# *EPA's Rule Writer's Guide to Executive Order 13045*

## *Guidance for Considering Risks to Children During the Establishment of Public Health-Based and Risk-Based Standards*

**Table of Contents**


| | |
|---|---|
| **Flow Chart for determining if your action is covered under Executive Order 13045, and the appropriate template language to use in Attachment A** | **Page 2** |
| **Questions and Answers regarding application of Executive Order 13045 and EPA's Policy on Evaluating Health Risks to Children** | **Page 4** |
| **Attachment A: Templates for Preambles** | **Page 11** |
| **Attachment B: Provisions of E.O. 13045 related to rule development** | **Page 23** |
| **Attachment C: Technical Support for Risk Assessors--Suggestions for Characterizing Risks to Children** | **Page 24** |
| **Attachment D: Text of Executive Order on Protection of Children from Environmental Health Risks and Safety Risks** | **Page 30** |
| **Attachment E: Text of Policy on Evaluating Health Risks to Children** | **Page 34** |

## Flow Chart for Determining if Your Action is Covered under Executive Order 13045, and the Appropriate Template Language to Use in Attachment A

1. Is this action based solely on technology performance or does this action involve sampling methodologies/test procedures; procedural rules; ecological standards not based on human health; information gathering rules; permit application rules; state program approvals; SIPs; FIPs; or specific standards established by Congress in statutes? ➜ **YES** ➜ Use Template F

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NO

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2. Is the Agency issuing this action in an emergency situation, or because it is obligated by law to act more quickly than normal review procedures allow? ➜ **YES** ➜ Use Template G

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NO

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3. Is this action economically significant? ➜ **NO**➜ Go to #7

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YES

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5.Were substantive actions in the rulemaking initiated before April 21,1997 or was an NPRM published before April 21, 1998? ➜ **YES** ➜ Use Template E

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NO

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| 6. Do you have reason to believe that your action addresses an environmental health risk or safety risk that may have disproportionate risk to children? (Disproportionate means that children's exposure, uptake, and/or susceptibility is greater than that of adults. Questions in Attachment C, "Technical Support for Risk Assessors," are typical of those you would ask when trying to determine disproportionality) | ➜ **NO** ➜ Use Template C |

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YES

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| Use Template A |

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| 7. Do you have reason to believe that your action addresses an environmental health risk or safety risk that may have disproportionate risk to children? (Disproportionate means that children's exposure, uptake, and/or susceptibility is greater than that of adults. Questions in Attachment C, "Technical Support for Risk Assessors," are typical of those you would ask when trying to determine disproportionality) | ➜ **NO** ➜ Use Template D |

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YES

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| 8. Use Template C |

# Questions and Answers Regarding Application of Executive Order 13045 and EPA's Policy on Evaluating Health Risks to Children

## Background

On April 21, 1997, the President signed an Executive Order (13045) entitled "Protection of Children from Environmental Health Risks and Safety Risks." This is the primary directive to Federal Agencies and Departments that federal health and safety standards now must include an evaluation of the health or safety effects of the planned regulation on children. The Executive Order applies to economically significant[1] rules that were initiated after April 21, 1997 or for which a notice of proposed rulemaking was published after April 21, 1998, which concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children. For rules subject to the Executive Order, agencies must explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

In addition to the Executive Order, EPA has established the principle that all EPA risk assessments, risk characterizations, and environmental and public health standards always will evaluate health risks to infants and children (see Question 3 for examples of actions that are exceptions.) This principle is articulated as follows in the "Policy on Evaluating Health Risks to Children," October, 1995, issued by the Administrator and Deputy Administrator of EPA ("EPA's Children's Health Policy"):

> ***"It is the policy of the U.S. Environmental Protection 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."***

EPA's "National Agenda to Protect Children's Health from Environmental Threats," October, 1996, further reinforces our commitment to children:

> ***"As a national policy, this Administration will ensure that all standards EPA sets are protective enough to address the potentially heightened risks faced by children -- so as to prevent environmental health threats***

[1] An economically significant rule is defined by Executive Order 12866 as any 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.

***wherever possible ...”***

Further, Executive Order 12898, “Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations,” directs each Federal agency to identify and address :

> **“...disproportionately high and adverse human health or environmental effects of its programs, policies and activities on minority and low income populations...”**

**1. What is the purpose of this guidance?**

We have provided this guidance as a tool that EPA rule writers[2] who are responsible for the development of regulatory actions may use to help them in complying with both Executive Order 13045 and EPA’s Children’s Health Policy. As with all the regulatory assessment-related mandates, the rule writers are responsible for determining whether the requirements of Executive Order 13045 and EPA’s Children’s Health Policy apply to their rule, and if so, what analysis or other actions satisfy those respective requirements. Since it is important that we make these decisions early in the rule’s development, the rule writer may use this guide to ensure that the Analytical Blueprint[3] prepared for the rule under development properly includes components called for by Executive Order 13045 and EPA’s Children’s Health Policy.

Please note that this guide does not provide guidance on how to conduct a Risk Assessment involving children’s issues. Risk assessors are directed to existing EPA risk assessment guidance documents for the latter. Attachment C to this guidance includes suggestions for the types of questions that a risk assessor could ask to characterize risk to children. It is to help users think about possible questions, but 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. Additional information and other factors may be relevant in deciding how to characterize risks to children.

**2. What rules are covered by Executive Order 13045, EPA’s Children’s Health Policy, and this guidance?**

Executive Order 13045 only applies to rules that:

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[2]/ This guidance uses the term “rule writer” to describe the manager of the rule development process, who draws upon a diverse set of resources -- legal, economic, engineering, risk assessment, etc. -- to draft a rule.

[3]/ The Analytical 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, etc.) 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 work group activities.

- are initiated after April 21, 1997 or for which a NPRM is published after April 21, 1998;
- are economically significant
- are based on health or safety risks; and
- for which EPA has reason to believe may disproportionately affect children.

By comparison, EPA's Children's Health Policy generally applies to all standards that the agency will develop where the authorizing statute either expressly authorizes or gives the agency the discretion to consider health or safety risks when making the regulatory determination. (See section 3 for exceptions to this general statement.) This guidance discusses how you determine whether Executive Order 13045 or EPA's Children's Health Policy apply to your rule, how you comply with the requirements of the Executive Order and the Policy, and includes template language for you to use in the preamble to your rule.[4]

**3. Are there any rules that are not covered by the Executive Order?**

Yes. The following rules are *not* covered by Executive Order 13045:
- Rules that are not economically significant rules
- Rules that were initiated before April 21, 1997, or whose Notice of Proposed Rulemaking was published before April 21, 1998
- Rules that are not based on health or safety risks; and/or
- Rules that the agency does NOT believe may disproportionately affect children.

EPA interprets the Executive Order as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required by section 5-501 of the Order has the potential to influence the regulation. Program offices need to determine, in consultation with their Steering Committee representatives and OGC, whether the statute authorizing the rule allows EPA to consider health or safety risks when making the regulatory determination at hand.

In general, the following rulemakings are not covered by Executive Order 13045 because they typically do not allow for the consideration of health or safety risks: rules based solely on technology performance; sampling methodologies and test procedures; procedural rules (e.g., how to file a claim); ecological standards not based on human health; information gathering rules; permit application rules; individual State program approval decisions; state implementation plan (SIP) call and federal implementation plan (FIP) 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.) Rule writers should note, however, that for a given rulemaking, there may be certain aspects of the regulation where consideration of health or

[4]Since the majority of rules the agency issues are not economically significant, most of EPA's rules are subject to EPA's Children's Health Policy.

safety risks is prohibited by law, while other aspects of the same regulation may allow the rulewriter to take into account considerations of health and safety risks to children (see box below).

Additionally, if a Program Office concludes, based on scientific and engineering judgment, that even though the agency has the discretion to consider health and safety risks for a given rulemaking, 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, that standard does not have to conduct additional analysis as required by Executive Order 13045. However, it would enhance the public's understanding of a standard's benefits if you included a brief description of what EPA knows about how the standard is protective of environmental health including that of children. In making this determination, the Program Office should consider the following factors, along with any other factors relevant to the particular rulemaking:

(1) the toxicity of the pollutants involved, with particular emphasis on their potential impact on children's health;

(2) the magnitude of the emissions/discharges of these pollutants in populated areas and/or the level of exposure; and

(3) the feasibility of obtaining additional pollutant reductions beyond that required by statute as the minimum level of stringency.[5]

Even if a rule is not covered by Executive Order 13045, if the rule includes any discussion of environmental health or safety, you are encouraged to include a characterization of 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 assessment or other economic analyses or risk assessments, you should include children's health considerations.

***What is an example of a regulation that has only some aspects covered by Executive Order 13045?***

An example of a type of standard that precludes EPA from considering health or safety risk in some aspects of the rulemaking is maximum achievable control technology (MACT) standards developed under sections 112(d) or 129(a) of the Clean Air Act. The statute requires determination of the minimum level of stringency (i.e., the "MACT floor") to be based solely on the performance of technology; thus, EPA cannot consider health or safety risks in determining the floor. However, in determining whether the MACT standard should be set at

[5]For example, if the MACT floor level of stringency already is high, there may not be a feasible, more-stringent technology available.

a more stringent level that requires the use of additional technology beyond that required to meet the floor, EPA may consider whether the pollutant being regulated disproportionately affects children. Moreover, an assessment of residual risk following implementation of the MACT standards may lead to standards developed under sections 112(f) and 129(h)(3) that would be covered by this guidance because they will be risk-based standards.

Similarly, in deciding which pollutants to regulate under various statutory provisions or whether a major source of a particular pollutant should be defined below the default threshold of 10 tons/year of any one pollutant or 25 tons/year of any combination of pollutants pursuant to section 112(a)(1) of the Clean Air Act, EPA may consider any disproportionate impact the pollutant has on children.

**4. How should I address children's risk if the Agency has to issue a regulation in an emergency or under a Court-imposed deadline?**

Executive Order 13045 stipulates that Agencies shall comply with the Order to the extent practicable in an emergency situation, or if the law obliges the Agency to act more quickly than Executive Order review procedures would allow. Further, Executive Order 13045 stipulates that the agency shall, to the extent practicable, schedule rulemaking procedures so as to permit sufficient time for completing an evaluation of the environmental health and safety effects of the planned regulation on children.

**5. How is this guidance related to existing activities to address risk to children?**

EPA Media Program Offices, Regions, and the Office of Research and Development have adopted principles established by EPA's internal policies into their activities according to the requirements and constraints of their respective programs. This guidance does not suggest that risk characterizations for children all follow the same formula. This guidance does suggest, in Attachment C, questions a risk assessor may consider for characterizing risk to children. Risk assessors, however, may include any and all information they believe relevant in addressing children's risk.

**6. What exactly is a risk characterization and how does it differ from a risk assessment?**

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.

EPA's Science Policy Council is preparing a "Risk Characterization Guide," scheduled for peer review in late 1998, to advise risk assessors in the preparation of risk characterizations for all EPA activities including standard development, and non-regulatory initiatives such as the *Design for the Environment* Initiative. The suggestions for children's risk characterization described in Attachment C will be forwarded to the Science Policy Council for consideration in their more broadly applicable guidance.

**7. How does a decision maker use a risk characterization for children?**

A decision maker relies on the rule writer to display information on several components including health risks, economics, and legal considerations, in scoping out regulatory options. A risk characterization for children, because it is the final stage in risk assessment, would typically provide a decision maker with answers to questions in the box below.

**RISK CHARACTERIZATION**

Are there studies documenting effects?
How complete are the studies in documenting potential effects?
Is there indication that children have sensitivities different than adults?
- qualitative differences?
- quantitative differences?

What are the exposures to children?
- do they differ significantly from those of adults?

What are the expected risks to children?
- relative to adults?
- relative to other subpopulations?

What are the strengths, weaknesses and uncertainties of the hazard, dose response, exposure and risk cases?

Display of the risk characterization for children provides the decision maker with an understanding of the merits and limitations of the data, the latter of which will include information on data gaps.

**8. How should I display the results of the risk characterization for children and its underlying data sources in a way that enables the public to understand and comment?**

The preamble clearly should state how the regulation is based on the results of the risk characterization for children; or, in the event of insufficient or inadequate data to characterize children's risk, how the regulatory decision addresses data gaps and subsequently protects children. In the event of absent or inadequate data on children, you should indicate in the preamble that the Agency searched for data to characterize children's

risk but was unable to identify satisfactory information. Therefore, EPA is moving forward with this regulation and is providing what information it found on early lifetime exposures for purposes of transparency and clarity. During the risk characterization, it also may become clear that the sensitivity of another population group is the primary health endpoint that influences the standard. This conclusion, if appropriate, also should be described in the preamble.

The risk characterization for children should be written clearly in plain language so that the public can understand and comment on how the Agency conducted the characterization, and on the data sources it used to identify toxicity, dose-response and exposure information for children. When a risk characterization for children is conducted, a summary discussion should be included in the appropriate sections of the preamble, using suggested template language provided in Attachment A.

During the pre-proposal notification, and/or during the proposed regulation phase, the public should be invited to submit or identify peer reviewed studies and data, of which the agency may not be aware, that assessed results of early life exposure to the product, substance or vector proposed for regulation. These may include animal studies, epidemiologic data, or clinical studies.

Actual risk assessment and risk characterization documents must be included in the rulemaking docket, and be made available to the public as supporting information for the rule.

**9. Where do I go if I have questions about Executive Order 13045?**

You should consult with the Steering Committee representative for your Program Office first, and then, if necessary, with the Regulatory Management Division, Office of Policy, or the Office of General Counsel or Office of Regional Counsel attorney who is assigned to your rule.

**10. Attachments to this guidance.**

**Attachment A**: Executive Order 13045: Templates for Preambles
**Attachment B:** Executive Order Provisions Related to Rule Development
**Attachment C:** Technical Support for Risk Assessors: Suggestions for Characterizing Risks to Children
**Attachment D:** Text of Executive Order 13045
**Attachment E:** Text of “Policy on Evaluating Health Risks to Children”

**Attachment A**

## Executive Order 13045, Children's Health Protection: Templates for Preambles

All EPA rules, both at proposal and final, must address the applicability of E.O. 13045. Rules that (1) were initiated after April 21, 1997 or for which a notice of proposed rulemaking was published on or after April 21, 1998; (2) are based on health or safety risks; *and* (3) are also economically significant under E.O. 12866, are subject to the Children's E.O. While the E.O. requires analysis only if the rule meets all of the above criteria, EPA's policy is broader in that it requires rulewriters to address children's health risks in rule preambles for all health-based and risk-based rules. If your rule does not involve regulatory decisions that are based on public health or safety risks, then the rule isn't subject to the E.O. but you must explain why the E.O. isn't applicable in the preamble.

The following are templates for the various regulatory determinations possible under the E.O. and EPA policy. (Your office may have additional guidance on the language that you may be required to include, so be sure to consult with your Regulatory Steering Committee Representative or manager.)

**TEMPLATE A: Rules that are subject to the E.O., because they:**

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

**TEMPLATE B: Rules that:**

- were initiated after April 21, 1997 or for which a notice of proposed rulemaking was published on or after April 21, 1998
- are economically significant
- are based on health or safety risks but
- EPA does NOT have reason to believe may disproportionately affect children

**TEMPLATE C: Rules that:**

- are NOT economically significant
- are based on health or safety risks and
- EPA has reason to believe may disproportionately affect children

**TEMPLATE D: Rules that:**

- are NOT economically significant
- are based on health or safety risks but
- EPA does NOT have reason to believe may disproportionately affect children

**TEMPLATE E: Rules that:**

- are economically significant and
- were initiated before April 21, 1997 or for which a Notice of Proposed Rulemaking was published before April 21, 1998

**TEMPLATE F: ALL rules where E.O. 13045 does not apply because of one of the following reasons:**

- The rule is based solely on technology performance
- The rule does not establish an environmental standard intended to mitigate health or safety risks
- The action approves a state program; approves a state rule implementing a Federal standard (e.g., SIPs); implements a previously promulgated Federal standard (e.g., FIPs); or implements specific standards established by Congress in statutes

**TEMPLATE G: When 13045 does not apply because the Agency is taking action in an emergency situation, or when the Agency is obligated by law to act more quickly than normal review procedures allow.**

# TEMPLATE A

**for rules that:**

**• Were initiated after April 21, 1997 or for which a notice of proposed rulemaking was published on or after April 21, 1998**
**• are economically significant**
**• are based on health or safety risks, and**
**• EPA has reason to believe may disproportionately affect children**

***The following paragraphs should appear in the "Administrative Requirements" section of the preamble*:**

**Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks**" (62 F.R. 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This **[proposed/final]** rule is subject to the Executive Order because it is an economically significant regulatory action as defined by E.O. 12866, and we believe that the environmental health or safety risk addressed by this action **[may have/has]** a disproportionate effect on children. Accordingly, we have evaluated the environmental health or safety effects of **[the product, substance or other vector responsible for such effects]** on children. The results of this evaluation are contained in **[reference all sections in the preamble and note that a copy of all document(s) have been placed in the public docket for this action]**.

***The following summary of substantive analysis and decisions under the E.O. should appear in the "Supplementary Information" section of the preamble, under a heading entitled "Children's Environmental Health," and handled in a fashion similar to your discussion of findings in a economic assessment or Regulatory Impact Analysis. Be sure it includes the following information:***

- the product, substance or other vector responsible for effects on children;
- the findings of hazard assessment, exposure assessment, risk characterization, etc. -- whatever is pertinent to the current step in the rule's development and supports your evaluation;
- an evaluation of alternative regulatory options and the one selected [describe the various options considered, or cross reference other parts of the preamble where they are discussed, and explain the preferred option];
- an explanation of why this option was preferable to other potentially effective and reasonably feasible alternatives;
- where the full analysis is located -- on file in the Administrative Record, official rule docket, preamble, etc.

***Insert the following if your action is a proposed rule:***

The public is invited to submit or identify peer-reviewed studies and data, of which EPA may not be aware, that assessed results of early life exposure to **[the product, substance or other vector proposed for regulation.]**

## TEMPLATE B

**for rules that:**

**• were initiated after April 21, 1997 or for which a notice of proposed rulemaking was published on or after April 21, 1998**
**• are economically significant**
**• are based on health or safety risks, BUT**
**• EPA does NOT have reason to believe may disproportionately affect children**

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***The following paragraphs should appear in the "Administrative Requirements" section of the preamble:***

**Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks**" (62 F.R. 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This **[proposed/final]** rule is not subject to E.O. 13045 because the Agency does not have reason to believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. Nonetheless, we have evaluated the environmental health or safety effects of **[the product, substance or other vector responsible for such effects]** on children. The results of this evaluation are contained in **[reference all sections in the preamble and note that a copy of all document(s) has been placed in the public docket for this action].**

***The following summary of substantive analysis and decisions under the E.O. should appear in the "Supplementary Information" section of the preamble, under a heading entitled "Children's Environmental Health," and handled in a fashion similar to your discussion of findings in a economic assessment or Regulatory Impact Analysis. Be sure it includes the following information:***

- the product, substance or other vector that you analyzed for potential effects on children;
- the findings of hazard assessment, exposure assessment, risk characterization, etc. -- whatever is pertinent to the current step in the rule's development and supports your evaluation;
- the reason(s) for your determination that the substance or vector will not disproportionately affect children;
- where the full analysis is located -- on file in the Administrative Record, official rule docket, preamble, etc..

***Insert the following if your action is a proposed rule:***

The public is invited to submit or identify peer-reviewed studies and data, of which EPA may not be aware, that assessed results of early life exposure to **[the product, substance or other vector proposed for regulation.]**

## TEMPLATE C

**for rules that:**

- **are NOT economically significant**
- **are based on health or safety risks, and**
- **EPA has reason to believe may disproportionately affect children**

For rules that are based on health or safety risks but are not economically significant, it is EPA's policy to develop a separate assessment of risks to infants and children or state clearly why this is not done. This should be done to the extent permitted by available data, e.g., a demonstration that infants and children are not expected to be exposed to the stressor. An evaluation of children's health risk should be commensurate with the type of rulemaking. For example, a minor technical amendment to a rule would be a significantly lower level of effort that revising a National Ambient Air Quality Standard, and the respective resources dedicated to an evaluation of children's health would reflect this difference.

***The following paragraphs should appear in the "Administrative Requirements" section of the preamble:***

**Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks**" (62 F.R. 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

While this **[proposed/final]** rule is not subject to the Executive Order because it is not economically significant as defined in E.O. 12866, we nonetheless have reason to believe that the environmental health or safety risk addressed by this action **[may have/has]** a disproportionate effect on children. As a matter of EPA policy, we therefore have assessed the environmental health or safety effects of **[the product, substance or other vector responsible for such effects]** on children. The results of this assessment are contained in **[reference all sections in the preamble and note that a copy of all document(s) has been placed in the public docket for this action].**

***A brief summary of substantive analysis and decisions should follow, in the "Administrative Requirements" section, and be handled in a fashion similar to your discussion of findings in a economic assessment or Regulatory Impact Analysis. Be sure it includes the following information as appropriate to the level of effort devoted to the assessment:***

- the product, substance or other vector responsible for effects on children;
- the findings of hazard assessment, exposure assessment, risk characterization, etc. -- whatever is pertinent to the current step in the rule's development and supports your evaluation;
- an evaluation of alternative regulatory options and the one selected [describe the various options considered, or cross reference other parts of the preamble where they are discussed, and explain the preferred option];
- an explanation of why this option was preferable to other potentially effective and reasonably feasible alternatives;
- where the full analysis is located -- on file in the Administrative Record, official rule docket, preamble, etc..

***Insert the following if your action is a proposed rule:***

The public is invited to submit or identify peer-reviewed studies and data, of which EPA may not be aware, that assessed results of early life exposure to **[the product, substance or other vector proposed for regulation.]**

## TEMPLATE D

**for rules that:**

- **are NOT economically significant**
- **are based on health or safety risks, BUT**
- **EPA does NOT have reason to believe may disproportionately affect children**

For rules that are based on health or safety risks but are not economically significant, it is EPA's policy to develop a separate assessment of risks to infants and children or state clearly why this is not done. This should be done to the extent permitted by available data, e.g., a demonstration that infants and children are not expected to be exposed to the stressor. An evaluation of children's health risk should be commensurate with the type of rulemaking. For example, a minor technical amendment to a rule would be a significantly lower level of effort that revising a National Ambient Air Quality Standard, and the respective resources dedicated to an evaluation of children's health would reflect this difference.

***The following paragraphs should appear in the "Administrative Requirements" section of the preamble:***

**Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks**" (62 F.R. 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This **[proposed/final]** rule is not subject to the Executive Order because it is not economically significant as defined in E.O. 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children [**describe reasons for this conclusion].**

***[If your data search found that data were absent or of insufficient quality, you should state this clearly in your reasons for concluding there is no disproportionate effect on children.]***

***Insert the following if your action is a proposed rule:***

The public is invited to submit or identify peer-reviewed studies and data, of which the agency may not be aware, that assessed results of early life exposure to **[the product, substance or other vector proposed for regulation.]**

## TEMPLATE E
**for all rules that:**

**• are economically significant**
**•were initiated before April 21, 1997, or Notice of Proposed Rulemaking was published before April 21, 1998**

***The following paragraphs should appear in the "Administrative Requirements" section of the preamble:***

**Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks**" (62 F.R. 19885, April 23, 1997) applies to any rule that: (1) was initiated after April 21, 1997, or for which a Notice of Proposed Rulemaking was published after April 21, 1998; (2) is determined to be "economically significant" as defined under E.O. 12866, and (3) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets all three criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This **[proposed/final]** rule is not subject to the Executive Order because **[use appropriate reason: substantive actions were initiated before April 21,1997 / EPA published a Notice of Proposed Rulemaking before April 21, 1998]**.

***[However, since it is EPA's policy since November 1, 1995, to consistently and explicitly consider risks to infants and children in all risk assessments generated during its decision making process including the setting of standards to protect public health and the environment, you should address whether the policy applies to your rulemaking. If it does, the level of detail required in Template A or B is not required; however, you are encouraged to include some discussion of the impact on children's health.]***

Nonetheless, as a matter of EPA Policy, **[include language either from Template C or D, as appropriate]**.

## TEMPLATE F

**for ALL rules that:**

**•are not based on health or safety risks because either (1) the rule is based solely on technology performance, or (2) because consideration of children's health will not provide a significant opportunity to improve children's health beyond the level offered by a technology-based approach. [Note that if the Agency has the discretion to consider health and safety risks, and concludes that there IS a significant opportunity to improve children's health, you should use Templates A, B, C, or D as appropriate for your rulemaking.]**

**or,**

**•are not based on health or safety risks because they do not establish an environmental standard intended to mitigate health or safety risks such as rules involving: sampling methodologies/test procedures; procedural rules; ecological standards not based on human health; information gathering rules; and permit application rules**

**or,**

**•do not establish further health or risk-based standards because the rule (1) approves a state program; (2) approves a state rule implementing a Federal standard (e.g. State Implementation Plans); (3) implements a previously promulgated health or safety-based Federal standard (e.g. Federal Implementation Plans); or (4) implements specific standards established by Congress in statutes (e.g. the Sulfur Dioxide Allowance Program under Title IV of the Clean Air Act)**

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***The following paragraph should appear in the "Administrative Requirements" section of the preamble:***

**Executive Order 13045: "Protection of Children from Environmental health Risks and Safety Risks"** (62FR19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

***Choose the following alternative language as appropriate for your regulation:***

***Alternative 1 (technology performance):***

EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation. This **[rule]** is not subject to E.O. 13045 because it is based on technology performance and not on health or safety risks.

***[If the Agency has the discretion to consider health and safety risks for a given rulemaking (in whole or in parts of the rule,) but you conclude there is not likely to be a significant opportunity to improve children's health protection beyond the level offered by a technology-based approach, you do not have to conduct an analysis of children's environmental health. However, even if a rule is not covered by E.O. 13045, if the rule includes any discussion of environmental***

***health or safety, you are encouraged to include a characterization of children's risk to the extent data are available.]***

***Alternative 2 (sampling methodologies/test procedures; procedural rules; ecological standards not based on human health; information gathering rules; and permit application rules):***

EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation. This **[rule]** is not subject to E.O. 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

***Alternative 3 (state program approvals; SIPs; FIPs; specific standards established in statutes by Congress):***

EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation. This **[rule]** is not subject to E.O. 13045 because it **[select the appropriate reason: approves a state program /approves a state rule implementing a Federal standard / implements a previously promulgated health or safety-based Federal standard / implements specific standards established by Congress in statutes.]**

## TEMPLATE G:

**When the E.O. normally would apply, ( i.e., economically significant rules that are based on health or safety risks), but does *not* apply because the Agency is taking action in an emergency situation, or when the Agency is obligated by law to act more quickly than normal review procedures allow.**

***The following paragraph should appear in the "Administrative Requirements" section of the preamble:***

**Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks**" (62 F.R. 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

Section 5-502 provides that in emergency situations, or where the agency is required by law to act more quickly than normal review procedures allow, the agency shall comply with the E.O. to the extent practicable.

**[As explained in section __ above or add explanation here],** this **[proposed/final]** rule is being issued under **[use appropriate reason(s): a) an emergency situation (describe circumstances) and/or b) obligations under the law to act more quickly than normal review procedures allow (describe circumstances)]**. Accordingly, the Agency is complying with E.O. 13045 to the extent practicable [**describe actions taken to comply].**

**ATTACHMENT B**

## Provisions of Executive Order 13045 Related to Rule Development

Section 1. Policy

1-101 "... to extent permitted by law and appropriate, and consistent with the Agency's mission, each Federal Agency:

(a) shall ***identify and assess***...; and

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

Section 2. Definitions

2-202 "***Covered regulatory action***" means any substantive action in a rule 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***...

Section 5. Agency Environmental Health Risk or Safety Risk Regulations

5-501 For each covered regulatory action ... Agency shall provide to OMB's Office of Information and Regulatory Affairs ...

(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.

**ATTACHMENT C**

# Technical Support for Risk Assessors: Suggestions for Characterizing Risks to Children

**1. Who conducts a risk characterization for children?**

Risk assessors are responsible for this. If the risk characterization is prepared in support of rule development, a rule writer is responsible for incorporating the children's risk characterization into the supporting materials needed for decision making.

**2. What are relevant exposures for children?**

Executive Order 13045 requires that Agency standards address *disproportionate* risks to children that result from environmental health risks or safety risks. This guidance interprets *disproportionate* as applying to a 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
- exposures to chemicals or radiation during infancy and childhood

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

**3. How does the risk characterization enable the decision maker to comply with the requirements of the Executive Order 13045?**

The fact that economically significant public health-related and risk-related rules will characterize risk for children satisfies the following requirement:

**(a) an evaluation of the environmental health or safety effects of the planned regulation on children [5-501(a)].**

In addition, if data are available, the rule writer, in close collaboration with risk assessors, may be able to provide a decision maker with the following information as part of the risk characterization:

- identify and explain default options and choices as they affect children
- identify and explain model options and choices as they affect children
- identify and explain the selection of endpoints from among multiple options
- in all cases, explain how the assessment might differ if other viable options were selected
- disclose ranges of predicted risk estimates, not just a single number
- provide information about incomplete data bases and the impact this has on the nature and quality of the risk assessment
- provide information on peer review status of the information supporting the risk assessment, as well as the risk assessment itself and the risk characterization
- identify the availability of alternate analyses from outside groups, and explain the alternate analyses

Understanding the merits and limitations of the data underlying the risk assessment for children assists the decision maker in addressing the following requirement of Executive Order 13045:

**(b) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency [5-501(b)]**

**4. How do I get started when conducting a risk characterization for children?**

Executive Order 13045 requires federal agencies to identify and assess environmental health risks and safety risks that may disproportionately affect children. When programs commence planning rules, the rule writer should work with risk assessors to begin accumulating information bearing on potential risks that are unique to children in terms of a child's susceptibility and /or exposure patterns. In some cases there will be incomplete information on potential children's risks or even a complete absence of information. The goal is to obtain adequate information for the assessment of risks, recognizing that you may fall short of reaching that goal.

The types of information that a risk assessor will seek include the requisite component parts of risk assessments, such as potential hazards or adverse effects; information on the sensitivity of children, relative to adults and other subpopulations, to the development of adverse effects; and exposure information, from which risks can be estimated and characterized. A child's sensitivity is 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, will be assembled and presented during the rulemaking process.

**5. What types of data would be helpful in characterizing risks to children?**

To ensure that programs evaluate the various types of information that are relevant to the assessment of risks to children, the following sets of questions are presented to help assessors remember and seek out relevant data. These questions are not meant to be inclusive or mandatory, but are illustrative of the information that can be valuable in the assessment and risk management processes.

**HAZARD CONSIDERATIONS**

1. Does the chemical belong to a class of compounds where exposure during development leads to adverse effects that may be manifest at any time during life:

- effects on potential parents' ability to reproduce and raise their young (i.e., parental exposure led to the ability to conceive but the fetus died in utero)?
- effects induced by in utero exposure?
- effects induced by extra utero exposure during development?
- does the chemical have a greater potential to produce an adverse effect because it persists in the environment or body, or bioaccumulate?

2. Are there studies or reports of hazards to infants and children or to developing animals?

3. Using guidance found in EPA risk assessment guidelines, how complete is the data base on potential hazards? What are the data gaps?

4. Is there information bearing on:

- 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 (hereditary factors)?
- target organ and system effects (e.g., nervous and immunological systems, lung, skin)?
- modulation of existing disease (e.g., exacerbate asthma)?

5. Are there effects unique to infants and children?
   - critical exposure periods?
   - exposure route/magnitude?
   - effects throughout life?

**DOSE RESPONSE/SUSCEPTIBILITY CONSIDERATIONS**

The current approaches to dose-response include the cancer slope factor, RfD and RfC, which constitute components of the risk part for cancer and noncancer assessments. For the dose part, either exposure or some internal dose might be the starting point. The following issues/questions are extra considerations for children as compared to a human adult approach.

Dosimetry issues:

1. Are any pharmacokinetic data considered to compare children to adults? If a toxic metabolite has been identified, and an internal dose is used in the dose-response, have specific children's physiological parameters been used in the derivation of the internal dosimetry, like inhalation rate, water consumption, and food consumption? Any adjustment for children's physiological parameters in the RfC calculation? Are the chemical pharmacokinetics different in children than in adults?

2. Has there been any consideration of the developmental or reproductive windows of exposure? What kind of exposure and effects were observed? Is there any information available on susceptible developmental stage?

Health effects response issues:

3. Is there any quantitative influence of age on the dose/response?

4. If the mode of action of agents is known, are there any specific childhood diseases that might need to be considered? (site concordance is usually not required for cancer)

5. Is there any information concerning the relative susceptibility of infants and children versus adults for the identified hazards? Are there data suggesting different No Observed Adverse Effect Levels (NOAELs)-Lowest Observed Adverse Effect Levels (LOAELs) for effects in children versus adults? In offspring versus parental?

6. If the dose-response for cancer is obtained from animal studies, has there been any consideration of exposure in the early life of the animals, or consideration of window of exposure susceptibility which could lead to early tumor formation in childhood?

7. For dose-response relationships obtained from adult animal studies, has there been any consideration given to extrapolating cancer slope factors to children using a different coefficient value for the power of the body weight? Has there been any consideration given to determining if this coefficient for extrapolating between young animals and infants and children is the same as that for adults?

8. If the dose-response for cancer is obtained from occupational epidemiologic studies, has there been any consideration for children?

9. For the RfD or RfC, especially if obtained from reproductive or developmental neurotoxicology, has there been any special consideration of post natal exposure and effects in children?

**EXPOSURE CONSIDERATIONS**

1. What population groups do you need to consider in the exposure assessment for children (fetus, infants, child, women of childbearing age, pregnant women, fathers)? Are there differences across racial and ethnic subgroups? What specific age groups need to be considered? Are there gender differences? Is there information on exposures to the groups of interest?

2. What are the anatomical and physiological characteristics of children that may lead to unique exposures? For example, does the assessment account for a child's:

- inhalation rate?
- body weight?
- skin surface area?

3. What are the behavioral characteristics of children that may lead to unique exposures? For example:

- playing on the floor and the ground,
- crawling,
- consumption rates for food and water, and/or preferential consumption of certain foods.
- consumption of breast milk (infants),
- spending a larger fraction of time indoors at home,
- pica/soil ingestion,
- mouthing activities (e.g., hand to mouth, object to mouth, etc.),
- being carried by adults
- personal hygiene.

4. There are several indirect factors that may associate higher exposures with the above behaviors. Examples include:

- contact with parents' clothing that has been contaminated at work (e.g., farm worker clothing contamination with pesticides),
- environmental tobacco smoke in the home,
- paint flaking from home surfaces,
- other characteristics of the child's environment (e.g., cleanliness of day care facilities),

- interactions with other children and adults that may lead to exposure,
- carpets in the home serving as a reservoir for such pollutants as: lead, mercury, bacteria, asbestos, fungi, insect parts, paint dusts, and solvents.
- geographic location of the residence
- occupational exposures to legally and illegally employed children

5. What chemical characteristics may indicate unique exposures? For example:

- What is the concentration of the chemical in the child's environment (e.g. home, lawn, garden)?
- What are the fate and transport properties of the chemical (e.g., dissipation rates)?
- Does the chemical cross the placenta?
- Is the chemical excreted in breast milk?
- Is the chemical used on or otherwise present in foods?
- Is bioavailability of the chemical via the various routes of exposure higher in children than in adults?

6. What routes (i.e., dermal, inhalation, and/or ingestion) of exposure need to be considered for children? For example, is dermal uptake of the chemical significant compared to other routes of exposure?

- For information on inhalation and ingestion rates, see the Exposure Factors Handbook.
- For information on dermal exposures, see the Exposure Factors Handbook and the Superfund Dermal Guidance.

7. Have children's exposures been aggregated across pathways (e.g., food, air, water, surfaces, etc.) and routes (e.g., dermal, inhalation, and ingestion)?

8. Is the child exposure pattern continuous or episodic, chronic or acute, and are there any critical time windows for exposure that need to be considered? Do exposures vary with age?

**6. What data sources and health scientists should I consult?**

The questions that you are encouraged to ask regarding children's risk have their source in EPA Risk Assessment Methodology Guidance Documents:

•Guidelines for Reproductive Toxicity Risk Assessment
•Guidelines for Neurotoxicity Risk Assessment
•Guidelines for Developmental Toxicity Risk Assessment
•Guidelines for Mutagenicity Risk Assessment
•Proposed Guidelines for Cancer Risk Assessment
•Guidelines for Exposure Assessment
•Exposure Factors Handbook, Volumes I, II, III

With the exception of the "Exposure Factors Handbook," which can be found at **www.epa.gov/ncea/exposfac.htm**, all the guidance documents described above can be found on EPA's Homepage at ***www.epa.gov/nceawww1/rafpub.htm***.

Further, EPA Media 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 should be consulted about the specific risk assessment guidance they use to implement their programs, and how that guidance includes consideration of children's health.

Rule writers are encouraged to request participation on rule development work groups of health scientists in the following EPA organizations:

- ORD's National Center for Environmental Assessment
- ORD's National Health and Environmental Effects Research Laboratory
- the Office of Prevention, Pesticides, and Toxic Substances
- the Science Policy Council
- the Risk Assessment Forum

Depending on the health effects and exposure routes of concern, risk assessors are also encouraged to consult with scientists in the following organizations:

- The Agency for Toxic Substances and Disease Registry
- The Center for Disease Control
- The Food and Drug Administration
- The National Institute for Environmental and Health Science
- The Public Health Service
- State and Local Health Departments

**7. What are the peer review requirements of a risk assessment for children?**

A risk assessment and resulting risk characterization for children is like any other risk assessment as to the requirements for peer review. As appropriate, you should solicit peer review consistent with EPA's Peer Review Handbook (***www.epa.gov/ORD/spc/prhandbk.pdf***).

**ATTACHMENT D**

# Executive Order on Protection of Children From Environmental Health Risks and Safety Risk

**Issued April 21, 1997**
**THE WHITE HOUSE**
**Office of the Press Secretary**
**For Immediate Release**

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)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,

© 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 decision making 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 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.

WILLIAM J. CLINTON

THE WHITE HOUSE,

April 21, 1997.

## ATTACHMENT E

### Policy[6] 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[7] [8] 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 crypto sporidium 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.

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[6]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.

[7]National Research Council. 1993. Pesticides in the Diets of infants and Children. National Academy of Sciences Press, Washington, DC.

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

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.