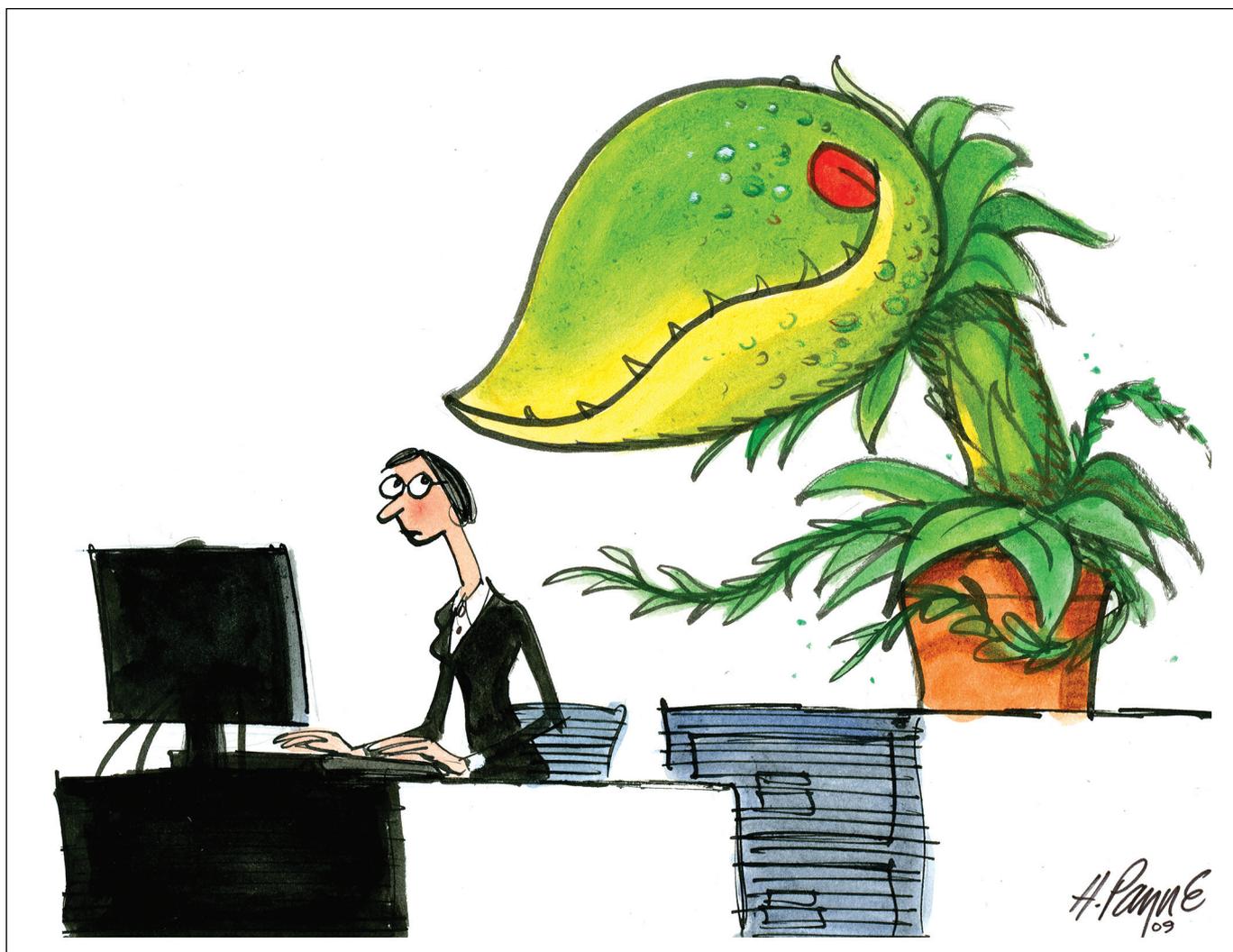


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Eyeballing IRIS

How the Obama administration addresses EPA's Integrated Risk Information System may very well represent its intentions for advancing the science and technology of risk assessment and risk management and its commitment to the federal-state partnership. The new White House must make a decision: does it lower or try to meet expectations?

Jim Solyst

In 2002, the Massachusetts Department of Environmental Protection determined that drinking water and waste-site cleanup standards needed to be promulgated for perchlorate, a chemical found in blasting agents, fireworks, military munitions, and other products. The substance had been detected in drinking water supplies, and the state determined it posed a risk to public health. Mass DEP embarked on a "rigorous scientific evaluation of the risks posed by perchlorate," as the agency announced. One of the first steps was to access the Integrated Risk Information System, a database that contains EPA's scientific position on the potential human health effects that may result from exposure to various chemicals in the environment. IRIS data provide the fundamental scientific components needed to develop health risk assessments. These assessments, in turn, provide the foundation for risk management decisions, such as whether EPA or Massachusetts should establish air and water quality standards to protect the public from exposure to perchlorate or set cleanup standards for hazardous waste sites containing the substance.

States, EPA regions, as well as some international

regulatory bodies depend on IRIS when they assess risk and make science-based decisions. There is no better source of information. Since it was established in 1986, IRIS has evolved into one of the world's most significant repositories for chemical risk information. It provides a unique service: peer-reviewed, agency-consensus numerical values such as reference doses on 540 chemicals. Thus, it is the first and most important information source that Massachusetts and all other states turn to for toxicological information.

However, in 2002 there was no IRIS assessment on perchlorate. In fact, there were no IRIS assessments (and still aren't) for many of the "emerging contaminants" that states like Massachusetts need to act on: formaldehyde, naphthalene, trichloroethylene, perfluorooctane sulfonate, perfluorooctanoic acid, and others. So Mass DEP was forced to conduct a scientific evaluation without the benefit of an IRIS assessment, at considerable expense.

Just how expensive was it? When asked by the Senate Committee on Environment and Public Works, a Mass DEP senior scientist estimated that the resources devoted to establishing a state perchlorate drinking water standard were approximately equal to nine person-years at a total cost of approximately \$1.35 million. Resources included expertise from toxicologists, chemists, engineers, attorneys, and program managers.

The cost of setting the standard is just the beginning. The state undoubtedly will continue to spend resources defending its decision. Other states are likely to be pressured into following the Mass DEP lead and set their own perchlorate standards. And although they will benefit from the Mass DEP work, they will still have to spend resources which could be better spent on other environmental health concerns.



Jim Solyst is a Principal Consultant with ENVIRON Corporation, a global health sciences and environmental engineering firm. He has been involved in IRIS and related risk issues while working at the National Governors' Association and the American Chemistry Council. He would like to thank Dr. Joe Rodricks, ENVIRON Principal and Co Founder, for his guidance in preparing this article.

Unfortunately the perchlorate story is representative of the state of IRIS: many assessments are outdated and few have been added in recent years, resulting in a growing backlog of incomplete chemical assessments. This state of affairs has not gone unnoticed. The Government Accountability Office issued a report last March and provided testimony for a September House Energy and Commerce subcommittee hearing. The GAO report concluded that IRIS is at serious risk of becoming obsolete because EPA has not been able to routinely complete timely, credible assessments. GAO and some in Congress contend that the involvement of the Office of Management and Budget and regulated federal agencies is the primary reason for the delays in finalizing key chemical assessments.

How the Obama administration addresses IRIS may very well represent its intentions for advancing the science and technology of risk assessment and risk management and its commitment to the federal-state partnership. IRIS is a dichotomy: it has tremendous name recognition, great credibility, and provides an essential service to a key EPA audience, state environmental regulatory agencies. In a time of strained EPA-state relations, IRIS sticks out as a product that provides a unique and valued service. Yet IRIS frustrates this audience and others by not expanding its service line, in particular by not issuing assessments on the chemicals of most concern. Because IRIS has been successful, its customers have high expectations. It remains to be seen if the expectations can be met.

Maximizing Potential

The IRIS database may be the most recognizable EPA brand in the field of chemical risk assessment, yet the program remains insular and has not maximized its potential for being the world's most significant repository for chemical risk information. IRIS is so well known and utilized because it provides an answer to the key question of "How clean is clean?" It not only helps determine drinking water contaminant levels it also helps regulatory bodies around the world determine how much of a chemical may be discharged into a river or lake. It allows questions to be answered such as, Which substances may be stored at a hazardous waste disposal facility? What is the appropriate cleanup level for a hazardous waste site? What should be the permit conditions for treatment, storage, or disposal of a hazardous

waste? What are the appropriate levels for air emissions from a facility?

Whether or not any information source can provide definite, bright-line answers to such complex scientific issues is debatable, but the fact is regulatory bodies need numerical values and IRIS provides numbers, such as an oral reference dose and inhalation reference concentrations — numbers that are used to arrive at decisions. However, arriving at these numbers involves heavy reliance on assumptions and policy decisions: Which models to use? Which studies to use and which one is the "critical" study? Any time science policy enters into the picture there is going to — and should be — rigorous debate. But the debate has contributed to a slowing down of the risk assessment process on key chemicals.

IRIS is a service provided by the National Center for Environmental Assessment, part of EPA's Office of Research and Development; it is not required by law or regulation. NCEA determines, based on suggestions from EPA programs offices and others, which chemicals warrant the development of an IRIS assessment. Manufacturers and users of chemicals are not required to submit information; to the contrary, typically they attempt, often with limited success, to provide information that will impact the outcome of the IRIS assessment. In this way, IRIS is much different than the European Union's REACH system, another newsworthy chemical management tool that requires manufacturers and users of chemicals to submit information. The REACH process will ultimately lead to chemical-specific risk assessments that will be available electronically. But that service is years off and for now, IRIS is much more important component of the decisionmaking process.

We agree with the GAO that IRIS needs to be fixed. The short-term reason is that the delay in issuing new IRIS assessments has made it difficult for states and other political jurisdictions to make science-based decisions. Ask any state environmental regulatory official facing increasing pressure to address the risks posed by a number of high profile chemicals. The answer is that unfortunately these controversial substances, and many others, are not included in IRIS. The longer-term reason is that IRIS is not being all that it can be. It could be the source of all things chemical risk assessment; not

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just EPA numerical values, but also the information site for the latest developments in the field and the point of entry to all relevant scientific articles and web sites. Furthermore, in a time when REACH threatens to be rolled out worldwide, EPA already owns the most prominent risk-based chemical database. But, unlike the European Union, EPA is not aggressively marketing its product. In fact, the agency cannot satisfy its most loyal and dependent customers.

IRIS is far from perfect; there are legitimate concerns about the quality of its risk assessments and the program's willingness to consider opposing views, particularly those offered by regulated parties. But it is the preeminent risk-based toxicological database in the world, and its enhancement — particularly speeding up the file development process for new chemicals — should be given priority attention by the new administration.

Who Uses IRIS?

Recently ORD contracted with ENVIRON International Corporation to develop an analytical approach to determine how IRIS is used by non-EPA decisionmakers and customers in general. The analysis found that IRIS is widely used globally by a variety of people. Frequent clients typically have training in toxicology, chemistry, biology, and related scientific disciplines. They work for various organizations and institutions, including not only federal and state governments but foreign governments, regional and global governmental organizations, industries that manufacture or use chemicals, trade associations representing those industries, consulting firms, academia, and research institutions.

Those who also use IRIS for regulatory purposes typically work for a government agency or a responsible party. In other words, some customers use IRIS because it is a useful source of information; while for other customers IRIS is mandatory, and those customers include state agencies. Customers who use IRIS

for general information often rely upon other databases to complement an IRIS assessment. Other databases exist, which can provide some help, but for domestic regulatory purposes there is no satisfactory alternative to IRIS. And using an IRIS file as the scientific basis for a regulatory decision is expected and seldom challenged. Finally, IRIS has high name recognition among state regulatory decisionmakers. Officials such as a secretary of a state environmen-

tal regulatory office will ask “What does IRIS say?” about the chemical of concern, meaning “what is the EPA position?”

ENVIRON conducted formal, in depth interviews with scientists from several states and had informal conversations with representative from many other states. The findings from the interviews were remarkably consistent: the absence of an IRIS assessment for a chemical of concern results in uncertainty and creates additional work for all parties.

Typically state agencies are not aggressively addressing chemical-specific issues; rather they are forced into action by political and public expression of concern. If a “dangerous” chemical is found in a drinking water supply the environmental regulatory department or the public health agency must assess the risk posed. All too often recently the chemical of concern is not in IRIS, but that does not relieve the state agency of its responsibilities. Thus, agency scientists must essentially develop their own IRIS assessment. To make things worse, because their decision was not based on an IRIS assessment, the agency scientists and decisionmakers will have to continuously defend their actions.

Frequent IRIS customers — including state agencies and regulated parties — have three core expectations or hopes. Chemical assessments should be continually updated — the numerical values do not necessarily have to change but the assessment should present all available new information; new assessments should be issued routinely, particularly for the emerging contaminants that states must address; and the IRIS web site should be the repository of all things risk assessment. IRIS at present does not deliver on these expectations — and perhaps the expectations are unfair — but there are worse things for a government product than having high expectations. The new administration must make a decision: does it lower or try to meet expectations.

The National Center for Environmental Assessment is one of many such centers within ORD. It is a science office, staffed and managed by scientists who don't think in terms of enhancing a product or a brand and certainly are not accustomed to negotiating the give and take that has come to be the norm in developing and issuing a new IRIS file. If the NCEA staff had it their way they would develop a file within the confines of their offices, only occasionally hearing from responsible parties. This insular way of doing business is comforting in many ways, but it is not the reality of what the current situation demands.

For most of its existence IRIS has operated under the radar and has not been subject to the intense scrutiny it is now receiving. Industry, particularly the chemical industry, diligently attempted to en-

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gage in the file development process, but seldom had an impact. Things have changed in the past eight years; the Bush administration Office of Management and Budget has been actively involved in reviewing draft IRIS assessments, and federal agencies that are also regulated parties, like the Department of Defense and Department of Energy — are increasingly aware of the impact IRIS assessments can have on their missions. Neither of these developments is unexpected or inappropriate. OMB is obligated to review agency-issued guidance, and IRIS assessments are certainly guidance; in fact in many cases an IRIS file is gospel. Federal agencies that are regulated parties should have the opportunity to contribute information and expertise to the file development process, just as industry and NGOs should have always had the opportunity — within well defined bounds — to contribute.

Can Expectations Be Met?

Our sense is that frequent IRIS customers don't terribly care who is to blame; they just want their expectations met. But they do wonder whether their concerns and needs are fully appreciated. A key issue to be addressed is whether the current institutional arrangement allows for customer expectations to be met. Specifically, should NCEA continue to be the home for IRIS? We believe there is no reason why NCEA cannot deliver on two of our three core expectations, but it will require a cultural change.

The easiest expectation to meet is to continually update the information in existing IRIS assessments. This does not necessarily mean changing the numerical value in the assessment but it does require NCEA to cite (and link to) relevant scientific literature, including peer-reviewed articles presenting research funded

A Better Use of Resources

The Integrated Risk Information System is a database on health effects from exposure to environmental contaminants. It is an invaluable source of dose-response assessments and toxicity values used in risk assessments and management decisions by environmental and public health agencies across the country.

Unfortunately, the rate at which new chemical assessments are added and existing files are re-evaluated has been decreasing for many years and has all but come to a halt. A revival of this essential but languishing program is urgently needed.

When state or federal agencies need toxicity values that are not published in the database, these groups often have no choice but to develop toxicity values outside of the IRIS assessment process. The conduct of independent dose-response assessments by multiple agencies is an inefficient use of public resources and such independent efforts are far more likely to lead to an incongruous patchwork of different regulatory standards across the country. Such inconsistencies frustrate industry and erode public confidence in governments' decisions about public health protection.

Most environmental scientists agree that broad stakeholder input, documentation of all available scientific data, and clear, comprehensive explanations of final decisions are important components of IRIS assessments. There is marked disagreement, though, about how final decisions on assessment reports should be made and who should make them. Some have argued for more extensive involvement of the regulated community, wider consideration of risk management fac-

tors (such as compliance costs), and greater emphasis on negotiation and consensus in the decision process. It is my belief, though, that consideration and/or incorporation of risk management issues in dose-response assessments could undermine the integrity and applicability of the IRIS toxicity values.

For IRIS dose-response values to be broadly applicable, they must be compatible with the agency mandates to protect the environment and public health. I believe that scientists trained in toxicology and risk assessment and working under EPA's mandate to protect public health are uniquely

positioned to analyze, interpret, and pass judgment on health effects information and dose-response data for use in environmental assessment and management. EPA's National Center for Environmental Assessment should make the final decision on dose-response assessments.

Negotiation and consensus among stakeholders (including federal entities subject to environmental regulatory requirements), should be settled outside of the IRIS process. Costs and politics should not be part of the toxicity assessment process but considered separately in risk management decisions.

Last but certainly not least, I believe that supporting NCEA with sufficient financial resources and reducing the role of cost considerations in toxicity assessments would go a long way toward enabling IRIS to reach its full potential, including accelerating the pace of toxicity assessments.

Carol Rowan West is the Director of the Office of Research and Standards at the Massachusetts Department of Environmental Protection.



Carol Rowan West

by regulated parties. The drafting of an IRIS assessment typically results in regulated parties' funding research they anticipate will be used in the final version of the assessment. Unfortunately it does not usually work that way; research takes time and it is likely the assessment will be issued before the research is complete. But the research — provided it is peer reviewed — should become part of the IRIS file, regardless of whether it was funded by DoD, industry, or even a nongovernmental organization.

The second expectation that NCEA can meet is to be less insular, be less of an EPA site and more of a federal government risk assessment site. The recently revised IRIS web site makes strides in that direction but much more needs to be done. The site provides links to all relevant EPA risk assessment guidance, tools, and information. In addition, it provides links to other governmental agencies, international agencies and NGOs, including the National Academy of Sciences. However, the site does not promote, or even necessary cite, studies that may challenge the traditional NCEA approach to conducting risk assessment.

The third core expectation of IRIS — that new chemical assessments will be issued in a timely manner — is the most challenging for NCEA. Meeting the challenge requires interagency coordination and negotiation, which is not normally the realm of a science office. NCEA management has undoubtedly experienced what they believe is inappropriate pressure to modify draft IRIS assessments. Conversely, OMB and other federal agencies (and certainly industry) have undoubtedly felt that NCEA has been intransigent and unwilling to accept the uncertainty of the science of risk assessment and the possibility that there is more than one right result.

The answer may be that a science office like NCEA should not be expected to make the final decision on an assessment that has significant impact on other federal agencies and private industry. Perhaps NCEA should have the principal science input, but the decision must be made by a designated federal entity whose charge is to fully consider the risk assessment as

well as the risk management considerations in making a decision. Such an approach would be driven by the inherent interagency conflict between NCEA and the regulated federal agencies. But shouldn't industry have the same rights and opportunities as the regulated agencies? Or put another way, shouldn't industry be expected to fund research that could improve the decisionmaking process? And would a federal coordinating entity be able to effectively manage industry input?

This leads to the thought of establishing a non-profit independent organization that could provide the necessary scientific credibility and coordination skills. An example exists: the Health Effects Institute, a nonprofit corporation chartered in 1980 as an independent research organization to provide high-quality, impartial, and relevant science on the health effects of air pollution. Typically, HEI receives half of its core funds from EPA and half from the worldwide motor vehicle industry. Other public and private organizations periodically support special projects or certain research programs. HEI is governed by an independent board of directors consisting of leaders in science and policy that are committed to the public-private partnership that is central to HEI.

Regardless of who manages IRIS, the program's quality and timeliness can be enhanced by the early involvement of stakeholders (particularly from key customers, such as state agencies) and from parties that can and should contribute funding for research (including affected federal agencies, industry and NGOs). With increased stakeholder involvement comes the need for increased transparency. Thus, EPA should routinely convene workshops in which scientific information and interpretations are introduced by stakeholders and a record of the science input is created. Such a process is routinely employed by NAS committees, wherein all interested parties are given the opportunity, in a public setting, to offer information and scientific interpretations for consideration by the committee as it begins its work.

The process of risk assessment has been instrumental to EPA, other federal and state agencies, industry, the academic community, and others in evaluating public-health and environmental concerns. IRIS has provided an essential contribution to this success. However, according to the committee that recently issued the National Research Council report *Science and Decisions: Advancing Risk Assessment*, risk assessment is at a crossroads, and its credibility is being challenged. The committee states, "Because it provides a primary scientific rationale for informing regulations that will have national and global impact, risk assessment is subject to considerable scientific, political, and public scrutiny." Certainly IRIS is facing a similar level of scrutiny; in fact, criticism of IRIS is representative of the broader issue of the role of risk assessment. One of the recommendations of the new NRC risk report is for EPA to "establish a formal process for stakeholder involvement in the framework for risk-based decision-making with time limits to ensure that decisionmaking schedules are met." The recommendation applies perfectly to IRIS; stakeholder involvement is essential, and time limits are critical if IRIS is to meet expectations. •

Meeting the challenge requires interagency coordination, not normally the realm of a science office