American Chemistry Council

Fax

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Fax: 202 395 1974	**Pages:** 2
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Re:	**cc:**

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This is a cover letter for the ACC comments to OMB on its draft report to Congress. The comments have been sent electronically. This fax is ~~to~~ intended to ensure that you have a copy of the signed ~~a~~ cover letter.

JOE J. MAYHEW
VICE PRESIDENT, REGULATORY
& TECHNICAL AFFAIRS

American Chemistry Council *Good Chemistry Makes It Possible*

May 24,2002

Mr. John Monall
Office of Information and Regulatory **Affairs**
Office of Management **and** Budget
NEOB, Room 10235
725 17th Street, NW
Washington, **DC** 20503

Dear Mr. Morrall:

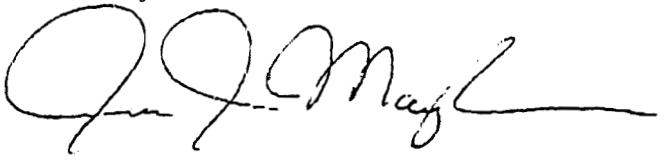
The American **Chemistry** Council submits **the attached** comments on the draft ***Report to Congress on the Costs and Benefits of Federal Regulations,*** which **was** published in the *Federal Register* on March 28,2002.

The Council is composed of the **country's** leading companies **engaged** in **the business** of chemistry. Council members **apply** the science of **chemistry** to **make** innovative products **and** services that make people's lives better, **healthier,** and safer. The Council is also committed to improved **environmental, health,** and safety performance **through** its Responsible ***Care*** **Program;** **common** sense advocacy designed to address major public policy issues; **and** health and environmental research **and** product testing.

Because it includes material describing a **wide** range of OIRA activities **and** initiatives, the draft **report provides an** excellent opportunity for the public to suggest improvements to **the** federal regulatory **system.** I hope **that many worthwhile** suggestions **will arise out** of *this* effort. I urge OMB to consider **seriously** these suggestions **and** implement **those** that have the greatest potential for benefiting **the public.**

If you think you need additional information on any of the topics raised in these comments, please contact Keith Belton **at the** Council. Keith *can* bc reached by phone (703/741-5909) or e-mail (keith_belton@americanchemistry.com).

Sincerely,



Keith **Belton@americancllernistry.com**
05'24'2002 02:14:27 PM

Record Type: Record

To: John F. Morrall III/OMB/EOP@EOP

cc: See the distribution list at the bottom of this message
Subject: **ACC** comments on OMB draft Report to Congress

Attached are comments from the American Chemistry Council to OMB on its draft Report to Congress on the Costs and Benefits of Federal Regulations. If you have any questions or need additional information, please call me at 703/741-5909 or just reply to this e-mail.

Three documents are provided. The first is a cover letter from Joe Mayhew of ACC. The second contains the ACC comments. The third is an attachment to the ACC comments.

(See attached file: cover letter.ACC comments.doc)(See attached file: OMB Draft Report to Congress.2002.comments.doc)(See attached file: **IRIS** FINAL 920.doc)

- cover letter.ACC comments.doc
- OMB Draft Report to Congress.2002.comments.doc
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COMMENTS TO THE OFFICE OF MANAGEMENT AND BUDGET

DRAFT REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS

67 FR 15014
March 28,2002

Submitted on
May 24,2002

The American Chemistry Council
Arlington, Virginia

Executive Summary

The American Chemistry Council is pleased to comment on the Draft Report to Congress on the Costs and Benefits of Federal Regulations (67 FR 15014-15045), written by the Office of Management and Budget (OMB). The Council is a trade association representing the leading companies engaged in the business of chemistry in the United States. These companies spent an estimated $20 billion to comply with all federal regulations in the year 2000.

The Council commends OMB for seeking input on regulatory costs and benefits, particularly suggestions for making the process better. The Council believes there are ample opportunities to change the current regulatory system in order to increase the net benefit to the public. This document describes some of these opportunities.

Regulatory Accounting. The draft report presents estimates of the costs and benefits of selected regulations issued between April 1, 1999 and September 30,2001. These estimates are subject to considerable uncertainty because of the different methods and assumptions used across agencies and even within agencies. The current draft report represents an incremental improvement over last year's report, but it does not ensure a realistic accounting because important methodological differences across agencies aren't eliminated and only a subset of regulations are considered. Ironically, as written, the draft report doesn't adhere to OMB's own data quality guidelines. OMB must devote more time and effort to this annual report in order to meet the needs of stakeholders.

Existing Regulations. In the draft report, OMB seeks nominations of existing regulations that should be revised in order to increase the net benefit to the public. The Council identifies five existing regulations for consideration: the hazardous materials transportation registration and fee program; export notification requirements under the Toxic Substances Control Act; the definition of solid waste under the Resource Conservation and Recovery Act; the reporting threshold for persistent, bioaccumulative, and toxic chemicals under the Emergency Community Preparedness and Right to Know Act; and the paperwork burden associated with the Toxic Release Inventory program. For each of these regulations, the Council has provided information on the underlying problem and proposed a specific, targeted solution that would provide a clear benefit to the public.

Paperwork Burden. The Council recommends that OMB disapprove information collection requests (ICRs) that don't meet basic data quality standards, particularly the standard of objectivity, which requires that information be accurate, reliable, and unbiased and that original agency data be generated using sound statistical methods. Burden estimates in ICRs often do not meet this standard.

Problematic Guidance. In the draft report, OMB asked for examples of "problematic" agency guidance documents. The Council is submitting two examples of such problematic guidance: the EPA Superfund indirect cost guidance and the EPA Integrated Risk Information System (IRIS). The former is an example of guidance that received inadequate notice and comment. The latter is an example of guidance that received inadequate peer review.

OMB Analytic Guidance. Aside from the issues identified in its draft report, OMB should also review its analytic guidance with respect to the role of stakeholders, value of information analysis, characterization of annualized costs and benefits, and standardization of procedures for estimating costs and benefits. The Council cautions OMB not to substitute guideline improvement with guideline enforcement, which continues to be insufficient. OMB should return *any* economically significant regulation to an agency if the accompanying economic analysis fails to comport with the fundamental principles of Executive Order 12866.

Prompt Letters. The DOT hazardous materials transportation registration and fee program is a strong candidate for a prompt letter. This program currently collects more funds than it can disperse under the statute. The issue here is how the excess funds can be used most productively: by keeping an excess of funds in the treasury or by allowing shippers to use these funds for business investment. The Council recommends that DOT finalize a rule it proposed two years ago to eliminate excessive funding; a prompt letter from OMB to DOT is an appropriate remedy.

Another candidate for a prompt letter is the EPA definition of solid waste. Contrary to statute, this rule actually impedes recycling. The Agency should alter this regulation in a targeted manner to promote resource conservation and recovery.

Science Advisory Panel. In recent years, agencies have increasingly developed regulations designed to collect and make available information to the public. The Council is concerned that, too often, not enough is known about the value of such information. Without some checks on the system, virtually any regulation designed to elicit information and make it publicly available can be justified. One way OMB can start to address this issue is by obtaining the necessary in-house expertise. If OMB cannot hire staff with this expertise, OMB ought to include experts on value of information analysis on its science advisory panel.

Resources. Since the beginning of the Clinton Administration in 1993, OIRA has seen its staff ceiling decline and its duties increased (e.g., the Unfunded Mandates Reform Act, the Small Business Regulatory Enforcement Act, and the Treasury and General Government Appropriations Act for Fiscal Year 2001). Although the staff ceiling was increased by five last year, this modest increase is insufficient for OIRA to do its job effectively. The Council believes the staff ceiling for OIRA should be raised significantly.

Introduction

The American Chemistry Council appreciates the opportunity to comment on the March 28,2002 draft report to Congress on the Costs and Benefits of Federal Regulations (67 FR 15014-15045).

The Council is composed of the country's leading companies engaged in the business of chemistry. Council members apply the science of chemistry to make innovative products and services that make people's lives better, healthier, and safer. The Council is also committed to improved environmental, health, and safety performance through its Responsible Care Program; common sense advocacy designed to address major public policy issues; and health and environmental research and product testing.

Companies in the business of chemistry spent an estimated $20 billion to comply with all federal regulations in the year 2000, a figure equivalent to $19,000 per worker. The largest share of this cost is attributable to environmental regulation (59%), followed by economic (15%), tax (14%), and workplace regulation (12%).[1]

Although conclusions about the value of federal regulation cannot be made solely on the basis of cost, the magnitude of these figures raises questions about cost-effectiveness. The Council commends OMB for seeking input on regulatory costs and benefits, particularly suggestions for making the process better. The Council believes there are ample opportunities to change the current regulatory system in order to increase the net benefit to the public. This document describes some of these opportunities.

Regulatory Accounting

Congress required OMB to issue an accounting statement of the total costs and benefits of federal rules and paperwork, both in the aggregate, by agency and agency program, and by major rule. Chapter II of the draft report presents the OMB estimates, with particular emphasis on 117 final major rules reviewed by OMB between April 1, 1999 and September 30,2001.

The Council appreciates the time and effort OMB took to improve the comparability of agency analyses with respect to major rules. In particular, OMB monetized agency-quantified estimates of regulatory impact, estimated the stream of benefits and costs over time, and calculated all monetized estimates in terms of 2001 dollars. The Council commends OMB for taking these steps and others to ensure the comparability of agency estimates. OMB also documented their contributions on a rule-by-rule basis in order to subject their analysis to scrutiny.

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[1] These estimates are based on a study by Crain and Hopluns *(The Impact of Regulatory Costs on Small Firms,* U.S. Small Business Administration Office of Advocacy, 2000) and on the Council's annual survey of environmental, health, and safety spending (see page 106 of Swift et al., *2001 Guide to the Business of Chemistry,* American Chemistry Council).

These actions, however laudable, are not adequate to ensure an accurate accounting of recently promulgated regulations because important methodological differences across and within agencies aren't eliminated. According to the draft report (Appendix D), "agencies have used different methodologies and valuations in quantifying and monetizing effects". The draft report elaborated upon this point, indicating that OMB did not standardize the methods agencies used to monetize benefits, the assumptions used to create baseline scenarios, or the procedures used to characterize uncertainty.

Another concern relates to the regulations subject to analysis. OMB only accounted for a subset of regulations.[2] Significant regulations (of which there are approximately 500 annually) are also subject to OIRA review and the majority of these were not factored into the accounting (nor did Congress require such an accounting). The sheer number of significant rules relative to major rules is likely to increase both the total cost and benefit figures presented in the draft report.

Ironically, the draft report doesn't adhere to OMB's own data quality guidelines *(Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information,* 67 FR 8452-8460). These guidelines require disseminated information to meet standards of utility and objectivity. The Council questions whether the figures presented in the report are useful (given that many regulations aren't considered) or objective (given the lack of standardization across agencies for valuing effects). In its final report, OMB should state that it cannot certify that the figures on costs and benefits meet the standards described in its own data quality guidelines.

OMB should devote more resources to this annual report in order to meet the intent of Congress and the needs of users of the information. To do this, the staff ceiling for the Office of Information and Regulatory Affairs (OIRA) should be increased. If additional staff are not forthcoming, however, OMB should not re-direct existing staff to regulatory accounting. Rather, OMB should better enforce its own guidelines in order to promote greater standardization of regulatory costs and benefits.

OMB should also use its expertise to estimate the impact of significant regulations. The final report should include a statement describing the extent to which these other regulations might alter the estimate of total costs and benefits for the 117 major rules reviewed by OMB between April 1, 1999 and September 30, 2001.

Regulations in Need of Revision

Congress required OMB to include "recommendations for reform" in its report. During the Clinton Administration, OMB complied with this mandate by listing reforms currently underway at federal agencies *(Report to Congress on the Costs and Benefits of*

[2] For the purpose of the draft report, OMB considered economically significant regulations under Executive Order 12866, major regulations under the Congressional Review Act, and rules meeting the threshold under the Unfunded Mandates Reform Act.

Federal Regulations, June *2000).* The Council was critical of that effort because it fell short of Congress' intent: to solicit the considered opinion of OMB career staff, Last year, OMB's final report to Congress *(Making Sense of Regulation: 2001 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on Slate, Local, and Tribal Entities,* December *2001)* included a description of existing regulations that are, in the view of OMB, "high priority" for reform. The Council believes that this was the first OMB report on the costs and benefits of federal regulation that actually met the intent of Congress, and the Council commends OMB for its effort.

In the draft report, OMB once again solicits public recommendations on reforms to specific existing regulations that, if adopted, would increase overall net benefits to the public. In order to respond to this request, the Council identified regulations (1) that are directed primarily at companies in the business of chemistry, (2) that have been the subject of Council advocacy recently, and (3) for which the Council has suggested an alternative that would clearly benefit the public. **As** a result of this exercise, the Council recommends that OMB identify the five regulations in Table 1 as "high priority" for reform. The Council believes the suggested reforms are modest in nature and would increase net benefits to the public.

Tliat Should B Changed To Increase Ne Benefits.

Name	*Agenc* Y	*Citation*	*Authority*	Problem	*Solution*
Hazardous materials transportation: registration and fee assessment program	DOT	49 CFR 107.601 49 CFR 107.608 **49** CFR 107.612 49 CFR 107.616	**HMTUSA**	Collected fees are higher than disbursements authorized by statute.	DOT should finalize its long-delayed proposed rule to lower fees.
Export notification requirements	EPA	40 CFR 707	TSCA	The benefits of certain kinds of notifications are negligible and negate the objective of the regulation.	Establish a de minimis exemption from notification.
Definition of solid waste	**EPA**	**40 CFR** 261.2(a)(2)(ii), 261.2c(1)-(3), 261.2 Table 1	RCRA	**Recycling** is discouraged.	Change certain RCRA regulations to promote recycling.
TRI burden reduction	EPA	"Form R , referenced in **40** CFR 372.85	EPCRA	Paperwork burden of TRI is excessive.	Change certain aspects of Form R.
PBT rule	EPA	**40** CFR 372.65	EPCRA	This rule isn't as cost-effective as it could be.	Modify rule to reduce burden while maintaining benefits.

Hazardous Materials Transportation Registration and Fee Program. The Council recommends that the U. S. Department of Transportation (DOT) Research and Special Program Administration (RSPA) change its registration and fee assessment program (49

CFR 107.601, 107.608, 107.612, and 107.616) under the Hazardous Materials Transportation Uniform Safety Act (49 U.S.C. §5108).

Since 1993, RSPA has conducted a national registration program for persons engaged in the offering for transportation or transporting certain categories and quantities of hazardous materials in intrastate, interstate, or foreign commerce. The purpose of this program is (1) to gather information about the transportation of hazardous materials and (2) to fund the Hazardous Materials Emergency Preparedness (HMEP) grant program. This grant program supports hazardous material emergency response planning and training activities by states, local governments, and Indian tribes.

Congress authorized this program to be funded at $14.3 million per year. Until 2000, however, fees collected under the program totaled less than 50% of the authorized level. On February 14,2000, RSPA published final rule HM-208C (65 FR 7297-7310) to adjust the fees. HM-208C expanded number of companies required to register and established a two-tiered fee schedule. This adjustment substantially altered the account balance. As a result, each year DOT collects approximately $6 million more than the $14.3 million allotted by Congress to fund the program.

By law DOT is required to adjust the amount of the annual registration fee "to reflect any unexpended balance in the account established under section 5116(i)." On December 7,2000, RSPA published a notice of proposed rulemaking, "Hazardous Materials: Temporary Reduction of Registration Fees" (HM-208D) (65 FR 76889-76894). This proposed rule would temporarily lower the registration fees. After the elimination of the expended balance, a permanent change to the registration fee would be adopted once RSPA has reevaluated registration fee levels to determine what changes are needed in future years. Changes would be based on variables such as remaining surplus and the number of registrants (small and large businesses). By temporarily reducing the registration fee for all registrants, the surplus would be eliminated and RSPA would gain time to evaluate the fee program before adopting the permanent fee.

RSPA has never finalized this rulemaking. Instead, it has delayed action twice: on May 2,2001 (66 FR 22079-22080) and March 14,2002 (67 FR 11456).

The Council believes that RSPA should finalize its proposed rulemaking. For DOT to continue to defer rulemaking and continue to over-collect the fees would be a violation of law and a waste of resources that would otherwise be invested more productively.

Export Notification Requirements. The Council recommends that EPA modify existing regulations (40 CFR Part 707.60-707.75) on export notification under the Toxic Substances Control Act. TSCA Section 12(b) requires that persons notify EPA if they export or intend to export to a foreign country chemical substances or mixtures subject to the certain provisions of TSCA. EPA must then notify the government of the country of destination of the first notification for each regulated chemical, including the regulatory

action taken by EPA or the availability of test data submitted on the substance or mixture. Annual notices of the first shipment are required.

EPA has traditionally interpreted TSCA Section 12(b) as applying to persons exporting shipments that contain the substance as an impurity or minor mixture component. The consequences of such an interpretation are significant. Exports containing a trace component of a covered chemical pose negligible risk and yet are responsible for the majority of notifications. The unintended consequence of such a system is that receiving embassies discount those notices that are sent.

The Council proposes that EPA establish a de minimis threshold of 1% for a listed chemical in a mixture below which the chemical is exempted from reporting, and a cutoff of 55 gallons or less of the chemical or 100 lbs, whichever measure applies, below which no 12(b) chemical notification is required. Such a change would focus the attention of foreign governments on shipments that are more likely to pose risks to human health and the environment.

In recent years, Section 12(b) notifications have increased as additionat substances are subjected to testing requirements. The need to address this issue now is particularly acute as EPA continues to move forward with proposed testing initiatives involving hundreds of chemicals.[3]

Definition of Solid Waste. The Council recommends that EPA alter its definition of solid waste. Despite the title and purpose of the Resource Conservation and Recovery Act, implementing regulations actually discourage recycling for many industrial secondary materials. The statute says that RCRA has jurisdiction over "discarded" materials, yet EPA (through 40 CFR 261.2) continues to assert jurisdiction over recycling activities, even if the material has not been discarded.

This fundamental problem stems not from the statute, but from EPA's historic interpretation of the law and the agency's entrenched opinions and regulations. Because certain secondary materials are classified as wastes, and frequently hazardous wastes, industrial facilities forego recycling to avoid the need for an onerous RCRA permit. **As** a result, secondary materials are sent for waste treatment and disposal rather than being reclaimed and reused. Current rules also increase reliance on virgin materials and waste management resources.

The Council believes EPA should narrow the focus of its regulations, defining solid waste consistent with court decisions on discarded material (i.e., disposed of, abandoned, thrown away). The impact of such a regulatory change would be to reduce compliance costs while increasing environmental benefits, thus increasing net benefits.

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[3] **EPA** has developed programs to gather basic toxicological data on 2800 high production volume chemicals (of which some 300-400 are candidates for a test rule), gather data and evaluate the risks posed by certain chemicals *to* children, and screen and test chemicals for endocrine-mediated effects.

Specifically, the Council recommends a new exemption at 40 CFR 261.2 (e) which would allow materials to be exempted from the definition of "waste" so long as they were not accumulated speculatively, not intentionally adulterated, and were actually reinserted into a manufacturing process. A facility would be responsible for keeping appropriate records to demonstrate that the streams were, indeed, recycled.

TRI Burden Reduction. The fastest growing paperwork burden imposed upon Council members stems from the TRI program under EPCRA. The reporting burden associated with TRI has grown an average of 14% per year since its inception, and further growth is likely. On the basis of EPA's cost estimates, the Council believes the cumulative cost of TRI reporting to be about $660 million per year.

To reduce the cost associated with TRI reporting, the Council suggests that changes be made to the Form R, which is the form facilities submit annually to EPA. Specifically, some aspects of the Form R can be removed without taking away from the public's right to know. The Council believes that relief from reporting the waste stream code, influent concentration range, and basis of estimate in Part II, Section 7A would provide the greatest reduction in burden without reducing or compromising the information necessary for communities to assess potential impacts from nearby facilities.

PBT Regulation. EPA recently issued a rule to add persistent, bioaccumulative, and toxic chemicals to the Toxic Release Inventory and to lower reporting thresholds for PBTs. This regulation, which greatly adds to the reporting burden under the TRI program, is unduly burdensome.

To improve the rule, EPA should narrow coverage to only those substances that are priority PBTs. Specifically, the bioaccumulation criterion should be set at 5000 BAF/BCF. The persistence criterion should be set at 6 months. The Council also recommends that the reporting threshold be raised to 100 pounds for priority PBTs and 0.002 pounds TEQ for dioxins and dioxin-like compounds. This change will result in nearly the same amount of data at a much lower cost. In addition, the Council believes **EPA** should consider additional burden-reduction measures, such as multiple-year reporting options for facilities with essentially static emissions or releases, and an extension of the "manufacturer-only" activity qualifier to all PBT substances. These changes will substantially reduce the $120 million annual cost that EPA estimated for the regulation.

Paperwork Burden

Although OMB has not solicited comments on its activities relating to the Paperwork Reduction Act, the Council is taking this opportunity to recommend that OMB take steps to improve agency estimates of burden and costs in infomation collection requests (ICRs).

Members of the Council are often perplexed by, and sometimes disagree with, the paperwork burden estimates prepared by federal agencies in ICRs. The Council believes agencies often make fundamental mistakes that significantly underestimate reporting burden and the associated costs. For the purpose of illustration, consider the following examples:

- In its supporting statement (dated January 31,2001) for the ICR covering the RCRA hazardous waste manifest system (OMB control number 2050-0039), EPA identified 145,974 respondents. To estimate average burden, EPA consulted with "fewer than ten" waste handlers in 1994 and 1995 and contacted these same people again in1996 and 1997.

- In its supporting statement for the ICR (OMB control number 2050-0072) covering section 311 and 312 of EPCRA (requiring firms to submit information on certain chemicals to state and local emergency responders), EPA identified 504,000 respondents. To estimate average burden, EPA solicited estimates from just five respondents.

- For its ICR on TSCA 8c reporting requirements (EPA ICR 1031.07, OMB control number 2070-0017), EPA did not consider two major components of burden: the time associated with staff training and the time associated with record maintenance.

- For its ICR on TSCA 5(a)(2) regarding significant new use rules (SNURs) (EPA ICR 1188.07, OMB control number 2070-0038), the Agency significantly underestimated the number of SNURs.

The Council recommends that OMB start disapproving ICRs that don't meet basic data quality standards, particularly the standard of objectivity, which requires that information be accurate, reliable, and unbiased and that original agency data be generated using sound statistical methods. Burden estimates in ICRs often do not meet this standard. If OIRA **were** to begin disapproving ICRs on this basis, agencies would improve the quality of their analysis.

Agency Guidance in Need of Revision

In the draft report, OMB asked for examples of "problematic" agency guidance documents. Although the term "problematic" is open to interpretation, a reading ***of*** the report suggests that OMB is particularly interested in guidance documents that have adverse impacts on the public due to inadequate notice-and-comment or peer review procedures.

The Council is submitting two examples of "problematic" agency guidance: the EPA Superfund indirect cost guidance and the EPA Integrated **Risk** Information System

(IRIS). The former is an example of a guidance that received inadequate notice and comment. The latter is an example of guidance that received inadequate peer review.

Superfund Indirect Cost Guidance. The Council believes EPA's guidance for charging indirect costs associated with Superfund cleanups is an example of problematic guidance that has not undergone adequate notice and comment procedures. The guidance can be found in three documents: a June 2, 2000 document, entitled "Guidance on Exercising Enforcement Discretion in Anticipation of Full Accounting Consistent With the 'Statement of Federal Financial Accounting Standards No. 4'" (65 FR 35339); the accompanying memorandum, "Accounting for Indirect Costs Associated with Superfund Site-Specific Activities"; and the revised methodology, entitled "Superfund Indirect Cost Rates for Fiscal Years 1990-2001" (October 2, 2000). EPA claims that the statutory authority for this guidance is the Federal Financial Management Improvement Act of 1966 (Title VIII, Public Law 104-208) and CERCLA section 113(a).

Having failed to revise its indirect cost methodology for calculating indirect costs under CERCLA through rulemaking (62 FR 22423, April 25, 1997), EPA issued a new methodology as "guidance" with no notice and comment. The economic impact is enormous as EPA shifts to private parties billions of dollars of costs. The revised methodology includes costs that are not recoverable under CERCLA, and fails to satisfy basic government cost accounting principles. For example, EPA intends to apply the rates retroactively to 1990 and to include in their indirect costs activities that have no nexus to CERCLA cleanups (*e.g.* failed rulemakings). The revised methodology fails to establish a link between the pool of indirect costs and the total EPA site costs that the Agency uses as its allocation base. In addition, the key inputs to an indirect cost accounting system – the indirect cost pool and the allocation base against which those costs are distributed – are both severely flawed.

Probst et al. *(Superfund's Future: What Will It Cost?,* Resources for the Future, 2001) used EPA records of the past cost of the program to estimate the future cost of the program. These researchers found this task complicated by agency financial management practices. Specifically, certain components of the Superfund program (program staff, management and support, and program administration) could not be accurately assigned to the removal or remedial programs.

The impact of the Agency's guidance is significant. EPA estimates that between $600 million and $700 million in additional past costs may be recovered under the revised rates. Looking forward, EPA expects to seek about $100 million more in indirect costs every year. Based on a comparison of costs charged in *one* fiscal year (1994), the U.S. General Accounting Office estimated that an additional $200 million would be charged to potentially responsible parties (PRP) under the revised rates. Assuming GAO's $200 million annual figure is applied to each fiscal year from 1990 to 2000, the revised methodology is likely to reap an additional $2 billion from PRPs.

The Council believes that the guidance should be rescinded and reissued only after the Agency resolves the underlying problems with its financial management system,

revises its "guidance" to address the issues already raised, and subjects its new "guidance" to public notice and comment. The Council also believes EPA should exercise more effective oversight of its contractors, who have been the subject of criticism for inflating cleanup costs.

IRIS. The Council believes that EPA's Integrated Risk Information System (IRIS) is an example of problematic guidance. The IRIS database (http://epa.gov/iris/) contains information on hundreds of chemicals. Federal and state officials use this information for regulatory purposes, but the information in IRIS is considered guidance.

Over the past decade, the Council has pointed out fundamental problems with IRIS: much of the information is outdated and/or poorly characterized, and much of it is developed using outdated scientific methods. The Council believes IRIS data don't comport with the Safe Drinking Water Act standard referenced in the OMB data quality guidelines. This standard requires the presentation of risk information to be "comprehensive" and "to specify peer-reviewed studies known to the agency that support [or] are directly relevant to . . . any estimate of [risk] effects".

The Council submitted a comprehensive reform proposal to EPA on September 18,2001 (attached). Included in this proposal was a recommendation for a rigorous peer review process that is open/transparent, external, independent, balanced, and fully documented.[4] In addition, the Council recommended that reviews of information in IRIS must be open to public comment. The Council recommends that OMB highlight the need for EPA to reform IRIS.

OMB Analytic Guidance

The draft report indicates that OMB is initiating a process to revise its formal analytic guidance documents. As part of this exercise, OMB is seeking comment on particular analytic issues that should be addressed.

The Council is familiar with certain OMB analytic guidance documents, in particular "Economic Analysis of Federal Regulations under Executive Order 12866" (January 11, 1996), "Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements" (March 22, 2000), and "OMB Regulatory Review: Principles and Procedures" (September 20,2001). The Council uses these documents in its review of economic analyses in support of federal rules.

In the draft report, OMB identifies a few issues that will be addressed in its review: the 7% discount rate, the latency between exposure to toxic agents and development of chronic diseases, methods employed to evaluate the risk of premature death, central estimates of risk, vulnerabilities of susceptible subpopulations, and the methods for valuing improvements to the health of children.

[4] This recommendation is fully consistent with the peer review provisions of the OMB guidance document entitled "OMB Regulatory Review: Principles and Procedures" (September 20,2001).

The Council believes these subjects are worthy of review. With respect to these particular issues, the Council notes that the latency issue continues to arise in the context of EPA rules (e.g., the arsenic rule).' The Council also notes that, in a recently published peer-reviewed article, Mrozek and Taylor *(Journal of Public Policy Analysis, 21* (2), *2002,253-270)* described a meta-analysis of estimates of mortality risk from labor market studies. These researchers concluded that the value of a statistical life is much lower than that typically used by regulatory agencies.

Aside from these issues identified in the draft report, the Council suggests that OMB also review other issues. Specifically, OMB should revise its guidelines on economic analysis to emphasize the appropriate role of stakeholders, to describe methods for valuing information, to better characterize the timing of regulatory impacts, and to better standardize benefits and costs for the purpose of regulatory accounting. The Council also believes OIRA should emphasize enforcement of its guidelines. Specifically, OMB should return *any* economically significant regulation to an agency if the accompanying economic analysis fails to comport with the fundamental principles of Executive Order 12866.

Role of Stakeholders. Current OMB guidelines are silent on the informational role of stakeholders, particularly the regulated community. This situation reflects the historical evolution of policy analysis, which was (and still is) viewed by practitioners as a purely technical exercise. The Council believes this philosophy is outdated. A not-so recent review of EPA cost-benefit analysis (Morgenstern, Richard D., ed., *Economic Analysis at EPA: Assessing Regulatory Impact,* 1997, Resources for the Future) concluded that the most useful economic analyses are those done in the most open manner, with participation by stakeholders early in the process.

Stakeholders have information that, if used by regulatory agencies, can increase the net benefits of regulation. For example, the identification of a reasonable number of regulatory (and non-regulatory) alternatives is not solely a technical exercise. Stakeholders are often a source of politically attractive alternatives[6], and OMB guidelines should reflect the need for agencies to identify alternatives only after consultation with all relevant stakeholders.

Stakeholders also can help regulatory agencies identify and collect the best available information for use in economic analysis. The Council's experience suggests that, more often than not, economic analysis in support of chemical regulation contains errors about the baseline scenario because the issuing agency used outdated or factually

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[5] Burnett and Hahn *(EPA's Arsenic Rule: The Benefits Do Not Justify the Costs,* AEI-Brookings Regulatory Analysis 01-02, January 2001) contended that EPA's "best estimate" of the benefits of the rule did not correctly account for the timing of benefits. EPA's Science Advisory Board *(Arsenic Rule Benefits Analysis,* August *200* 1, EPA-SAB-EC-01-008) concurred, noting that the latency issue is better described by the term "cessation-lag".

[6] For example, regulated entities suggested that EPA issue a regulation to streamline sixteen different agency regulations relating to process vents, storage tanks, and leak detection and repair. This suggestion culminated in the consolidated air rule (65 FR 78268), issued by EPA on December 14, 2000.

incorrect information. These errors might have been detected had the regulatory agency consulted with industry experts during development of the economic analysis.

Federal agencies often craft regulations that have unintended consequences. One way to minimize unintended consequences is to subject regulatory proposals to public scrutiny. Trade associations, for example, are often the first to spot a potential problem with a proposed rule because their membership includes those who will be responsible for regulatory compliance.[7]

The Council applauds OMB for promoting the concept of "transparency" in the regulatory decision-making process.[8] A transparent regulatory process is valuable because it allows regulators to benefit from information provided by those with significant expertise. The Council recommends that OMB revise its guidelines to underscore the importance of stakeholders with respect to (1) identification of regulatory alternatives, (2) description of the baseline, and (3) identification of unintended consequences.[9]

Value of Information Analysis. Increasingly, federal regulations require the generation of data on chemicals for consideration by regulators and/or the public. Not only is this type of regulation increasing in the United States, it is also increasing in other regions of the world, most notably the European Union.''

This phenomenon is well illustrated by environmental regulations, which have been identified by Crain and Hopkins as the most costly category of regulation. The recently published Semiannual Regulatory Agenda (67 FR 22729, May 13,2002) of the United States identified 131 proposed rules under development at EPA. On the basis of a cursory analysis, the Council determined that **34** of these 131 proposed rules (26%) are fundamentally about information collection and/or dissemination. These **34** proposed rules are authorized under a wide variety of statutes: CAA (11), EPCRA (6), TSCA (5), FIFRA (5), CWA (4), SDWA (1), RCRA (1), and CERCLA (1).

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[7] For example, the Council discovered that EPA's economic analysis in support of its proposed rule on cross-media electronic recordkeeping and reporting (CROMERRR) was based on the incorrect assumption that the record-keeping provisions were voluntary. The Council was among the first to highlight this incorrect assumption, which led the Agency to significantly underestimate the cost of the proposal.

[8] For example, in recent months, OIRA has improved implementation of the public disclosure provisions of E.O. **12866,** increased the amount of information available on its website, adopted an open-door approach to meetings with outside parties, and initiated electronic submission of comments on certain policies and reports.

[9] In his comments to OMB on its draft 2001 report to Congress, Richard Belzer suggested that agencies develop an analytical protocol prior to development of an economic analysis. This protocol would be subject to public scrutiny. Belzer's idea would also address the Council's concern about the role of regulated entities.

[10] The European Union is in the process of developing a chemical regulation policy that will increase dramatically the amount of chemical information available to the public. Described in a European Commission white paper, "Strategy for a Future Chemicals Policy", this new policy is expected to cost **$7.2** billion over a fifteen-year period. This figure includes the cost of data generation and program administration, but does not include costs associated with **risk** management or losses in consumer surplus.

The Council believes agencies seldom estimate benefits of rules requiring information collection and/or dissemination. Table 7 of the draft report identifies **34** economically significant rules, 6 of which are fundamentally about information collection. According to this table, the issuing agency failed to estimate benefits for **4** of these 6 rules.

The Council recognizes that information provision is a legitimate focus of government regulation, but the Council is less clear about the technical criteria regulatory agencies use to determine when information provision becomes excessive.

Given the trend for regulators to collect and/or disseminate information, OMB ought to consider providing specific guidance to agencies on how to value information. OMB ought to promote the use of value of information analysis as a decision-making tool with potentially wide applicability across the federal government.

Characterization of Annualized Costs and Benefits. The Council urges OIRA to issue more specific guidance on how agencies characterize benefits and costs in economic analyses. For example, OSHA's economic analysis in support of its ergonomics rule (which was disapproved by Congress) estimated annualized costs and benefits over a ten-year period. Other economic analyses present costs and benefits in just one future year. The Council believes that the full stream of benefits and costs provides a richer source of information. OMB guidance ("Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements") suggests that agencies should "consider" characterizing streams of costs and benefits. OMB should strengthen this language.

Standardization of Costs and Benefits. **As** stated previously, OMB has yet to produce an adequate accounting of federal regulations, in part because of difficulties in standardizing methods across and within federal agencies. OMB can improve its regulatory accounting by requiring agencies to use certain preferred methodologies and assumptions. OMB should learn from its experience in preparing reports to Congress on the costs and benefits of regulation. By identifying the most important methodological discrepancies across and within agencies, OMB can suggest preferred methods in its guidelines. Such an exercise should improve the quality of regulatory accounting.

Enforcement. The Council cautions OMB not to substitute guidance development for guidance enforcement, which currently is inadequate. Previous studies (Hahn et al., *Assessing the Quality of Regulatory Impact Analyses*, AEI-Brookings working paper 00-01, January 2000) have shown that agencies seldom follow the most basic analytical principles embodied in the executive order. Yet the current return rate (2.6% according to Table 2 in the draft report) suggests a less-than-vigorous adherence to the Graham memo of September 20, 2000, which stated that failure to comport with the analytical principles in E.O 12866 would be cause for a return. OMB should return *any* economically significant regulation to an agency if the accompanying economic analysis

fails to comport with the fundamental principles of Executive Order 12866.[11] Only through such a policy will OMB provide the necessary incentive for agencies.

Prompt Letters

The draft report describes the prompt letter as a "modest device to bring a regulatory matter to the attention of agencies." The draft report also states: "there is no reason why members of the public should not suggest ideas for prompt letters to the OIRA Administrator". Accordingly, the Council recommends that OMB consider two existing regulations candidates for prompt letters: the DOT hazardous materials transportation registration and fee assessment program and the EPA definition of solid waste.

The DOT program is a strong candidate for a prompt letter. This program currently collects more funds than it can disperse under the statute. The issue here is how the excess funds can be used most productively: by keeping an excess of funds in the treasury or by allowing shippers to use these funds for business investment. The Council recommends that DOT finalize a rule it proposed two years ago to eliminate excessive funding; a prompt letter from OMB to DOT is an appropriate remedy.

Another strong candidate for a prompt letter is the EPA definition of solid waste. Contrary to statute, EPA regulation actually impedes recycling. The Agency should alter this regulation in a targeted manner to promote resource recovery.

For more information on these two regulations, see the section of this document entitled "Regulations in Need of Revision".

OMB Science Advisory Panel

Chapter I, part H of the draft report describes the formation of **a** scientific advisory panel to OIRA that "will suggest initiatives to OIRA, evaluate OIRA's ongoing activities, comment on national and international policy developments of interest to OIRA, and act as a resource and recruitment mechanism for OIRA staff." The Council believes such an advisory body would help supplement OIRA's limited staff resources, particularly on technical matters. The Council recommends that OIRA include experts in value of information analysis on this advisory panel.

In recent years, agencies have increasingly developed regulations designed to collect and/or make available information to the public. The Council is concerned that, too often, not enough is known about the value of such information. Without some

[11] These fundamental principles include describing the significance of the underlying problem, explaining the need for a regulatory solution, using the best available information, identifying the available alternatives, assessing the costs and benefits associated with each alternative, and determining the net benefits of each alternative.

checks on the system, virtually any regulation designed to elicit information and make it publicly available can be justified. One way OMB can start to address this issue is by obtaining the necessary in-house expertise. If it cannot hire staff with this expertise, OMB ought to include experts on value of information analysis on its science advisory panel.

The Council also wishes to caution OMB with respect to this advisory panel. Even the most knowledgeable academics don't possess the know-how that comes with day-to-day familiarity with regulatory compliance. Expert advice should be seen as a complement to—but not a substitute for—input from the regulated community.

Resources

The draft report includes a brief history of OIRA, its duties, and its resources. Table 4 of the draft report, which shows the staff ceiling within OIRA since its inception, is particularly striking. Since the beginning of the Clinton Administration in 1993, OIRA has seen its staff ceiling decline and its duties increased (e.g., the Unfunded Mandates Reform Act, the Small Business Regulatory Enforcement Act, and the Treasury and General Government Appropriations Act for Fiscal Year 2001).

Although the staff ceiling was increased by five last year, this modest increase is insufficient for OIRA to do its job effectively. The Council believes the staff ceiling for OIRA should be raised significantly.

Conclusion

The Council appreciates the opportunity to comment on the draft report to Congress. In particular, the Council appreciates the opportunity to submit comments on many different aspects of the federal regulatory system under the purview of OIRA. If additional information is needed, please contact Keith Belton by phone (703/741-5909) or e-mail (keith_belton@americanchemistry.com).

Comments to the U.S. Environmental Protection Agency

Needs for Health Assessments on EPA's Integrated Risk Information System

66 FR 37958-37959
July 20,2001.

Submitted on
September 18,2001

The American Chemistry Council
Arlington, Virginia

Executive Summary

A recent National Academy of Sciences report on strengthening science at EPA noted, "strong scientific performance is important not only to enable EPA to make informed and effective decisions, but also to gain credibility and public support for the environmental protection efforts of EPA and the nation." (NAS, 2000) Support for stronger EPA science has been widespread among scientists and others, both within EPA and outside in the wider community. We believe that the Integrated Risk Information System (IRIS), one of the most visible and important elements of EPA's science management, is an excellent focal point for promoting this widely shared goal.

A thorough rethinking of the IRIS system is central to EPA's strengthening the use of quality science in environmental decision-making, both at the federal and state levels. The fundamental problems with IRIS will not be solved by small, incremental changes and additions to the effort. Rather, EPA must comprehensively and unflinchingly rethink what measures and resources are needed to make essential, fundamental improvements to IRIS.

Numerous assessments of IRIS — including the Agency's own 1994 Quality Action Team report — concur with the basic finding that IRIS needs significant improvement. Attachment A of these comments summarizes the conclusions and recommendations of many qualified parties, demonstrating the urgency of the needed reform. EPA staff, commendably, have made a number of changes to the system beginning in 1994 to try to respond to these needs, but, as our comments detail, these changes, although directionally correct, fall far short of the fundamental rethinking that is needed.

This need for focused attention on the improved management of science at EPA and on IRIS reform in particular is a concern on the part of scientists and managers in numerous organizations regardless of whether they work for EPA, other government agencies, industry, or public interest groups. Everyone will benefit from an up-to-date, reliable, and high quality IRIS system.

We recognize that any such reform will necessarily be very resource intensive. Consequently, as part of our recommendations for the creation of a better IRIS, the Council proposes a new approach whereby producers of chemicals and other interested parties would be given the opportunity to develop and submit IRIS toxicological reviews to EPA for the Agency's evaluation and incorporation into the IRIS database. This would

allow EPA to concentrate more of its resources on a thorough review of the studies and analyses submitted by outside parties and on making all decisions regarding the appropriate health values rather than on the initial gathering and organizing of information. This collaborative approach, with appropriate quality safeguards, has worked well for other EPA programs, and EPA's initial experiments in this direction for IRIS need to be greatly expanded and institutionalized in the form of a new approach that effectively and efficiently leverages private resources.

In this larger context, therefore, of improving the management of science at EPA and in particular rethinking the IRIS system, the Council submits the following detailed recommendations for the creation of a new IRIS system in response to EPA's *Federal Register* request for an identification of needs. Our comments below primarily focus on questions 4 and 5.

We begin with the following conclusion that frames our IRIS-specific comments and recommendations:

IRIS has become one of the most frequently cited sources of health effects values for regulatory purposes. IRIS must be up-to-date, reliable, and of the highest scientific quality in order to match the important function it serves. Despite some changes in recent years, the current IRIS system falls far short of fulfilling these requirements. These shortcomings significantly undermine the credibility of the IRIS system and compromise the use of good science at **EPA.** This situation must not be allowed to continue; fundamental rethinking is necessary and **EPA** must seize the opportunity of this Congressionally mandated needs assessment to undertake this rethinking.

As one of our contributions to this rethinking process, we recommend that EPA design its new IRIS system to achieve the following 5 management principles:

I. Toxicological reviews and the resulting health values contained in the IRIS database must be as up-to-date as reasonably possible, incorporating the latest relevant studies and methodologies. Those studies that vary in quality, methodology, and significance must be evaluated according to a consistent "weight-of-evidence" approach. In particular, the new IRIS must:

- Encourage users to nominate IRIS files that are in urgent need of updating. A rigorous but efficient process must be established by which chemical assessments and/or health values in IRIS can be identified as priority candidates for updating

because of highly relevant new studies, or new peer reviewed methodologies or science policies. Within such a process, nominating parties must be required to articulate a sound scientific rationale regarding how the new data might significantly change the current IRIS assessment for the particular chemical or the uses of that information for **risk** assessment.

- Set and track specific target dates for updating existing IRIS files. Create specific organizational accountability for meeting these targets.

- Establish criteria under which "partial reviews" of IRIS files (e.g., revising a Reference Concentration without changing the cancer potency factor) will be appropriate from a scientific standpoint. Partial reviews must be allowed not only for portions of individual files but also on a multi-file basis when more current peer reviewed guidelines might apply to a broad group of files.

- Publish an annual notice in the ***Federal** Register* indicating when each toxicological review or health value (beginning prospectively with those updated or added by the IRIS pilot project) reaches its 5-year anniversary. The notice should request information regarding whether the review and the health values are up-to-date with current peer reviewed studies, methodologies or science policies. In addition, the Agency should itself conduct a literature search for the same purpose. On the basis of the input from these inquiries, the Agency should publish its decision that the identified IRIS file is still scientifically appropriate and supportable, or will be updated.

Reflect the latest peer reviewed science policies, by having each new and updated IRIS file:

- Carefully consider relevant epidemiological and other data and apply causation analysis principles. ***(see*** Hill, A.B., 1965).

- Contain exemplary hazard and dose-response characterizations that can constitute a model for all other Agency assessments, consistent with the principles of EPA's Risk Characterization Policy.

- Display a thorough and transparent treatment of uncertainty, data gaps, and variability.

11. IRIS must incorporate a rigorous peer review process that is open/transparent, external, independent, balanced and fully documented:

Specifically, following the Agency's Handbook and AIHC principles of peer

review *(see Attachment B)*, the new IRIS system must:

- Expand its use of public comment periods to obtain input from scientists (and others) in the public who may be knowledgeable but who are not chosen to serve on the peer review panel. These public comments should be provided to the peer reviewers for their use in review of the IRIS documents.

- Schedule external peer reviews to occur after the IRIS assessment process is tentatively complete, but sufficiently early to constructively influence the final outcome of the assessment (that is, they must be able to inform the internal EPA consensus process).

- Provide an opportunity through the *Federal Register* for the public to suggest external peer reviewers for a particular file.

- For significant changes to existing files, new files, or when stakeholders request, hold in-person external peer review meetings open to the public (as opposed to letter reviews). These meetings should be announced in advance through the *Federal Register,* and should provide sufficient opportunity for meaningful public comment.

- Include the entire Peer Review Record in the on-line IRIS file. This should include the individual internal and external peer review comments, the Agency's consensus review comments, and the public comments received in the peer review meetings.

- Respond to internal and external peer reviewer comments and include the responses in the on-line IRIS file.

III. More chemicals must be added to IRIS as necessary to meet the decision-making needs of EPA program offices and other users on a timely basis. In particular, the new IRIS system must:

- Develop a realistic timeline of regulatory needs (i.e., a list of chemical assessments needed for regulatory decisions, and when they will be needed) to compare against the time needed to develop a toxicological review under IRIS. This will permit additions or updates to IRIS to be appropriately prioritized and funded, and allow the Agency to deliver the review in time for it actually to be used by the requesting program office.

- Base IRIS priorities, both for updating and adding new files, on regulatory timelines.

IV. The new IRIS system must include contextual information on the reliability of each file, consistent with high standards of risk communication and characterization. In particular, the IRIS files must:

- Include information indicating when a chemical has been nominated for review, is undergoing review, or has cleared the independent scientific peer-review process, together with a link to the supporting information and documentation.

- Flag any health value based on a toxicological review more than **5** years old and provide information about the status of any request for comment concerning its currency and any subsequent decision whether to "recertify" the value for another 5 years or to update it.

- Include a list of regulatory actions or decision-making actions taken regarding a chemical (reinstating a previous practice in the IRIS system).

- NOT include new analyses and values for acute effects or ecological effects at this time. It is important that the current content of IRIS be upgraded and updated first before the content of the IRIS system is significantly expanded.

V. The new IRIS system must be funded, staffed, and managed according to an objective and transparent annual needs assessment and a priority setting and budgeting and accountability process, incorporating the following:

A. Needs Assessment

- Starting with the responses to the Congressionally mandated needs assessment, develop and take public comment on an initial needs assessment that candidly assesses the needs and associated resource estimates of creating a new IRIS system that truly meets the current and future needs of its users, regardless of current budgetary and personnel constraints. Once complete, this needs assessment must be updated annually as **part** of the budget cycle with the assistance of public input.

- **As** a way of meeting the increased resource needs that will be identified in this needs assessment, develop a new approach whereby interested parties would be allowed and encouraged to develop and submit toxicological reviews to EPA for its evaluation, revision, determinations of all health values, and incorporation into the IRIS database.

- Within the resource estimates of this initial needs assessment, consider a wide range of options/alternatives, including updating every file every 5 years, updating every file every 10 years (or a minimum of 60 / year), and instituting the partial reviews and 5-year reviews as well as the important quality improvement recommendations made within these comments. For the most part, these options are not mutually exclusive.

- Institute streamlined Agency consensus processes that are timely, emphasize accountability and oversight, and are sufficiently robust to handle the increased workload.

- Require that health values developed by EPA program offices outside of the IRIS process be submitted for an Agency-wide consensus review as part of the IRIS peer review and public comment process.

B. Budgeting and Accountability

- Provide a fully dedicated staff and budget. The increased workload inherent in a new and improved IRIS system cannot be met through the current practice of relying on resources from other programs to meet IRIS needs.

- Reflect in EPA's IRIS budget submission to Congress the extent to which the needs identified in the needs assessment are being met by the proposed budget.

- To strengthen the accountability of IRIS for achieving the recommended science management improvements, make IRIS a significant part of EPA's Government Performance & Results Act sound-science objectives.

- Recommend that an appropriate science advisory committee be established (e.g., Science Advisory Board, Board of Scientific Counselors) to provide an annual review of the IRIS program's progress toward making the necessary improvements and to advise the program as needed.

C. Priority Setting

- Replace the current, largely subjective, criteria by which priorities for updating are established with new objective criteria.

- In assigning priorities to chemicals for updating, explain how these new criteria justify the inclusion of each chemical in the priority list.

- Discontinue the practice of prioritizing IRIS updates based upon the availability of an IRIS manager from a program office or under the collaborative program to perform the assessment. Priorities must be assigned instead on the basis of objective needs.

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I. INTRODUCTION

The American Chemistry Council (Council) is pleased to provide the following comments in response to EPA's Request for Information on Needs for Health Assessments on EPA's Integrated Risk Information System (66 FR 37958-37959) (July 20,2001).

EPA's Integrated Risk Information System (IRIS) is one of the most visible and important components of EPA's management of science for regulatory and other programmatic purposes, both within EPA and in numerous other organizations, including state environmental programs. For this reason it has been the focus of a number of reviews with regard to its importance, its opportunities and its shortcomings.

We discuss some of these important studies in Attachment A to these comments. With regard to the general need to strengthen EPA's science, the National Academy of Sciences' (NAS) report, *Strengthening Science at the Environmental Protection Agency,* and EPA's own *Safeguarding the Future: Credible Science, Credible Decisions,* both provide important summaries of problems and proposals pertaining to Agency science. Addressing specific IRIS issues, the NAS report, *Science and Judgment in Risk Assessment,* identified the need to keep the IRIS files up to date and addressed other IRIS issues. EPA's own Risk Assessment Council undertook a broad review of IRIS as well through a Quality Action Team (QAT) and concluded that EPA needed to make a stronger commitment to the system and increase the resources devoted to it. A July 2000 study commissioned by EPA, *Characterization of Data Uncertainty and Variability in IRIS Assessments Pre-Pilot Vs Pilot/Post-Pilot* highlighted the continuing lack of sufficient information on uncertainty and variability in IRIS files. In addition, the Council submitted a study to EPA dated March 17,2000, *Screening-Level Assessment of the Need to Update EPA's IRIS Database,* which provided an analysis of the extent to which IRIS files are out-of-date.

Commendably, EPA staff have instituted changes in the IRIS system intended to respond to some criticisms of the system described in these reports. However, these changes fall far short of what is needed to match the reality of the state of the IRIS system with the role that IRIS has assumed over the years as one of the most frequently cited sources of health effects values for regulatory purposes. The quality of the IRIS system directly affects the quality of science practiced at EPA and in numerous other regulatory programs, as well as the credibility of the resulting regulations that affect millions of people.

At least half the challenge for EPA is for staff and management alike to admit that IRIS, due to the many ways its values are used, remains in serious straits, despite the recent attempts at improvement. Once that fact is accepted, EPA can seize this opportunity to recognize IRIS's unmet needs and create a new IRIS system that matches in quality the role that it plays in regulatory decisions today and the role it must play in

the future. A continuation of small, incremental changes in the IRIS system will simply not suffice.

Adequate resources have always been a serious bottleneck for the IRIS program. To create a new IRIS system that EPA and others can use with confidence, both new EPA resources and new ways of managing the work need to be found. In this spirit, the Council recommends that EPA consider a new approach with the public through which external parties (such as chemical producers who have extensive expertise) can develop IRIS toxicological reviews for submission to EPA for critical review and decision-making.

An approach that allows and encourages companies to provide toxicological information should increase the amount of current information available to EPA. The Organization for Economic Cooperation and Development Business and Industry Advisory Committee, national chemical industry associations, and individual companies assist in promoting the collecting of information, and in ensuring that necessary tests are conducted in a timely manner. The approach we are urging also builds on pilot projects currently underway, such as the International Life Sciences Institute peer review centers for excellence project, and other *ad hoc* Agency collaborative efforts. We believe such collaboration must become the core-operating mode for IRIS so that EPA can focus its limited resources primarily on the functions of the IRIS process that are uniquely governmental in nature.

11. THE IRIS SYSTEM

While a new and highly improved IRIS system is absolutely essential to sound science at EPA, it is not necessary that the IRIS system try to become the sole source of final toxicological values for the Agency. Indeed, any toxicological value that reflects the latest scientific studies and has satisfied independent peer review requirements should be deemed acceptable to serve the same role as an IRIS value (i.e., as a starting point for a risk assessment and rulemaking). The key is ensuring that both IRIS and non-IRIS values meet high-quality scientific standards. As EPA has stipulated in *General Electric* Co. *v. Browner* (D.C. Cir. No. 93-1251), IRIS values are not binding on EPA program or regional offices. EPA reiterated this policy in its Sept. 7,2001, *Federal Register* notice (44 CFR Part 141), signed by EPA Administrator Whitman, which reads in part, "IRIS values are not legally binding and are not entitled to conclusive weight in any rulemaking" (p46929). To avoid running afoul of the Administrative Procedure Act, EPA must consider in any regulatory proceeding all relevant and credible information regarding the toxicity of a substance.

Although IRIS must be regarded as only one source of toxicological values, it is nevertheless EPA's consensus database and, as such, plays a decidedly prominent role among such data sources. Indeed, IRIS may be regarded at some level as a "keeper of the

standards" for EPA toxicological assessments. Program and regional offices should consult the IRIS database as a repository of information when considering any revision to existing health values, and such revisions should meet the fundamental requirements for IRIS described in these comments. With this important role comes the additional responsibility for IRIS to meet quality assurance, timeliness, and other standards described by **NAS,** the QAT, and the Council in its comments below. That responsibility cannot be met with the current IRIS structure and resources. Rather, adequate dedicated staff resources and new management approaches are absolutely essential if IRIS is to evolve from an over-burdened, lagging system populated with out-of-date toxicological values to an appropriately high-quality information source.

We recommend that EPA structure its rethinking of the IRIS system to achieve the following five management principles:

I. Toxicological reviews and the resulting health values contained in the IRIS database must be as up-to-date as reasonably possible, incorporating the latest relevant studies and methodologies. Those studies that vary in quality, methodology, and significance must be evaluated according to a consistent "weight of evidence" approach.

11. IRIS must incorporate a rigorous peer review process that is open/transparent, external, independent, balanced and fully documented.

111. More chemicals must be added to IRIS as necessary to meet the decision-making needs of EPA program offices and other users on a timely basis.

IV. The new IRIS system must include contextual information on the reliability of each file, consistent with high standards of risk communication and characterization.

V. The new IRIS system must be funded, staffed, and managed according to an objective and transparent annual needs assessment and a priority setting and budgeting and accountability process.

We address each of these five principles in greater detail below along with recommendations for implementing the principles.

I. Toxicological ev and the resulting health values contained i the **RIS** database must be as up-to-date as reasonably possible, incorporating the latest

relevant studies and methodologies. Those studies that vary in quality, methodology, and significance should be evaluated according to a consistent "weight-of-evidence" approach.

A. The Current Situation

In earlier submissions to EPA (August 29,2000, letter to the Science Advisory Board Re: *Characterization of Uncertainty and Variability in IRIS;* April 4,2000, letter to William Farland, including the attached ICF report, *"Screening-Level Assessment of the Need to Update EPA's IRIS Database"),* the Council has documented that most IRIS assessments are more than 10 years old. In its study ICF Consulting took a random sample of 35 chemicals from the pre-IRIS pilot universe and conducted a literature search and abstract review for studies that "appear useful" to revising IRIS files. ICF estimated the average number of citations per chemical that appeared useful for updating the IRIS assessment for the chemical, the IRIS cancer assessment, and the IRIS non-cancer assessment, by calculating the sample mean and median for each. For 91% of the sample, at least one study appeared useful to revising a file. For 69%, at least **5** studies appeared useful. With a 95% degree of confidence, the average number of total citations per chemical that appeared useful for revising an IRIS value was between 8 and 16, and the estimated median was between 5 and 13.

Because the current system lacks the dedicated staff and resources, as well as a well thought-out system for regularly updating IRIS files, significant new studies are not assessed and (as appropriate) incorporated into the IRIS assessment for years after they are completed, if at all. Thus, in many instances when IRIS values are used in a regulation, they are many years out of date.

This situation has several negative consequences: It places an unreasonable burden on individual EPA program offices to review the quality of the IRIS values and available scientific information during the regulatory process – reviews that, due to the press of regulatory demands, often may not get done adequately or at all. Similarly, state regulators are forced to choose between using the out-of-date information or undertaking an independent hazard and dose-response review of a chemical during a regulatory or other decision making process. Further, if new data languish unevaluated, the scientific community is discouraged from attempting to fill data gaps identified in the original IRIS review with the goal of better understanding a chemical's hazard and dose-response. Out-of-date numbers are used, or real data are displaced by default assumptions.

Even studies conducted under Toxic Substances Control Act (TSCA) test rules or Enforceable Consent Agreements are not added to IRIS on a timely basis, although EPA Office of Prevention, Pesticides, and Toxic Substances scientists typically critically review these studies and they are published in the peer-reviewed literature. The benefit of this research is partially lost if it is not incorporated in IRIS for wider use. EPA has an

obligation in the case of studies required under TSCA to make sure that the reviews meet Agency quality standards and to get the results into IRIS.

One way to correct portions of out-of-date values is to conduct "partial reviews," a mechanism the Council supports. Ideally, the process should allow easy incorporation of important new information, whether it changes a reference dose (RfD), reference concentration (RfC), or cancer potency value. For example, when the IRIS database file says reproductive studies are not available and subsequently a 2-generation reproductive study is completed, the study's conclusions should be reflected in IRIS. A workable partial update process ideally would place the initial burden on the submitter; use dedicated EPA resources to manage the partial update process; and use external peer reviewers to ensure reliability. Partial reviews should be considered especially when a particular IRIS value is to be applied in a regulatory situation and a regulated party or a Program Office challenges the technical basis of this value. Partial reviews should also be considered when, based on more recent scientific information, another Agency, state, or scientific body has developed a value that differs substantially from the IRIS value.

In addition, currently, IRIS reviews do not always: 1. Follow the most advanced science policies that EPA has developed; 2. Contain exemplary hazard and dose-response characterizations; or 3. Provide transparent treatment of uncertainty, data gaps, and variability.

IRIS does not always use the most up-to-date information on mode-of-action (e.g., explicit consideration of whether the endpoints are relevant to humans) or the most up-to-date cancer guidelines to determine whether a chemical causes cancer through a nonlinear or threshold mode of action. If a chemical has a nonlinear or threshold mode of action, then a margin of exposure approach, uncertainty factor [or other low-dose model] should be used. IRIS also should use methods of route-to-route extrapolation with a relevant scientific basis. Innovative approaches to establishing RfCs and RfDs should be encouraged throughout EPA, including in the IRIS program. For example, PB/PK information should be used to adjust uncertainty factors, as recommended by the recent International Program on Chemical Safety (IPCS) scheme ***(see*** IPCS 1999). The EPA Office of Water and Office of Research and Development (ORD) are considering adoption of this IPCS scheme, and IRIS should do the same.

Besides failing to reflect the most up-to-date studies, many IRIS values are not fully consistent with the most up-to-date hazard and dose-response characterization methods. This is particularly true for chemicals for which significant quantities of human epidemiological data exist. For example, although EPA has repeatedly and unequivocally endorsed the use of a "causation criteria" approach when evaluating epidemiological data (EPA, Proposed Guidelines for Carcinogen Risk Assessment (1996) ("Guidelines"); EPA, Guidelines for Neurotoxicity Risk Assessment, 63 Fed. Reg. 26926 (1998)), IRIS does not commonly present evaluations of epidemiological data that are consistent with

these guidelines, even though EPA's 1996 Proposed Guidelines provide a number of explicit recommendations and criteria for evaluating a body of literature in order to establish whether a particular chemical causes a particular effect. [i]

Currently, toxicologists appear to dominate the IRIS process to such an extent that human/epidemiological data may not be adequately incorporated in the IRIS file development. Epidemiologists should be included routinely in the reviews, and the services of specialist physicians (neurologists, endocrinologists, etc.) should be included when it is appropriate to involve such experts on teams assessing new chemicals or re-visiting outdated IRIS files.

Many IRIS entries are also not fully consistent with the most up-to-date dose-response assessment methods, particularly for chemicals that cause cancer and for which older potency factors are still embedded in IRIS. Although EPA is also exploring new ways to determine uncertainty factors for RfD and RfC estimation, the IRIS program has not even updated its existing IRIS background document for RfDs to reflect the Agency's standard uncertainty factor practice over the last 12 years. Likewise, some of the pre-1994 RfCs are inconsistent with the 1994 RfC guidance. When one or more chemicals are found to have identical mechanisms of action but differing potencies (DNA binding, cholinesterase inhibition), then RfDs in IRIS should reflect the best estimates of the potencies. IRIS toxicological values do not consistently incorporate these latest methods.

B. Recommendations for Improvement

The new IRIS must:

- Encourage users to nominate IRIS files that are in urgent need of updating. A rigorous but efficient process must be established by which chemical assessments and/or health values in IRIS can be identified as priority candidates for updating because of highly relevant new studies, or new peer reviewed methodologies or science policies. Within such a process, nominating parties must be required to articulate a sound scientific rationale regarding how the new data might significantly change the current IRIS assessment for the particular chemical or the uses of that information for risk assessment.

- Set and track specific target dates for updating existing IRIS files. Create specific organizational accountability for meeting these targets.

- Establish criteria under which "partial reviews" of IRIS files (e.g., revising a Reference Concentration without changing the cancer potency factor) will be appropriate from a scientific standpoint. Partial reviews must be allowed not only for portions of individual files but also on a multi-file basis when more current peer reviewed guidelines might apply to a broad group of files.

- Publish an annual notice in the ***Federal Register*** indicating when each toxicological review or health value (beginning prospectively with those updated or added by the IRIS pilot project) reaches its 5-year anniversary. The notice must request information regarding whether the review and the health values are up-to-date with current peer reviewed studies, methodologies or science policies. In addition, the Agency should itself conduct a literature search for the same purpose. On the basis of the input from these inquiries, the Agency should publish its decision that the identified IRIS file is still scientifically appropriate and supportable, or will be updated.

Reflect the latest peer reviewed science policies, by having each new and updated IRIS file:

- Carefully consider relevant epidemiological and other data and apply causation analysis principles. ***(see*** Hill, A.B., 1965).

- Contain exemplary hazard and dose-response characterizations that can constitute a model for all other Agency's assessments, consistent with the principles of EPA's Risk Characterization Policy.

- Display a thorough and transparent treatment of uncertainty, data gaps, and variability.

11. IRIS must incorporate a rigorous peer review process that is open/transparent, external, independent, balanced and fully documented.

A. The Current Situation

Appropriate peer review is an indispensable part of the process by which scientific findings and interpretations receive credibility and acceptance. The Council recognizes that EPA, under the Pilot Program, has instituted an external peer review, in addition to the internal consensus (EPA) peer review, for each of the revised and new IRIS toxicological reviews and IRIS summaries that have been developed through the Pilot. This is a significant improvement to the pre-Pilot process but must be enhanced. The Council believes that external peer reviews have been conducted inconsistently within the pilots.

We urge EPA to revisit its peer review process for IRIS, because we believe that it deviates significantly from the provisions of the EPA Peer Review Handbook (2000). We also recommend the American Industrial Health Council (AIHC) peer review principles as useful guidance on this important issue. The Presidential/Congressional

Commission on Risk Assessment and Risk Management in its 1997 report also makes important recommendations on peer review that the Council additionally endorses as elements of strong a peer review program. (Per the recommendation of the Commission, EPA must provide not only peer review of the IRIS assessment, *per* ***se,*** but also peer review and expert commentary on the application of the assessment in regulation.)

IRIS peer review is disturbingly inconsistent. Recently, one of the Council's CHEMSTAR Panels was told by an EPA IRIS chemical manager that there would not be a public comment period on the chemical of interest. When the CHEMSTAR representative pointed out that a particular industry toxicologist was a renowned expert on that chemical, and would therefore like to present comments, the EPA chemical manager admitted that this was true, but indicated that the views of external toxicologists are irrelevant to the IRIS process because IRIS values simply represent EPA consensus views on specific chemicals. Obviously, such a lack of public process and refusal to consider the views of potential outside peer reviewers and stakeholders undermines the scientific credibility of the IRIS assessments.

Specific recommendations for addressing these concerns about IRIS peer review follow.

B. Recommendations for Improvement:

Specifically, following the Agency's Handbook and AIHC principles of peer review *(see Attachment B)*, the IRIS system must:

- Expand its use of public comment periods to obtain input from scientists (and others) in the public who may be knowledgeable but who are not chosen to serve on the peer review panel. These public comments must be provided to the peer reviewers for their use in review of the IRIS documents.

- Schedule external peer reviews to occur after the IRIS assessment process is tentatively complete, but sufficiently early to constructively influence the final outcome of the assessment (that is, they must be able to inform the internal EPA consensus process).

- Provide an opportunity through the *Federal Register* for the public to suggest external peer reviewers for a particular file.

- For significant changes to existing files, new files, or when stakeholders request, hold in-person external peer review meetings open to the public (as opposed to letter reviews). These meetings must be announced in advance through the *Federal Register,* and must provide sufficient opportunity for meaningful public comment.

- Include the entire Peer Review Record in the on-line IRIS file. This must include the individual internal and external peer review comments, the Agency's consensus review comments, and the public comments received in the peer review meetings.

- Respond to internal and external peer reviewer comments and include the responses in the on-line IRIS file.

111. More must be done to IRIS as necessary to meet the decision needs of EPA program offices and other users on a timely basis.

A. Current Situation

Without a doubt there are chemicals that should be evaluated and added to the IRIS system. Increasingly, decisions by EPA program offices and others rely heavily on risk estimation, and where chemicals are involved, sound hazard and dose-response assessments are essential prerequisites. Moreover, EPA programs and others are now forced to do an extensive evaluation of certain chemicals to make regulatory and other decisions without the benefit of the IRIS information. For example, the Air Office's residual risk program must make regulatory determinations beginning in 2002 for 188 hazardous air pollutants, less than half of which are in IRIS today. Furthermore, many of those on IRIS are out-of-date.

The needs assessment mandated by Congress and cited in this *Federal Register* notice is a step in the right direction toward identifying chemicals that should be added to IRIS. However, before EPA commits to undertake a review of a chemical not already in the system, the Agency should undertake a realistic appraisal of the timeline for regulatory and program decisions as compared to the timeline for adding the chemical to IRIS to make sure that the IRIS review process will in fact produce useable information in time for the scheduled decision making. The Council's recommendations for chemicals that should be added to the IRIS database and files that should be updated have been transmitted to EPA in the past. Additional recommendations will be made as separate submittals.

As with updating files, the lack of resources has apparently played a role in determining how many new chemicals can be added to the system. The suggestions we make below for increasing the resources for updating IRIS files are largely relevant here as well. However, before EPA devotes significant new resources to adding new chemicals to the IRIS system, the Agency needs to address the relative priority of updates versus additions. In our view, IRIS priorities for updating and adding IRIS files should be based on a comprehensive regulatory timeline that indicates what chemical

assessments will be needed for regulatory purposes and when.

EPA program offices working on regulatory initiatives involving multiple chemicals (or even a single chemical) often refuse to consider information or health values inconsistent with IRIS, even when the information is based on more recent peer-reviewed scientific data. When a program office does decide to use more current peer-reviewed information, IRIS representatives sometimes oppose the action (or withhold concurrence), reasoning that the use of the more current information represents a "piecemeal" revision to IRIS. Neither of these situations is acceptable and suggests a fundamental breakdown in the science process at the Agency, which ought to incorporate new peer-reviewed science when it is available.

B. Recommendations for Improvement

The New IRIS must:

- Develop a realistic timeline of regulatory needs (i.e., a list of chemical assessments needed for regulatory decisions, and when they will be needed) to compare against the time needed to develop a toxicological review under IRIS. This will permit additions to IRIS to be appropriately prioritized and funded, and allow the Agency to deliver the review in time for it to be actually used by the requesting program office.

- Base IRIS priorities, both for updating and adding new files, on regulatory timelines.

IV. The new IRIS must include contextual information on the reliability of each file, consistent with high standards of risk communication and characterization.

A. Current Situation

To date, IRIS does not acknowledge officially or warn users that the hazard values online and downloaded daily from the official IRIS Website may not reflect current data. The information provided up front in the IRIS file indicating the date of last significant revision does not provide information regarding the relative currency of the values compared to new scientific information, making these dates useless as a reference. The more important consensus date is buried near the back of the file. Few people understand its significance. Of course, even very recently updated files may be quickly called into question by new information.

Users, including risk assessors and risk managers, are entirely on their own to determine whether the IRIS values are current, and which of the more recent studies may be relevant to a current decision about the toxicological characterization of the chemical.

This is scientifically misleading and undermines the credibility of even the files that are relatively up-to-date. Therefore, the current IRIS is, in effect, highly unreliable. Even when a file or value is actually up-to-date, there is no way for a user to recognize this easily or to rely on the file with confidence.

B. Recommendations for Improvement

The IRIS files must:

- Include information indicating when a chemical has been nominated for review, is undergoing review, or has cleared the independent scientific peer-review process, together with a link to the supporting information and documentation.

- Flag any health values that result from a toxicological review more than **5** years old (beginning prospectively with those updated or added by the IRIS pilot project) and include information reflecting the status of the request for comment concerning its currency and any subsequent decision whether to "recertify" the values for another 5 years or to update the file.

- Include a list of regulatory actions or decision-making actions taken regarding a chemical (reinstating a previous practice in the IRIS system).

- NOT include new analyses and values for acute effects or ecological effects at this time. It is important that the current content of IRIS be upgraded and updated first before the content of the IRIS system is significantly expanded.

V. The new IRIS system must be funded, staffed, and managed according to an objective and transparent annual needs assessment and a priority setting and budgeting and accountability process.

A. Current Situation

There appears to be consensus both within and outside the Agency that "strengthening science" should be **an** overriding priority at EPA. There seems to be equally strong consensus that the IRIS system is central to a quality assured hazard and dose-response assessment across the Agency. However, as discussed in these comments, the IRIS system is lagging significantly as a unifying, quality assured database for the Agency. Each month, IRIS becomes less and less authoritative as individual program offices of necessity must promote individualized "scientific" approaches and develop individualized science assessments. ORD has also failed to update IRIS files in a timely manner, while program offices struggle without any values for a chemical or the inability to get a toxicological review of that chemical included in ORD's priority list for an IRIS

update.

EPA has not conducted a comprehensive needs assessment of IRIS in the past. Consequently, IRIS managers generally have had only the recommendations of EPA program offices to judge the need for new or updated IRIS values. Even these program office recommendations may be distorted by the frequent but unwritten requirement that the nominating office must put up from its own budget the resources necessary to conduct the review. Until now, other users of IRIS have not even been asked to identify IRIS needs. The Congressionally mandated needs assessment is an excellent way to start this rethinking of the IRIS system.

Many of the shortcomings identified are due to the Agency's lack of dedicated resources necessary to make IRIS an efficient and current system. Resources have been dependent to a large degree upon *ad hoc* voluntary contributions from program offices rather than dedicated resources. We believe it is clearly time for EPA to move beyond this situation and to adopt an appropriate dedicated system to produce IRIS values. In addition, it appears that the principal bottleneck to additional reviews is in the Full Time Equivalent (FTE) allocation, not in the dollar allocation.

B. Recommendations for Improvement

The Council offers the following recommendations on conducting a comprehensive needs assessment, and on the priority setting and budgeting processes.

A. Needs Assessment

- Starting with the responses to the Congressionally mandated needs assessment, develop and take public comment on an initial needs assessment that candidly assesses the needs and associated resource estimates of creating a new IRIS system that truly meets the current and future needs of its users, regardless of current budgetary and personnel constraints. Once complete, this needs assessment must be updated annually as part of the budget cycle with the assistance of public input.

- **As** a way of meeting the increased resource needs that will be identified in this needs assessment, develop a new approach whereby interested parties would be allowed and encouraged to develop and submit toxicological reviews to EPA for its evaluation, revision, all determinations of health values, and incorporation into the IRIS database.

- Within the resource estimates of this initial needs assessment, consider a wide range of options/alternatives, including updating every file every 5 years, updating every file every 10 years (or a minimum of 60 / year), and instituting the

partial reviews and 5-year reviews as well the important quality improvements recommendation made within these comments. For the most part, these options are not mutually exclusive.

- Institute streamlined Agency consensus processes that are timely, emphasize accountability, and are sufficiently robust to handle the increased workload.

- Require that health values developed by EPA program offices outside of the IRIS process be submitted for an Agency-wide consensus review as part of the IRIS peer review and public comment process.

B. Budgeting and Accountability

- Provide a fully dedicated staff and budget. The increased workload inherent in a new and improved IRIS system cannot be met through the current practice of relying on resources from other programs to meet IRIS needs.

- Reflect in EPA's IRIS budget submission to Congress the extent to which the needs identified in the needs assessment are being met by the proposed budget.

- To strengthen the accountability of IRIS for achieving the recommended science management improvements, make IRIS a significant part of EPA's Government Performance & Results Act sound-science objectives.

- Recommend that an appropriate science advisory committee be established (e.g., Science Advisory Board, Board of Scientific Counselors) to provide an annual review of the IRIS program's progress toward making the necessary improvements and to advise the program as needed.

C. Priority Setting

- Replace the current, largely subjective criteria by which priorities for updating are established with new objective criteria.

- In assigning priorities to chemicals for updating, explain how the new criteria justify the inclusion of each chemical in the priority list.

- Discontinue the practice of prioritizing IRIS updates based upon the availability of an IRIS manager from a program office or under the collaborative program to perform the assessment. Priorities must be assigned instead on the basis of objective needs.

Conclusion

The Council appreciates the opportunity to present its recommendations for fully evaluating the needs IRIS must address to become an efficient, up-to-date system for scientifically assessing and publishing the highest quality EPA consensus toxicological values. We welcome future opportunities to cooperate with the Agency in its initiatives to improve this important database and to help EPA improve the management of science within EPA.

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[i] As EPA knows well, analyzing the contribution of evidence from a body of human data requires examining available studies and weighing them in the context of well-accepted criteria for causation. A judgment is made about how closely they satisfy these criteria, individually and jointly, and how far they deviate from them. Existence of temporal relationships, consistent results in independent studies, strong association, reliable exposure data, presence of dose-related responses, freedom from biases and confounding factors, and high level of statistical significance are among the factors leading to increased confidence in a conclusion of causality. Generally, the weight of human evidence increases with the number of adequate studies that show comparable results on populations exposed to the same agent under different conditions. The analysis takes into account all studies of high quality, whether showing positive associations or null results, or even protective effects. In weighing positive studies against null studies, possible reasons for inconsistent results should be sought, and results of studies that are judged to be of high quality are given more weight than those from studies judged to be methodologically less sound. Generally, no single factor is determinative. For example, the strength of association is one of the causal criteria. **A** strong association (i.e., a large relatively risk) is more likely to indicate causality than a weak association. However, finding of a large excess risk in a single study must be balanced against the lack of consistency **as** reflected by null results from other equally well-designed and well-conducted studies. In this situation, the positive association of a single study may either suggest the presence of chance, bias or confounding, or reflect different exposure conditions. On the other hand, evidence of weak but consistent associations across several studies suggests either causality or the same confounder may be operating in all of these studies. (emphasis added).

EPA's Guidelines are consistent with a large body of literature that stresses the importance of **epidemiological studies in assessing the human health risks of chemicals and placing animal** studies **into** the correct context (Cook, 1982; Dinman and Sussman, 1983; Layard and Silvers, 1989). It is now understood that a chemical that produces a particular effect in the tissues of one species of laboratory animal may not have that effect in the same type of tissue in other species or, for that matter, may have no similar effect in any other species (Gold et al., 1998). It is also recognized that not all positive findings in animal cancer bioassays predict that a chemical poses carcinogenic risks to humans (Goodman and Wilson, 1991; Gold et al., 1997, 1998) because chemicals may have different mechanisms of action and pharmacokinetics in different species (Dietrich and Swenberg, 1991; Hard and Whysner, 1994). **As** just one example, it is now known that certain chemicals produce tumors in laboratory animals via a mode of action that simply does not occur in humans (e.g., alpha-2u globulin)'. Epidemiological studies are invaluable in helping risk assessors determine whether risks predicted by the animal model are likely to actually exist for the human population.

EPA's Guidelines are also consistent with the increased use of formal "causation analysis" to answer the ultimate question of whether exposure to a particular chemical causes an increased risk of disease. The Guidelines mention seven causation criteria -- existence of temporal relationships, consistent results in independent studies, strong association, reliable exposure data, presence of dose-related responses, freedom from biases and confounding factors, and high level of statistical significance. At least ten criteria have

been proposed for establishing cause and effect relationships (Hill, 1965; Evans, 1976; Hackney and Linn, 1979; Doll, 1984; Guidotti and Goldsmith, 1986; Mausner and Kramer, 1985; Monson, 1988; Hernberg, 1992). However, as typically applied, the scientific demonstration of causation requires satisfaction of all or most of six fundamental "causation criteria" (Hill, 1965; Mausner and Kramer, 1985; Monson, 1988; Rothman, 1988; Hernberg, 1992; IARC, 1987): strength of association; dose-response; specificity of association; consistency of association; biological plausibility; and temporally correct association,