, senior EPA managers may find this Guide useful in helping to ensure that children's health considerations are appropriately addressed in the ADP.

C. Why is a Revision of the 1998 Rule Writer's Guide Necessary?

Since the issuance of the first *EPA's Rule Writer's Guide to Executive Order 13045* in 1998, EPA has published several new guidance documents relating to risk assessment, regulatory policy, and action development. We are revising the Guide to reflect these new developments. In addition, this Guide more clearly integrates EPA's Policy on Children's Health with the ADP, and provides an updated list of related guidance documents.

D. What is the History of Protecting Children’s Health at EPA?

The EPA has a longstanding history and vigorous interest in addressing environmental public health impacts of vulnerable populations. In 1994, Executive Order (EO) 12898, “Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations,” recognized the concept of disproportionate health risks. EO 12898 directed each federal agency to identify and address disproportionately high and adverse human health or environmental effects that its programs, policies, and activities might have on minority and low-income populations (59 FR 7629, February 16, 1994). At the same time, a growing body of scientific knowledge began to emerge demonstrating that children may suffer disproportionately from environment health and safety risks. These risks arise because children generally eat more food, drink more water, and breathe more air relative to their size than adults do, and consequently may be exposed to relatively higher amounts of contaminants. Normal childhood activity, such as putting hands in mouths or playing on the ground, can result in exposures to contaminants that adults do not face. In addition, environmental contaminants may affect children disproportionately because their immune system defenses are not fully developed and their growing organs are more easily harmed.^{1, 2} In response to this emerging science, EPA’s Science Policy Council developed an Agency-wide policy, Policy on Evaluating Health Risks to Children (see Attachment B). This policy was issued by the Administrator and Deputy Administrator in October 1995 to ensure that we consistently and explicitly evaluate environmental health risks to infants and children in all of the risk assessments, risk characterizations,³ and environmental and public health standards that we set for the nation. Subsequent provisions in the Food Quality Protection Act of 1996 and the Safe Water Drinking Act Amendments of 1996 underscored this policy by requiring a focus on the evaluation of children’s exposures and toxicities in the context of risk assessment.

In September 1996, the Agency announced a seven-step National Agenda to Protect Children’s Health from Environmental Threats by:

- Ensuring that all standards set by EPA are protective of any heightened risks faced by children;
- Developing a scientific research strategy focused on the gaps in knowledge regarding child-specific susceptibility and exposure to environmental pollutants;
- Developing new, comprehensive policies to address cumulative and simultaneous exposures faced by children;
- Expanding community right-to-know allowing families to make informed choices concerning environmental exposures to their children;

¹ National Research Council. 1993. Pesticides in the Diets of Infants and Children. National Academy of Sciences Press, Washington, DC.

² National Research Council. 1994. Science and Judgment in Risk Assessment. National Academy of Sciences Press, Washington, DC.

³ Risk characterization is the process of describing, for the benefit of decision makers and the public, the conclusions of a risk assessment and its strengths and limitations. In preparing a risk characterization, a risk assessor supporting the rule writer would display key information from hazard identification, dose-response analysis, and exposure assessments. The risk assessor would access a combination of qualitative and quantitative information and information about uncertainties.

- Encouraging parental responsibility for protecting their children from environmental health threats by providing them with basic information;
- Encouraging and expanding educational efforts with health care providers and environmental professionals so they can identify, prevent and reduce environmental health threats to children; and
- Providing the necessary funding to address children’s environmental health as a top priority among relative health risks.

On April 21, 1997, the President signed Executive Order 13045 entitled “Protection of Children from Environmental Health Risks and Safety Risks” (see Attachment A). EO 13045 states:

“[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.”

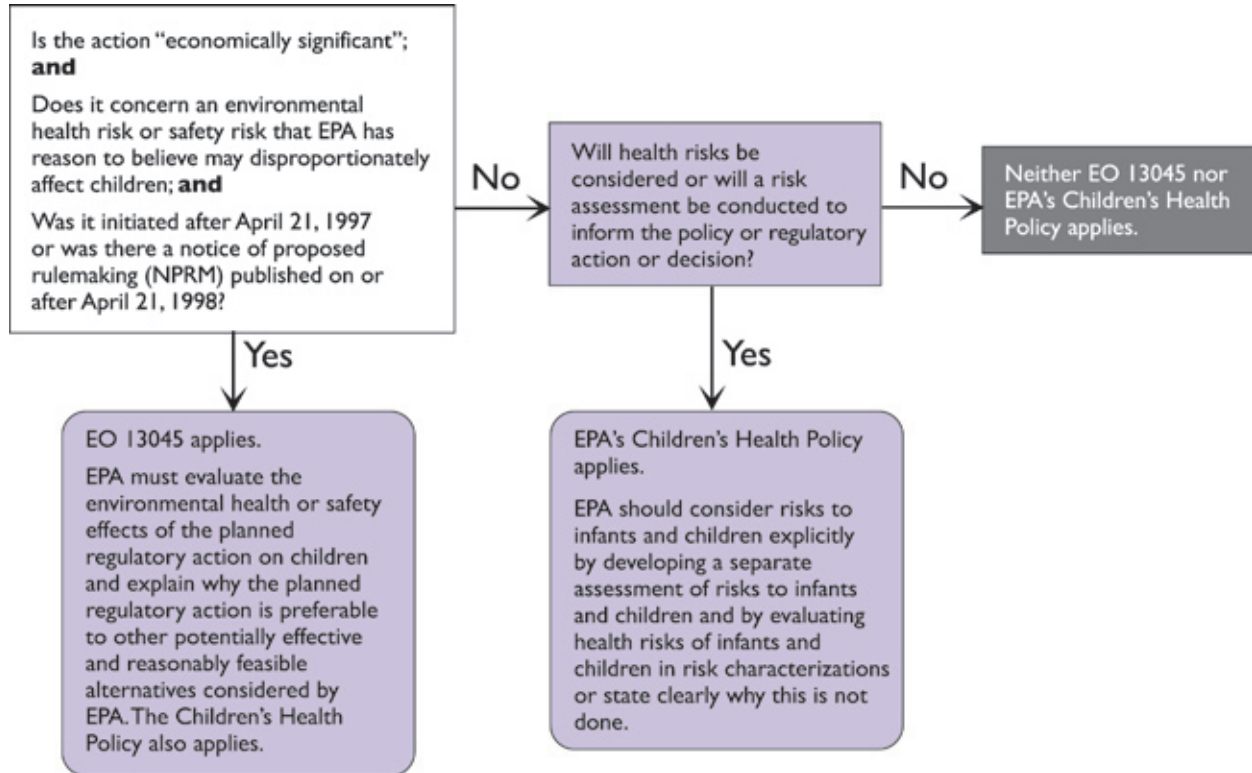
Following the issuance of EO 13045, in 1998, EPA published its first guide for EPA staff, *EPA’s Rule Writer’s Guide to Executive Order 13045*, to consider risks to children during the development of regulatory actions. Additional guidance documents including the 2000 *Guidelines for Preparing Economic Analyses* and the 2003 *Children’s Health Valuation Handbook* serve as references for analysts conducting economic analyses of EPA regulations and policies that may affect risks to children’s health.

E. How is this Guide Organized?

This Guide is organized into two parts. Part I is designed to help Agency staff involved in developing actions determine whether an action is subject to EO 13045 and/or EPA’s Policy on Children’s Health. Part II discusses the key issues related to evaluating children’s health as a part of the ADP. A separate document, “Guide to Considering Children’s Health When Developing EPA Actions: Preamble Templates,” explains how to address EO 13045 in rule preambles, covering various situations. It is available in the Office of Policy, Economics, and Innovation’s (OPEI’s) ADP library at <http://intranet.epa.gov/adplibrary>.

Below is a flow chart to show how Agency staff can most effectively use this Guide. It outlines the broad criteria that may be used in determining the applicability of the EPA’s Children’s Health Policy and the EO 13045.

Figure 1: Flow Chart Summary Regarding Applicability of EO 13045 and EPA's Children's Health Policy



Part I

Applicability of EPA's Children's Health Policy and Executive Order 13045

This section discusses how to determine whether EPA's Children's Health Policy and/or EO 13045 apply to Agency actions. The Children's Health Policy generally applies to Agency actions that are informed by risk assessments. Therefore, this Guide first discusses the Children's Health Policy, which is generally applied to a broader group of Agency actions than EO 13045, which applies only to certain regulatory actions.

A. What Agency Actions and Policies are Covered by EPA's Children's Health Policy?

EPA's Policy on Evaluating Health Risks to Children (see Attachment B) calls on the Agency "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." The applicability of the policy does not depend on whether risks are "disproportionate" or different from risks to adults. Under the Children's Health Policy, to the degree permitted by available data in each case, the Agency should develop a separate assessment of risks to infants and children or state clearly why such an assessment is not done.

When a risk assessment is prepared in support of action development, Agency staff are responsible for incorporating a children's health risk assessment and characterization into the supporting materials needed for decision-making. When Agency staff commence planning for development of an Agency action, staff should work with risk assessors to begin accumulating available information bearing on potential risks that are unique to infants and children in terms of a child's susceptibility and/or exposure patterns. In some cases, staff may have incomplete information or uncertainty on potential children's risks or even a complete absence of information. In those cases, staff should work with risk assessors to properly document information gaps.

However, if Agency staff determine that the Children's Health Policy does not apply to their specific action because the action will not consider health risks or a risk assessment will not be conducted, no further analysis is required.

Attachment C presents an overview of the four steps of risk assessment and suggests questions for Agency staff involved in action development to consider and ask risk assessors in evaluating the various types of information that are relevant to the assessment of risks to children. These questions are not meant to be exclusive or mandatory, but are illustrative of the information that can be valuable in the assessment and risk management processes. The types of information that a risk assessor will seek include the typical components of risk assessments from which risks can be estimated and characterized such as: potential hazards or adverse effects; information on the sensitivity of children to the development of adverse effects (dose-response) relative to adults and/or other life stages; and exposure information. A child's sensitivity may manifest as qualitatively different than an adult's (e.g., congenital malformation) or quantitatively different (e.g., being affected at lower doses than adults). All this information, to the extent practicable, should be assembled and presented during the action development process.

Please note that this guide does not provide guidance on how to conduct a risk assessment involving children's issues. Instead, risk assessors are directed to existing EPA risk assessment guidance documents. While Attachment C includes suggestions for the types of questions that action development workgroup members and risk assessors could ask to characterize risk to children, it should not be interpreted as indicating that a risk characterization for children is strictly or solely based upon application of the suggested questions. It is not a checklist. Each action presents unique circumstances so additional information and other factors may be relevant in deciding how to characterize risks to children. Attachment D lists some of the guidance documents that address the state of the science and current Agency policies related to risk assessment.

Since it is important that decisions on the analytical approach be made early in the action development process, Agency staff may use this guide (see Part II) to ensure that Analytic Blueprints⁴ include components called for by EPA's Children's Health Policy and EO 13045.

B. What Agency Actions are Covered by EO 13045?

Executive Order 13045 only applies to rules that:

- Are initiated after April 21, 1997 or for which a notice of proposed rulemaking was published on or after April 21, 1998;
- Are economically significant; and
- Concern health or safety risks that EPA has reason to believe may disproportionately affect children.

EPA interprets EO 13045 as applying to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation.

⁴ The Analytic Blueprint can range from a simple summary of the action, a listing of the requirements applicable to the development of the action (e.g., scientific, technical, economic) and a schedule, to a comprehensive, detailed work plan identifying all the steps, each specific analytical need and the responsible parties, resource needs and a fairly detailed schedule of workgroup activities.

For each regulatory action that meets these criteria, per Section 5-501 of EO 13045, EPA shall provide the following information to the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs for review:

- An evaluation of the environmental health or safety effects of the planned regulation on children; and
- An explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA program offices should determine, in consultation with their Regulatory Steering Committee (RSC) representatives (see <http://intranet.epa.gov/adplibrary/contacts.htm#rsc> for current list of representatives) and Office of General Counsel (OGC), whether the statute authorizing the rule allows EPA to consider health or safety risks when making the regulatory determination at hand.

If a rulemaking is not covered by EO 13045, but it discusses environmental health or safety, it is advisable to characterize children's risk to the extent the data are available. For example, if a program office is conducting a human health assessment as part of a Regulatory Impact Analysis (RIA) or other economic analysis or risk assessment, EPA's Policy on Evaluating Health Risks to Children applies and children's health considerations should be discussed in the preamble so that the implications for children's health are thoroughly documented.

Regulatory actions not subject to EO 13045 may still be covered by the Agency's Children's Health Policy if they are informed by a risk assessment or other consideration of health risks. For example, if a regulatory action or rule is not economically significant or does not concern risks that disproportionately affect children's health and therefore does not fall under the purview of EO 13045, characterization of children's risks may still be called for by EPA's Children's Health Policy, if children are among the population affected by the rule.

A companion document, *Guide to Considering Children's Health When Developing EPA Actions: Preamble Templates*, available in the ADP library <http://intranet.epa.gov/adplibrary>, contains suggested templates for the preamble language if the action is a proposed or final rulemaking.

1. Which Agency Actions are Economically Significant?

EO 13045 adopts the definition of "economically significant" from EO 12866, "Regulatory Planning and Review," as any rulemaking that "may have an annual effect on the economy of \$100 million or more or 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." For further information on the interpretation of "economically significant," see *EPA's Guidelines for Preparing Economic Analyses* and OMB's *Circular A-4*.

2. What is a Disproportionate Risk or Impact to Children's Health?

Disproportionate risks or impacts to children, in general, may occur when:

- Children are more sensitive to a particular pollutant or agent being considered in the rulemaking; or
- Children are more likely to be exposed or are likely to be exposed to higher levels of the pollutant or agent than adults are.

In interpreting disproportionate risk or impact, it may be helpful to think in terms of the broad range of early life, pre-natal and post-natal, environmental exposures that may affect the incidence of disease or alter development. Early life exposures include:

- Parental occupational exposures to toxicants before conceiving a child;
- Maternal exposures during gestation; and
- Exposures to chemicals or radiation during infancy and childhood.

Early life exposures also may result in health effects that manifest either in early life or in adulthood. A risk assessment for environmental health effects in children would include information on exposures at each stage of development and on broad range of outcomes, provided data were available.

Attachment C includes a set of questions EPA staff involved in action development can ask risk assessors to ensure that the various types of information relevant to the assessment of risks to children are considered and may be useful in addressing the issue of disproportionate risks.

3. What is the Role of EO 13045 in Setting Technology-based standards?

Generally, EPA may be statutorily precluded from considering health or safety risks when setting certain technology-based standards. However, if allowed by statute, EPA may consider whether a particular pollutant affects human health, and specifically disproportionately affects children, when determining whether a technology-based standard should be set at a level that is more stringent than a level based solely on the performance of technology.

EPA program offices have latitude to determine when children's health risks should be evaluated when developing technology-based standards (please see Appendix C for factors to consider and ask risk assessors in determining whether to conduct a children's health risk evaluation). If a program office concludes, based on scientific and engineering judgment, that there is not likely to be a significant opportunity in the regulation to improve children's health protection beyond the level that would be achieved by considering a strictly technology-based approach, additional analyses may not be expected or appropriate under EO 13045.

C. Which Agency Actions are Not Covered by the Executive Order?

The following regulatory actions are generally not covered by EO 13045 because they do not allow consideration of health or safety risks or they may not be determined as economically significant. Please note these items are not listed in the EO as being exempt. Rather this list was determined through internal EPA negotiations when the first rule writer's guide was developed.

- Rules based solely on technology performance (however, see discussion above in Section B);
- Some sampling methodologies and test procedures (however see discussion above in Section B);
- Procedural rules (e.g., how to file a claim);
- Ecological standards not related to human health;
- Information gathering rules;
- Permit application rules;
- Individual state program approval decisions;
- State Implementation Plan and Federal Implementation Plan rulemakings promulgated pursuant to section 110 of the Clean Air Act; and
- Rules implementing specific standards established by Congress in statutes (e.g., the Sulfur Dioxide Allowance Program under Title IV of the Clean Air Act).

Agency staff involved in action development should include an explanation in the preamble to the proposed and final rulemakings if the rule is not covered by EO. While the EO may not apply to the actions listed above, the actions may be covered by the Children's Health Policy. Please refer to companion document *Guide to Considering Children's Health When Developing EPA Actions: Preamble Templates* in OPEI's ADP Library for templates as guidance for language that can be used in preambles for the rulemaking.

D. Is EO 13045 Applicable to Rules Issued in an Emergency or Under a Court-imposed Deadline?

EO 13045 stipulates that agencies shall comply with EO 13045 to the extent practicable in an emergency situation or if the law obliges the agency to act more quickly than EO review procedures would allow. In order to avoid such conflicts, EO 13045 specifies that the agency shall, to the extent practicable, schedule rulemaking procedures to permit sufficient time for completing an evaluation of the environmental health and safety effects of the planned regulation on children.

E. Where do I Go if I Have Questions about EO 13045 or the Children's Health Policy?

Staff should consult with the Regulatory Steering Committee representative for their program office first (see <http://intranet.epa.gov/adplibrary/contacts.htm#rsc> for current list of representatives). Then, if necessary, consult with the Regulatory Management Division, Office of Regulatory Policy and Management in OPEI, or the OGC or Office of Regional Counsel attorney who is assigned to the rule. In addition, staff can contact the Office of Children's Health Protection and Environmental Education (OCHPEE) for general inquiries about children's health issues in risk assessments.

Part II

Evaluating Children's Health During the Action Development Process

This section of the guidance describes the key issues related to evaluating children's health in the ADP:

- Getting the workgroup underway;
- Getting early guidance and preparing the Preliminary Analytic Blueprint (PABP);
- Developing the Detailed Analytic Blueprint (DABP);
- Completing the data gathering, consultation, peer review, analysis, and options development;
- Selecting options; and
- Developing the proposed action.

What is the Action Development Process?

The ADP is a method for producing quality actions, such as regulations, policies and risk assessments. It ensures that EPA uses the best available information to support its actions and that scientific, economic and policy issues are adequately coordinated with the various stages of action development. Activities that implement EO 13045 and EPA's Children's Health Policy should be undertaken within the framework of this process. For more information, see *EPA's Action Development Process: Guidance for EPA Staff on Developing Quality Actions* available on OPEI's intranet site <http://intranet.epa.gov/adplibrary>.

While some of the ADP steps described above may be relevant only to Tier 1 and Tier 2 actions, tiering level does not preclude the applicability of either EO 13045 or Children's Health Policy. Staff should consider risk to children throughout the ADP regardless of tiering level.

A. Getting the Workgroup Underway

1. What does the Workgroup do about Children's Health?

The workgroup should consider risks to children's health at several stages in the ADP, as discussed in the following sections. Workgroup members influence the scope and content of analyses of children's health issues that support a rulemaking.

What is the Workgroup?

The workgroup consists of representatives from interested program offices and Regions. The workgroup develops the draft regulation or other action, involving its members throughout the ADP. Workgroup members represent the position of their program office or Region. Tier 1 and Tier 2 actions call for formation of action development workgroups. Even though Tier 3 actions do not normally call for teams/workgroups, the lead program should consider the level of assistance needed from Regions and other offices to produce a quality action.

Workgroup members, as representatives of their program office or Region, should keep their senior management informed of children’s health issues and decisions in a timely manner so that the program office or Region can formulate appropriate responses.

During the first meeting of the workgroup, the chair of the workgroup should ensure that the workgroup considers, among other preliminary issues, whether a health risk assessment is likely to be needed. If children may be affected by the health and/or safety risks addressed by the rule (and especially if they may be disproportionately affected, depending on the availability of adequate data), the workgroup should establish the nature of the desired analyses early. For Tier 1 and Tier 2 actions, this means describing these analyses in the Analytic Blueprint.

For rules where children’s risk is an important consideration, the workgroup could consider consulting with individuals with expertise in children’s health (e.g., pediatricians, exposure and risk assessors experienced in children’s health). Depending on the scope of the action and required analysis, a workgroup member could be designated to serve as the lead for the analysis of children’s health issues and to coordinate the various analyses that may be conducted.

B. Getting Early Guidance and Preparing the Preliminary Analytic Blueprint (Tier 1 and Tier 2 Actions)

1. What is Early Guidance?

Early guidance from management is used to establish policy priorities and communicate expectations for the workgroup. Senior managers identify issues of significant concern and guide the process of developing the action. Early guidance always comes from senior management, although the level of management giving guidance differs for Tier 1 and Tier 2 actions:

- **Tier 1:** The Administrator or Deputy Administrator provides early guidance, with input from participating Assistant Administrators and Regional Administrators (AAs/RAs) from across the Agency. If the guidance isn’t given directly to the workgroup, the lead AA/RA is responsible for assuring that it is communicated to them.
- **Tier 2:** The lead AA/RA, in consultation with other participating AAs/RAs, gives early guidance to the workgroup. The lead AA/RA should consider policy issues and priorities of other AAs/RAs when giving early guidance. In some cases, the AAs/RAs may delegate this authority explicitly to an Office Director.

Preparation of the preliminary analytic blueprint is the process through which the workgroup communicates with senior management on early guidance. For more information on early guidance and timelines, see EPA’s *Action Development Process: Guidance for EPA Staff on Developing Quality Actions* available on OPEI’s intranet site <http://intranet.epa.gov/adplibrary>.

2. Why Should the Analytic Blueprint Address Children's Health Evaluation?

The ADP calls on workgroups to draft Analytic Blueprints for Tier 1 (Administrator's priority actions) and Tier 2 (cross-media and/or actions with significant issues) actions. Careful consideration of children's health concerns in a blueprint can improve a regulation by facilitating cross-Agency sharing of valuable information, expertise, and perspectives, and by fostering early agreement on key questions through a structured workgroup process and written document. This early planning can help foster collaborative efforts to develop a well-supported and documented action and avoid last minute workgroup debates over the type of information or analyses that should be available.

Early in the ADP, rule writers should work with risk assessors to begin accumulating information bearing on potential risks to children, such as differences between children and the general population with respect to susceptibility and/or exposure patterns. In some cases, information on potential risks to children may be incomplete or even completely absent. The goal is to obtain adequate information for the assessment of risks, to the extent feasible.

What is an Analytic Blueprint?

An Analytic Blueprint is a document that spells out a workgroup's agreed-upon plans for the data collection and analyses that will support development of the rule. The Blueprint describes how the information will be collected, peer reviewed, and used to craft the action within a specific budget and time frame. The term "analyses" includes not only formal assessments of regulatory impacts, but also all qualitative discussions and processes that help EPA decide which action to undertake, including assessments of scientific, economic, legal, policy, stakeholder, and compliance-related information. Analytic Blueprints are used for Tier 1 and Tier 2 actions. An Analytical Blueprint is not usually used for Tier 3 actions, but it is encouraged (and some programs may routinely use it). For more information, see EPA's *Action Development Process: Guidelines for Preparing Analytic Blueprints* on the Regulatory Management Division intranet site <http://intranet.epa.gov/adplibrary>.

3. How Should a Preliminary Blueprint Address Children's Health?

For all actions subject to EPA's Children's Health Policy and/or EO 13045, the Analytic Blueprint should outline the risk assessment to be prepared. Technical aspects of specific assessments may vary widely, but all risk assessments should be structured to provide complete, concise, and transparent summaries of the risk impacts of the actions under consideration. For more information, see EPA's *Risk Characterization Handbook*.

The PABP should be used to "flag" possible children's health issues and concerns and associated data and analytical needs. It is not necessary to describe in detail all the necessary analyses of children's health. It is more important to seek workgroup agreement on the need to analyze children's health impacts and to obtain the data, expertise, and resources to conduct the analyses.

What is a Preliminary Analytic Blueprint?

The ADP calls for developing a Preliminary Analytic Blueprint and a Detailed Analytic Blueprint. The PABP is an early planning document that describes the major issues that need to be addressed in rule development to meet statutory, regulatory, and Agency requirements. The purposes of the PABP are to:

- Promote management involvement by supporting early management guidance on basic issues;
- Alert workgroup members and their offices to areas where work should begin;
- Identify data needs and plan collection efforts; and
- Outline the Detailed Blueprint.

The PABP should briefly explain the nature of potential children’s health impacts from the action. This information should include the following:

- The agents that are or may be causing adverse effects in children;
- The nature of the known or suspected adverse impacts;
- The sources of exposure and the pathways from release to the affected populations; and
- The identity and size of the potentially affected population, for example:
 - Does the agent in question affect children, infants, or cause adverse developmental effects in the womb through maternal exposure?
 - Are all children, only children in specific locations or regions, or only children with pre-existing health conditions (such as asthma) or genetic dispositions affected?
 - Are specific ethnic or socioeconomic groups disproportionately affected?

It is essential that the PABP identify important questions, even if they may not need detailed evaluation to answer or may not be answered in detail early in the ADP. This way, all members of the workgroup and participating offices will be aware of the issues and can provide input regarding the scope and magnitude of the necessary analyses.

Once developed, the workgroup submits the PABP to senior management within 60 days of the date the tier designation was approved by OPEI. This allows workgroup members to consult with their management on general direction for the action. Each workgroup member provides the PABP to senior management for his or her consideration in providing early guidance to the workgroup. All members of the workgroup should agree the PABP is ready to be provided to senior management before this occurs. If workgroup members cannot agree, the issues of disagreement should be presented to management for resolution. The expectation is that management will give early guidance within 30 days of receiving the PABP.

C. Developing the Detailed Analytic Blueprint?

The DABP should describe in detail all planned activities related to children’s health, including both the children’s health risk assessment and the benefits assessment, each of which is discussed below. The DABP may stage the analysis to include, as discussed in Part II.D below, both (1) a preliminary analysis to confirm that children’s health may be significantly affected, estimate the magnitude of such impacts, and guide the initial development of any options regarding children’s health and (2) a detailed analysis of the final options sufficient for decision makers to select the final action.

What is a Detailed Analytic Blueprint?

The Detailed Analytic Blueprint builds on the Preliminary Analytic Blueprint to provide decision makers with a detailed description of both the information that will be available to help them to select options and the analyses and other activities that will be conducted to prepare this information. A DABP serves four purposes:

- Incorporates senior management guidance received on the PABP;
- Alerts management and various offices to any important issues that have arisen since the PABP;
- Helps the workgroup plan and schedule the analysis; and
- Documents the agreement among the workgroup participants and management on the scope and framework of the analysis.

1. How should the Detailed Blueprint Address the Children's Health Risk Assessment?

If EPA decides to prepare a quantitative or qualitative evaluation of children's health risks, the DABP should describe:

- The office and workgroup members with lead responsibility for the preliminary and detailed assessments of children's health risks (see below);
- The data needs and data sources for the assessment;
- The scope and basic methodology of the assessment;
- The outputs of the assessment; and
- The schedule and resources required to prepare the assessment.

The sections of the DABP related to children's risk issues should be authored, where possible, by workgroup members or technical experts experienced in children's risk assessment. Each major step in the assessment should be spelled out clearly, including the interactions between disciplines (e.g., fate and transport modeling and toxicology). The risk assessment may consist of several independent analyses that are integrated to provide a detailed characterization of children's risks. Attachment C lists some suggested questions to ask risk assessors as a children's health risk analysis is being planned.

Attachment D lists some guidance documents that address, to some degree, the state of the science and current Agency policies related to risk assessment. Any or all of those documents may be useful, depending on the action under consideration. However, a specific guidance document may not be sufficient to address all the important issues arising in the course of the assessment. In addition to these documents, it is important to consult knowledgeable risk assessment professionals at the outset of the analysis.

In addition, EPA program offices have issued risk assessment guidance for the implementation of their particular program needs (e.g., "Risk Assessment Guidance for Superfund"). Individual program offices may be consulted about the specific risk assessment methods they employ and how their methods address children's health risks. Other groups at EPA play important roles in the development of risk assessment methods, such as Office of Research and Development's (ORD's) National Center for Environmental Assessment, ORD's National Health and Environmental Effects Research Laboratory, the Science Policy Council, and the Risk Assessment Forum. Rule writers and/or action development workgroup chairs should contact their RSC representative to ask them to contact ORD's RSC representative for consultation, as appropriate, regarding including other risk assessment experts in the workgroup. By working through the RSC, this will ensure that everyone involved is informed and that the work group list in the Rule and Policy Information and Development System (RAPDIS) is updated.

Depending on the health effects and exposure routes of concern, risk assessors may also consult with scientists in the Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, National Institute of Environmental Health Sciences, Public Health Service, and state and local health professionals.

2. How should the Detailed Blueprint Address the Children’s Health Benefits Assessment?

When developing the children’s health risk assessment, it is important to consider the data needs for various regulatory analyses such as an RIA or an economic analysis (EA). If potential children’s health effects form a significant proportion of the benefits of the proposed options, it is important to quantify the potential children’s health impacts and compare these health outcomes across the options.⁵ In such cases, the evaluation of potential children’s health effects would be part of the cost analysis, rather than the benefits assessment, but the technical principles remain the same. As noted above, when determining the scope and methodology for analysis, approaches to quantify risks and risk reductions over time and approaches to monetize these benefits should be considered carefully. Individuals experienced in economic analyses of children’s health should be involved in selecting and planning the approaches used to develop monetary benefit measures.

General guidance related to the economic analysis of health issues can be found in the *Guidelines for Preparing Economic Analyses* and specific guidance related to the valuation of children’s health can be found in the *Children’s Health Valuation Handbook*.

D. Options Development

The next step in the ADP is completing the data gathering, consultation, peer review and analysis. This step for the children’s health evaluation is often conducted in the stages described below, and ultimately supports options development and selection.

1. What is a Preliminary Analysis of Children’s Health?

A preliminary analysis may be prepared to confirm that children’s health may be significantly affected by the action and to estimate the magnitude of these impacts under different options. A large part of the preliminary analysis is the collection of data related to children’s health impacts and the identification of lingering data gaps that may need to be addressed in the detailed analysis or to support option selection.

2. What Kinds of Information are Needed to Support the Preliminary Analysis?

The preliminary analysis of children’s health should include, to the extent possible, a complete children’s health risk assessment, which includes hazard identification, dose-response assessment, exposure assessment, and risk characterization. Data needs may vary, but should include:

- Descriptive information about the nature of adverse effects in children, infants, and the unborn caused by the agents in question to support hazard identification;

⁵ Occasionally, proposed actions may have adverse effects on children’s health (presumably balanced by greater benefits of other kinds).

- Studies of the relationship between exposure to the agents and adverse effects that can be used to derive dose-response relationships for children and other specially sensitive subpopulations;
- Detailed information about how children are exposed to the agents and how the exposure can be expected to change under the options being considered; and
- Information about the relationship between adverse effects and economic impacts, such as latency, age distributions of morbidity and mortality associated with exposure, length of illness or disability, severity of permanent impairments, medical costs, and other monetary surrogates.

Gaps in any of these types of information should be identified by workgroup members or designated experts in risk and economic assessment so that they can be addressed in the detailed analysis. This is best done by “working through” the analysis for each option under consideration, as discussed below.

3. What does the Preliminary Analysis Cover?

The preliminary analysis of children’s health characterizes the estimated current or baseline children’s health risks, their associated or surrogate costs, and the impacts of each option under consideration. The preliminary analysis should cover the full range of options being considered. It should provide a sufficient level of detail to distinguish major differences in health impacts across the options or sets of options. The preliminary analysis may be used to group and/or rank options in terms of their relative children’s health impacts. (Parallel analyses may categorize options based on compliance costs, information costs, affordability, unfunded mandates, and other factors.) The preliminary analysis helps to focus the detailed analysis on the most desirable options and on key analytical and/or procedural issues, such as the sensitivity of costs and benefits to the timing of compliance, assumptions related to dose-response, and discount rates. Parallel analyses may categorize options based on compliance costs, information costs, affordability, unfunded mandates, and other factors.

The preliminary analysis of children’s health may generate draft documents to include in the EA or RIA or result in a stand-alone risk assessment, depending on the specific action under consideration. The preliminary analysis also provides an important opportunity to conduct peer review. Having the risk assessment internally and externally reviewed at this stage can help to establish credibility and to identify potential problems in a timely manner. Experts in the relevant areas of children’s health should be represented in the peer review process. For more information, see EPA’s [Peer Review Handbook](#) (Science Policy Council, ORD, draft, 2005).

4. What are the Detailed Analysis and Options Development?

The preliminary analysis is used to guide both the development of detailed (final) options and the more detailed analyses of these options. The process of getting to the “final” options is usually an iterative process; as analyses become more detailed, options are fine-tuned to maximize, within constraints, benefits, and reduce costs and increase feasibility. At the end of the process, the detailed options are supported by similarly detailed analyses sufficient to provide support for option selection. The detailed analysis should (1) provide information that will allow decision makers to select the final action and (2) fulfill Executive and statutory requirements for regulatory analysis.

The detailed analyses aims at producing documents that describe the basis for the regulatory decision to stakeholders and the public and that fulfill regulatory analysis requirements. Incorporating children's health analyses into the regulatory support documents is fairly straightforward. The actual children's health risk assessment could be included in the EA or RIA as an attachment or by reference with only a summary in the actual text of the EA or RIA. Either of these approaches will allow easy review of the technical aspects of the assessment by experts in the field, and easy revision to the EA or RIA if aspects of the children's risk assessment change in response to new data or public comments. Additionally, children's health analyses could also appear in the environmental justice section where discussions of subpopulations occur.

5. Where can I Find Good Examples of Regulatory Analyses that Comprehensively Address Children's Health Issues?

The appropriate methods are likely to vary depending on the programs, media, environmental contaminants and actions under consideration. With the exception of a few agents that predominantly affect children, such as lead, detailed analyses of children's health have generally not been included as prominent aspects of RIAs. Many important issues related to the quantification and monetization of children's health impacts are the subject of ongoing research. In general, the most recent analyses are most likely to provide useful models for approaches to evaluating children's health.

In seeking out such models, rule writers should consult with senior management in their offices for recommendations. In addition, they should consider searching the National Center for Environmental Economics (NCEE) database of RIAs available at <http://yosemite1.epa.gov/ee/epa/eed.nsf/pages/RegulatoryImpactAnalyses.html> for useful information, along with databases related to specific technical issues that may arise in the analyses of children's health issues or health issues in general. For example RIAs see the [Clean Air Interstate Rule](#)⁶ and the [Economic Analysis of Toxic Substance Act Section 403: Lead-based Paint Hazard Standards](#)⁷. Often, approaches to incorporating health outcomes into regulatory analyses first appear in the economic literature or discussion papers before they are actually applied in practice. Consult with knowledgeable Agency professionals (in NCEE or OCHPEE, for example) when scoping the economic analyses of children's health issues.

E. Options Selection

Options selection is the last step in the ADP before the workgroup completes drafting the action. In this step, the workgroup identifies the significant issues and several options to resolve each issue. Senior management then selects those options that would best achieve the goals of the action.

⁶ 70 *Federal Register* 25162, May 12, 2005.

⁷ EPA, Office of Pollution Prevention and Toxic Substances, December 21, 2000.

1. How are Children's Health Considerations Factored into Options Selection?

Selecting an action from among many options is a complex process. The extent to which impacts on children's health risks figure in the process will vary considerably across actions. Neither the EO 13045 nor the Children's Health Policy requires regulatory decisions to be made based solely on children's risk, even if such risks are disproportionate. How children's risk will factor into options selection depends, first, on the operative requirements of the statute under which the action is being taken. Children's health considerations often may be subsumed in the general requirements for rulemaking and cost-benefit balancing (e.g., "with an adequate margin of safety" or "such that the benefits justify the costs").

2. How should Children's Health Considerations be Presented to Decision Makers?

In presenting the results of the children's health evaluation to decision makers, a rule writer should be sensitive to the specific statutory and other important criteria that decision makers will use to select an option. Where children's health benefits represent the major consideration for taking action, it is vital that the nature and magnitude of risks be clearly presented in some detail. For example, the following questions might be answered:

- Are there studies documenting effects? How complete are the studies?
- Is there indication that children have sensitivities different than those of adults? What are the qualitative and quantitative differences?
- What are the exposures to children? Do they vary significantly from those of adults? How do they vary – more or less?
- What are the expected risks to children relative to adults and other subpopulations?
- What are the strengths, weaknesses, and uncertainties of the hazard evaluation, dose-response analysis, exposure assessment, and risk characterization?
- Are the databases used for the risk assessment complete? And, what impact does the completeness or incompleteness have on the quality of the risk assessment?
- What is the peer review status of the information supporting the risk assessment, as well as the risk assessment itself and the risk characterization?
- Are there alternative analyses conducted by outside groups and what are their conclusions?

To the extent that cost-benefit comparisons are part of the decision process, the economic consequences should be fully specified using appropriate health cost equivalents and economic surrogates. Alternatively, cost-effectiveness analysis or marginal cost-effectiveness can be used to support the selected option. Consultations with senior management can help establish the relative importance of specific cost-benefit elements during the course of the ADP. Care should be taken to solicit such information and to tailor the analyses accordingly.

F. Developing the Proposed Action

In this step, the workgroup prepares the action under the leadership of the workgroup chair. In the case of a regulatory action, this step includes preparing the rule and preamble and the supporting documents. As part of this step, the evaluation of children’s health is incorporated.

1. What should be in the Preamble?

A companion ADP document, *Guide to Considering Children’s Health When Developing EPA Actions: Preamble Templates*, available in the ADP library <http://intranet.epa.gov/adplibrary> contains suggested templates for the preamble language if the action is a proposed or final rule. More extensive discussions of children’s health impacts may be needed if they constitute a major element of regulatory benefits.

In general, the preamble should clearly state how the regulation is supported by the results of the risk characterization for children. If the data to characterize children’s risk are insufficient or inadequate, the preamble should describe how the regulatory decision addressed these data gaps and how the Agency searched for data to characterize risks, but was unable to identify satisfactory information.

2. What Happens Next?

Once the proposed action has been developed, a package (the action and supporting documentation) is presented for Final Agency Review (FAR) for Tier 1 and Tier 2 actions. If the proposed action meets the criteria for a “significant” action, the proposed action is reviewed by OMB per EO 12866, “Regulatory Planning and Review.” As stated earlier, for those actions that fall under the purview of the children’s health EO (regulatory actions that may concern health or safety risks that the Agency has reason to believe may disproportionately affect children and may be “economically significant”), EPA is directed to provide the following information to OMB’s Office of Information and Regulatory Affairs for review:

- An evaluation of the environmental health or safety effects of the planned regulation on children; and
- An explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

Finally, the lead program prepares the action for the Administrator’s signature and publication in the *Federal Register*. The lead AA/RA is responsible for requesting the Administrator’s signature via an Action Memo. The lead AA/RA then submits the complete package to OPEI. OPEI reviews the package and after approval by the AA/OPEI, transmits the package to the Office of the Executive Secretariat for the Administrator’s signature. If the regulatory action does require OMB review, then the lead program needs to prepare a package for submission to OMB after FAR for rules in Tiers 1 or 2. Tier 3 actions generally do not have a FAR and may go directly to OMB when appropriate. OPEI’s Regulatory

What is Final Agency Review?

FAR is the last point for internal EPA review of an action and all FAR comments reflect each participating Assistant Administrator’s views. FAR meetings are chaired by the Director of OPEI’s Regulatory Management Division, or his/her representative, and are held to confirm that: all issues have been resolved or elevated; the action package is ready for OMB submission (if required) or signature; and all EPA and external requirements have been met.

Management Division (RMD) transmits the package to the AA/OPEI for approval to send the package to OMB. Once AA/OPEI approves submission, RMD forwards the action to OMB. More details for these final steps are outlined in the EPA's *Action Development Process: Guidance for EPA Staff on Developing Quality Actions* (<http://intranet.epa.gov/adplibrary>).

REFERENCES

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- Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations. 59 FR 7629, February 16, 1994.
- Executive Order 13045: Protection of Children from Environmental Health and Safety Risks. 62 FR 19885, April 21, 1997, as amended by EO 13229 (66 FR 52013, October 11, 2001) and EO 13296 (68 FR 19931, April 21, 2003).
- Food Quality Protection Act of 1996, Public Law 104-170, August 3, 1996.
- OMB. Economic Analysis of Federal Regulations under Executive Order 12866. January 11, 1996.
- OMB. Circular A-4. September 17, 2003.
- Safe Water Drinking Act Amendments of 1996, Public Law 104-182, August 6, 1996.

Attachment A

Text of Executive Order 13045

(Executive Order 13045 of April 21, 1997, as amended by Executive Order 13229 of October 9, 2001 and Executive Order 13296 of March 18, 2003)

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 rulemaking, 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 rulemaking 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 breath, 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.

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) 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, executive departments, the Environmental Protection Agency, 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. Each report shall also detail the accomplishments of the Task Force from the date of the preceding report. 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 8 years from the date of this order.

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 a biennial 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 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 published biennially 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.

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.

Attachment B

Text of EPA Policy on Evaluating Health Risks to Children



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

OFFICE OF
THE ADMINISTRATOR

OCT 20 1995

MEMORANDUM¹

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 policy 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

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.

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

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.

Attachment C

Rule Writer's Questions for Risk Assessors

The following questions are designed to help rule writers* enter into a meaningful dialog with risk assessors. In general, risk assessment follows four steps: hazard evaluation, dose-response analysis, exposure assessment and risk characterization. Each of these steps is discussed below, along with some pertinent questions. It should be emphasized here that the “big picture” question is whether/how risk assessors considered children’s unique exposures and toxicity.

Please note that this attachment does not provide guidance on how to conduct a risk assessment involving children’s issues. Instead, risk assessors are directed to existing EPA risk assessment guidance documents.

A “Framework for Assessing Health Risks of Environmental Exposures to Children” is under development within the Office of Research and Development. An external review draft of the Framework is available at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=150263>. Agency staff should consult with ORD on applying the Framework to inform development of Analytical Blueprints and supporting risk assessments for actions under consideration.

A. Hazard Evaluation

Hazard evaluation involves determining if a stressor (i.e., chemical, microbe, or radiation source) can cause adverse health effects in humans and what those effects might be. This step most often involves input from toxicologists for chemicals, health physicists for radionuclides, microbiologists for bacterial and viral contamination, and epidemiologists where human studies are available.

Question 1: Are there epidemiologic or laboratory animal toxicology data derived from studying hazards to the fetus, infants and/or children?

* As mentioned on page 1, for the purposes of this document “rule writer” is shorthand for the intended audience - participants on action development workgroups and any other Agency staff involved in developing actions.

Question 2: Is there information (from animal or epidemiologic studies) bearing on specific health endpoints of concern, including, but not limited to:

- Effects on the embryo and fetus (developmental toxicity) including malformations, growth retardation and death?
- Effects on postnatal development (e.g., sexual and mental maturation)?
- Reproductive effects?
- Endocrine disruption?
- Target organ and system effects (e.g., nervous and immunological systems, lung, and skin)?
- Modulation of existing disease (e.g., exacerbate asthma)?

Question 3: Has the possibility of a **window of susceptibility** (i.e., the time of an exposure with respect to age or life stage is associated with a specific toxic outcome and/or unique dose-response sensitivity) been evaluated?

Question 4: Has a mode-of-action (MOA) been identified which explains the process by which a stressor causes toxicity? Does this MOA consider the impact of early life exposure?

B. Dose-Response Analysis

Dose-response analysis involves evaluating the quantitative relationship between dose and toxicological responses. For certain chemical substances, dose-response evaluation may involve modeling the frequency of adverse effects, such as cancer, in the exposed population. More frequently, dose-response evaluation for adverse non-cancer effects identifies threshold exposure levels that are “likely to be without significant harm” under the specified conditions of exposure (also known as Reference Doses [RfD] for oral dosing or Reference Concentrations [RfC] for inhalation exposure). While non-cancer effects are usually characterized with RfDs or RfCs, it is important to note that non-cancer effects have been characterized with continuous dose-response functions for major rulemakings involving well characterized pollutants (e.g., particulate matter, ozone, lead), which facilitates much more detailed and informative analysis of risks to children and risk reductions expected from rulemaking

Question 5: Do children’s dose levels differ from adults and are there differences in response to a given dose in children compared to adults?

Question 6: If the toxic agent is a carcinogen, is the MOA associated with early life sensitivity, such as is the case for carcinogens acting via a mutagenic MOA; see EPA’s 2005 Guidelines for Carcinogen Risk Assessment and Supplemental Guidance for Assessing Susceptibility from Early Life Exposure to Carcinogens? Have age-adjustment factors been applied?

Question 7: Are there any developmental toxicity studies from which to analyze dose-response?

C. Exposure Assessment

Exposure assessment estimates the levels of the agents that come in contact with children and other populations of concern. Examples of unique childhood behavior that can impact exposure include playing indoors on the floor and outdoors on the ground; preferential consumption of certain foods; consumption of breast milk (infants); spending a larger fraction of time indoors at home; pica/soil ingestion; and mouthing activities (e.g., hand to mouth, object to mouth).

Question 8: How does childhood exposure differ from that of adults and why? What childhood age groups were considered in the exposure assessment? See EPA's 2005 [Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants](#) and [Child Specific Exposure Factors Handbook](#).

D. Risk Characterization

Risk characterization is the last phase of the risk assessment process that estimates the potential for adverse health effects to occur from exposure to a stressor and evaluates the uncertainty involved. A rule writer should review the [Risk Characterization Handbook](#) and consult with senior management to clarify major issues in this area. Important questions might include:

Question 9: What are the scientific uncertainties in the data and /or tools used to assess how risks for children differ from that of adults? What can be done to reduce these uncertainties?

Question 10: What are the important assumptions being made in the analysis?

Attachment D

Resources

We work in a dynamic environment. References, guidelines are always being updated. Therefore, users of this guide should always check with the appropriate sources (e.g. their Regulatory Steering Committee representative, the action development workgroup representatives from particular offices and/or the Action Development Library) to ensure that you are using the most recent guidance on each aspect of the action.

Action Development Resources

Action Development Library is available at <http://intranet.epa.gov/adplibrary>.

EPA, OPEI. *EPA's Action Development Process: Guidance for EPA Staff on Developing Quality Actions*. Action Development Library. June 30, 2004. <http://intranet.epa.gov/adplibrary/policy.htm>.

EPA, OPEI. *EPA's Action Development Process: Guidelines for Preparing Analytical Blueprints*. Action Development Library. September 2004. <http://intranet.epa.gov/adplibrary/policy.htm>.

Economic Analysis Resources

EPA, OCHP and OPEI. *Children's Health Valuation Handbook*. October 2003.

EPA, Office of the Administrator. *Guidelines for Preparing Economic Analyses*. September 2000.

OMB. *Circular A-4*. September 17, 2003.

Risk Assessment Resources

Daston., G., E. Faustman, G. Ginsberg, P. Fenner-Crisp, S. Olin, B. Sonaware, J. Bruckner, and W. Breslin. *A Framework For Assessing Risks to Children from Exposure to Environmental Agents*, *Environ Health Perspect* 112:238-256, 2004.

EPA A Framework for Assessing Health Risks of Environmental Exposures to Children. National Center for Environmental Assessment, Washington, DC; EPA/600/R-05/093A.2006

EPA. Toxicity and Exposure Assessment for Children's Health. (TEACH: a database of toxicity information) 2005.

EPA, National Center for Environmental Assessment, ORD. Child Specific Exposure Factors Handbook. 2006 (external review draft).

EPA, National Center for Environmental Assessment, ORD. Exposure Factors Handbook, Volumes I, II, III. August 1997.

EPA, Office of Science Policy, ORD. Risk Characterization Handbook. December 2000.

EPA, Office of Science Policy, ORD. EPA's Peer Review Handbook, Draft, 2005. See also, EPA's Peer Review Program web page.

EPA, Risk Assessment Forum. Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants. 2005.

EPA, Risk Assessment Forum. Guidelines for Carcinogen Risk Assessment. March 2005.

EPA, Risk Assessment Forum. Guidelines for Developmental Toxicity Risk Assessment. December 1991.

EPA, Risk Assessment Forum. Guidelines for Exposure Assessment. May 1992.

EPA, Risk Assessment Forum. Guidelines for Mutagenicity Risk Assessment. September 1986.

EPA, Risk Assessment Forum. Guidelines for Neurotoxicity Risk Assessment. April 1998.

EPA, Risk Assessment Forum. Guidelines for Reproductive Toxicity Risk Assessment. October 1996.

EPA Risk Assessment Forum. Supplemental Guidance for Assessing Susceptibility from Early Life Exposure to Carcinogens. March 2005.

