IV. Recommended Executive Order

Federal Focus is hereby proposing that the Director of the Office of Management and Budget consider the following draft Executive order for submission to the President with a recommendation that he adopt it.[164]

EXECUTIVE ORDER _____ OF _____, 1991

Environmental Risk Assessment and Risk Management

By the authority vested in me as President by the Constitution and laws of the United States of America, and in order to improve consistency among federal agencies and to enhance scientific credibility and impartiality in assessing the risks of potential environmental hazards, characterizing and communicating the results of those risk assessments and utilizing them as the basis for regulatory decisions that represent sound investments in the health, safety, and welfare of the country while minimizing regulatory burdens, it is hereby ordered as follows:

Sec. 1. *Definitions.* For purposes of this Order:

(a) "Risk assessment" refers to the process of identifying hazards and quantifying or describing the degree of risk they pose for exposed individuals, populations, or resources. It also refers to the document containing the explanation of how the assessment process has been applied to an individual substance, activity, or condition, and includes such documents regardless of whether they are prepared for purposes of considering a regulatory decision.

(c) "Risk management" refers to the regulation of risks through rules of general applicability and individual regulatory actions.

(d) "Negative data" refers to data indicating that under certain conditions a given substance or activity did not induce an adverse effect.

164. Pursuant to the procedural requirements in 1 CFR Part 19.

Sec. 2. *Applicability.* To the extent permitted by law, this Order applies to all risk assessments and risk management decisions on health, safety, and ecological risks, including those of a site-specific, substance-specific, or product-specific nature.

Sec. 3. *Effective date.* Except as otherwise specifically provided herein, the provisions of this Order are effective immediately.

Sec. 4. *Risk Assessment Principles.* To the extent permitted by law, all departments and agencies shall adhere to the following principles when preparing risk assessments:

(a) Risk assessments and all of their components shall be, to the maximum extent possible, scientifically objective and include all relevant data. Determinations concerning the appropriate degree of conservatism, safety factors, uncertainty factors or margin of safety to be incorporated in a regulatory decision shall be reserved for the risk management decision process. To the extent that selection of any assumption, inference, or model for a risk assessment involves, wholly or partially, policy or value judgments, such policy or value judgments shall be clearly identified as such and explained and justified.

(b) Selection of low-dose extrapolation models and assumptions shall be based on all available scientific data, including biological, metabolic, pharmacokinetic, and mechanistic data. In the absence of clear supporting data and scientific rationale, no single model or threshold/no-threshold assumption shall be preferred.

(c) Negative laboratory or epidemiological data of sufficient quality that are not consistent with positive experimental results or low-dose extrapolations shall be considered on the basis of scientific judgment, and without any bias based on "conservatism" or value judgments, and if they are not incorporated into the risk assessment, the scientific basis for not incorporating them shall be explained.

(d) If reasonably available, empirical exposure data shall be utilized rather than assumptions or modeling. To the extent empirical data are not available, exposure assumptions or modeling, whether for an average-case scenario or a worst-case scenario, shall reflect exposures that are reasonably expected.

Sec. 5. *Science Policy and Inference Guidance for Risk Assessments.*

(a) Within one year of the date of this Order, and from time to time thereafter as he deems necessary, the Director of the Office of Science and Technology Policy shall issue uniform guidance for all departments and agencies on aspects of risk assessment where there is a difference of scientific opinion or a lack of adequate data and the choice of a position involves policy or a mixture of policy and scientific judgment. Such

guidance shall be consistent with and subordinate to the risk assessment policy principles stated in section 4 of this Order and shall be binding on all departments and agencies to the extent permitted by law.

(b) The subjects addressed by such guidance shall be at the discretion of the Director, and he shall consider inclusion of guidance on at least the following subjects: interspecies scaling factors, dose-response modeling, treatment of tumors that do not appear to be malignant, thresholds, use of the maximum tolerated dose, weighting of positive findings from sensitive species, and definition of adverse health effects.

(c) Such guidance shall be developed in consultation with the Federal Coordinating Council on Science, Engineering and Technology, the National Research Council, the Council on Competitiveness, the Office of Management and Budget, the Council on Environmental Quality, and such other departments and agencies, offices, organizations or persons as the Director deems advisable.

(d) Any guidance promulgated under this section shall permit divergence by a department or agency in particular cases on the basis of overriding scientific data or the requirements of law.

(e) Guidance promulgated under this section shall be reviewed by the Director at least every four years, after requesting comments from all entities and persons consulted in accordance with subsection c. A particular provision of the guidance shall be reviewed whenever any department or agency formally requests such review and supports its request with significant new data or scientific rationale. In addition, the Director shall consider supplementing the guidance upon formal request by any department or agency.

Sec. 6. *Risk Characterization Principles.* In characterizing risk in risk assessment documents, regulatory proposals and decisions, budget documents, and legislative recommendations, departments and agencies shall:

(a) If a numerical estimate of risk is provided, provide an unbiased expected-value estimate for the average individual. Upper-bound or conservative estimates or estimates for sensitive or more-highly-exposed populations may be provided in addition to the expected-value estimate. If an upper-bound estimate is provided, the lower-bound estimate will also be provided. If the available data are, in the best judgment of the department or agency, inadequate to provide an estimate of the expected value, this judgment shall be clearly stated along with a narrative explanation of the limitations and uncertainties, and both upper- and lower-bound estimates shall be provided.

(b) Present, to the extent possible, along with expected-value and upper-bound or conservative estimates of risk, to the extent possible, the distribution of probabilities for various possible results.

(c) Where a number of different health, safety, or ecological effects are possible from exposures to the same substance, process, activity, or condition, provide separate estimates for each of the significant effects. If the risk assessment is intended to address only a single route of exposure, provide any available estimates or qualitative information regarding risks from other pertinent routes of exposure, and any information regarding the likelihood of synergism or antagonism as a result of exposures from other sources.

(d) Clearly and succinctly acknowledge any significant limitations in the data or current scientific understanding.

(e) A risk assessment that is significantly different from a risk assessment for the same substance, process, activity, or condition prepared by another department or agency, or by another office, or under another program, of the same department or agency, shall explain the scientific, policy, or legal justification for the inconsistency.

(f) Where possible, describe risk by multiple comparisons with best estimates of other risks that are familiar to and routinely encountered by individuals. Any differences in the levels of uncertainty for such risk estimates shall be noted.

(g) Include, for discretionary proposed and final regulatory actions, an evaluation of significant substitution risks and risk tradeoffs that are likely to occur and that would significantly affect assessment of net benefits. If the regulatory action is a major rulemaking action within the meaning of Executive Order 12291, such evaluation shall consist of a risk assessment under the provisions of this Order based on all reasonably available relevant data.

(h) Explain any differences of opinion between the department or agency and an official peer review body, and explain why the agency does not agree with that body's opinion.

Sec.7. *Risk Characterization Guidance.*

(a) Within one year of the date of this Order, and from time to time thereafter as he deems necessary, the Director of the Office of Management and Budget shall issue uniform guidance for all departments and agencies on risk characterization. Such guidance shall be consistent with and subordinate to the risk characterization principles stated in section 6 above, and shall be binding on all departments and agencies to the extent permitted by law.

(b) The subjects addressed by such guidance shall be at the discretion of the Director, and he shall consider inclusion of guidance on at least the following subjects: expression of uncertainties, distribution of probabilities for outcomes, calculation of expected values, a uniform concise format for summarizing risk assessment results, and a system for integrated ranking of different risks.

shall apply the following principles, to the extent permitted by law, in making risk management decisions:

(a) Take into consideration the magnitude and likelihood of substitution risks and risk tradeoffs when assessing "net benefits" under Sections 2(c) and 3(d)(1) and (3) of E.O. 12291.

(b) Avoid the regulation of insignificant or *de minimis* risks. In deciding whether a risk is significant, the following factors shall be considered at a minimum: the probability of a given effect occurring, the level of uncertainty or confidence associated with the risk assessment data, the severity of the effect, and the number of persons potentially exposed. In considering the severity of an effect, officials shall take into account factors such as reversibility and whether significant morbidity, damage, or functional impairment is involved.

(c) Set margins of safety, safety factors, and uncertainty factors so as to protect against health, safety, or ecological effects that are significant and can be reasonably expected to occur, and consider the following factors, among others: the significance or severity of the effect to be prevented; the level of uncertainty in the risk assessment; technical feasibility; cost; and the range of sensitivity in the human or biotic population likely to be affected.

(d) To the degree that performance can be measured or reasonably imputed, utilize performance standards or ends rather than design or technology standards or means.

Sec. 9. *Review of Risk Assessments and Risk Management Decisions.* This Order shall not affect any risk assessments or risk management decisions previously made, except as follows:

revision of a risk assessment or risk management decision in accordance with the foregoing provisions of this Order or on the basis that significant new scientific data or understanding has become available.

(b) Within six months of receipt of a petition, the department or agency shall determine whether the potential benefits and the significance of the new data or understanding are sufficient to justify a review and shall inform the petitioner.

(c) If the agency or department notifies the petitioner that it will undertake a review, the review shall be completed, and any final decision issued, no later than one year after the petitioner is so notified.

Sec. 10. *Implementation and Oversight.*

(a) The Director of the Office of Management and Budget shall be responsible, subject to the direction of the Council on Competitiveness, for ensuring that all departments and agencies comply with the requirements of this Order when proposing and issuing rules that are subject to Executive Order 12291.

(b) The Director of the Office of Management and Budget, the Director of the Office of Science and Technology Policy, and the Council on Competitiveness shall, from time to time, recommend, jointly or separately, after consultation with each other, revisions to this Order as they deem advisable.

(c) The head of each department or agency shall designate a senior policy official to be responsible for ensuring that the department or agency complies as fully as possible with the requirements of this Order, and shall publish notice of such designation in the *Federal Register.* The duties of the designated official shall include: (1) educating other officials, employees, and contractors concerning the requirements of this Order; (2) accepting petitions for review under section 9 of this Order, and ensuring that the department or agency complies with the section's time requirements; (3) preparing and submitting annually to the Director of the Office of Management and Budget, the Director of the Office of Science and Technology Policy, and the Council on Competitiveness a concise report on petitions for review received and action taken, any complaints received concerning non-compliance by the department or agency, and any problems experienced in interpreting the Order; and (4) transmitting, on behalf of the agency head, to the entities specified in subsection b any recommendations for clarification or revision of this Order.

Sec. 11. *Judicial Review.* This Order is intended only to improve the internal management of the Federal government, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person.