Integrated Risk Information System Program

Summary Report from November 2012 Public Stakeholder Meeting

U.S. Environmental Protection Agency

INTEGRATED RISK INFORMATION SYSTEM (IRIS) PROGRAM

PUBLIC STAKEHOLDER MEETING

NOVEMBER 13, 2012

Executive Summary

On November, 13, 2012, the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Program convened its first public stakeholder meeting to discuss the IRIS Program. The meeting was held in person at EPA's Potomac Yards facility in Arlington, VA, and by webinar/teleconference. More than 450 individuals, from a wide variety of stakeholder organizations from multiple sectors, registered to participate in the meeting. Stakeholders provided comments on several aspects of the IRIS Program, including communication, transparency, throughput, trust, stakeholder engagement, and others.

The November 13, 2012, IRIS public stakeholder meeting was intended to be the beginning of an ongoing dialogue with stakeholders. The IRIS Program is currently considering ways to engage stakeholders in the future – both about the IRIS Program in general and about specific IRIS health assessments. To enhance communication with stakeholders, the IRIS Program created a new IRIS listserv[1] to regularly update stakeholders about news and events from the IRIS Program. Announcements will also be made in EPA's public Human Health Risk Assessment research program monthly bulletin.

EPA's IRIS Program is committed to engaging stakeholders in a meaningful way, and the Program welcomes comments and input from all stakeholders.

[1] To be added to the IRIS listserv, please sign up at:
https://public.govdelivery.com/accounts/USAEPA/subscriber/new?topic_id=USAEPA_517

Introduction

EPA's Integrated Risk Information System (IRIS) Program is committed to engaging stakeholders, ensuring transparency, and using the best available science in IRIS assessments. IRIS is a human health assessment program that evaluates quantitative and qualitative information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS Program, EPA provides high quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic noncancer health effects; oral slope factors and inhalation unit risks for cancer health effects; and information about a chemical's cancer causing potential. When IRIS toxicity values are combined with specific exposure information, government and private entities can use IRIS to help characterize the public health risks of chemical substances in various situations, supporting risk management decisions to protect public health. Environmental protection decisions, which are based in part on IRIS assessments, can have potentially large impacts on the environment, human health, and the economy. Engaging stakeholders can help facilitate the development of IRIS assessments and promote public discussion of key scientific issues. Therefore, stakeholder and scientific engagement is an important part of supporting the best decisions possible.

History of Stakeholder Engagement in IRIS

The IRIS Program considers a stakeholder to be any individual or group that participates in, has an impact on, or could be affected by products produced by the IRIS Program. Public and stakeholder engagement has always been an important part of the IRIS assessment development process. The May 2009 IRIS process provides for public and stakeholder nomination of chemicals for assessment; a public listening session for each draft assessment; public review and comment of draft documents; a public peer review process; and two opportunities for review and comment on draft assessments by other EPA scientists and other Federal agencies and White House offices. The IRIS Program has recently reaffirmed its commitment to proactive stakeholder engagement and is considering ways to further engage stakeholders in the IRIS Program in general and when developing IRIS health assessments.

November 13, 2012, Public Stakeholder Meeting

On November 13, 2012, EPA's IRIS Program convened its first public stakeholder meeting to discuss the IRIS Program in general. The meeting was intended to begin a series of dialogues between the IRIS Program and stakeholders. The goals of the meeting were to:

1. Proactively engage stakeholders in the IRIS process;
2. Listen to views and needs of IRIS users in an open and respectful environment;
3. Facilitate improvements to IRIS; and
4. Initiate an ongoing dialogue between the IRIS Program and stakeholders.

This public stakeholder meeting took place on November 13, 2012, in EPA's Potomac Yards facility. The meeting was also available by webinar/teleconference. This report provides a brief summary of the public stakeholder meeting.

Meeting Agenda

The meeting agenda was designed to provide brief structured presentations and remarks from EPA officials and individuals from several different stakeholder organizations. This was followed by a moderated open forum session designed to elicit comments and feedback from stakeholders participating in person and by webinar/teleconference. Dr. Glenn Paulson, EPA's Science Advisor, provided welcoming remarks, and Dr. Kenneth Olden, the Director of EPA's National Center for Environmental Assessment (NCEA) – home of the IRIS Program – shared his vision for the future of the IRIS Program. Dr. Vincent Cogliano, the Acting Director of the IRIS Program, provided an overview of some recent improvements to the IRIS Program and IRIS assessments. These presentations were followed by a panel session during which stakeholders provided their views on the IRIS Program. Panelists included:

1. Mary Fox, MPH, PhD, Assistant Professor in the Department of Health Policy and Management at Johns Hopkins Bloomberg School of Public Health
2. David Fischer, MPH, JD, Senior Director in the Chemical Products and Technology Division at the American Chemistry Council
3. Gloria Post, PhD, DABT, Research Scientist at the New Jersey Department of Environmental Protection
4. Richard Denison, PhD, Senior Scientist at Environmental Defense Fund
5. Chuck Elkins, JD, President of Chuck Elkins & Associates
6. Linda Birnbaum, PhD, DABT, ATS, Director of the National Institute of Environmental Health Sciences and the National Toxicology Program

Copies of speaker and panelist prepared presentations or remarks can be found at the IRIS public meeting website, http://www.epa.gov/iris/publicmeeting/stakeholders-kickoff/index.htm.

Meeting Attendees

A total of 477 individuals registered to attend the meeting; 95 registered to attend in person and the remainder registered to attend by webinar/teleconference. While approximately 100 of the attendees were EPA employees, more than 75% were from outside of EPA. Of the EPA employees attending, about one-third was staff from EPA's program and regional offices – key stakeholders of the IRIS Program. The rest were from EPA's National Center for Environmental Assessment (NCEA), home of the IRIS Program, or other parts of EPA's Office of Research and Development. Of those attendees who were not EPA employees, a wide variety of stakeholder organizations from multiple sectors (e.g., industry, academia, non-profit organizations, etc.) were represented. Figure 1 shows the breakdown of attendees from within and outside of EPA. Figure 2 shows the diversity of stakeholder organizations represented at the meeting.

Figure 1. *Breakdown of attendees from within and outside of EPA*

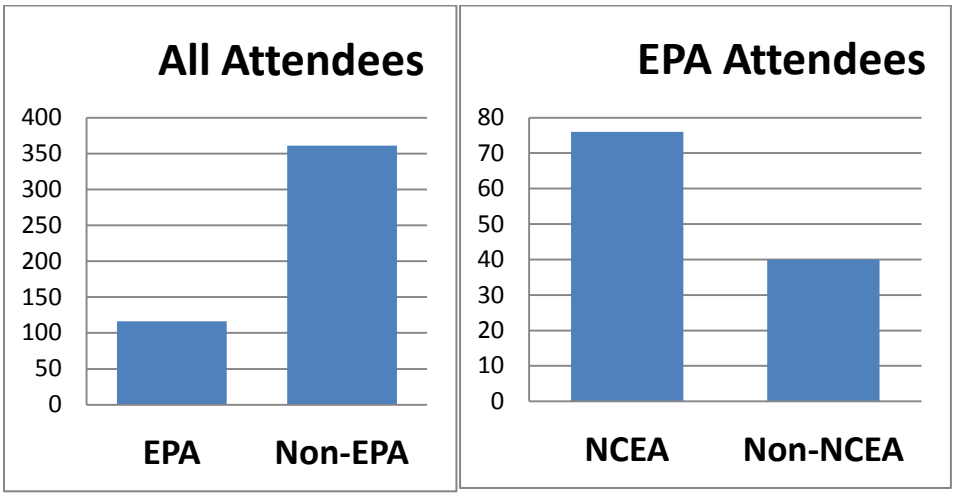
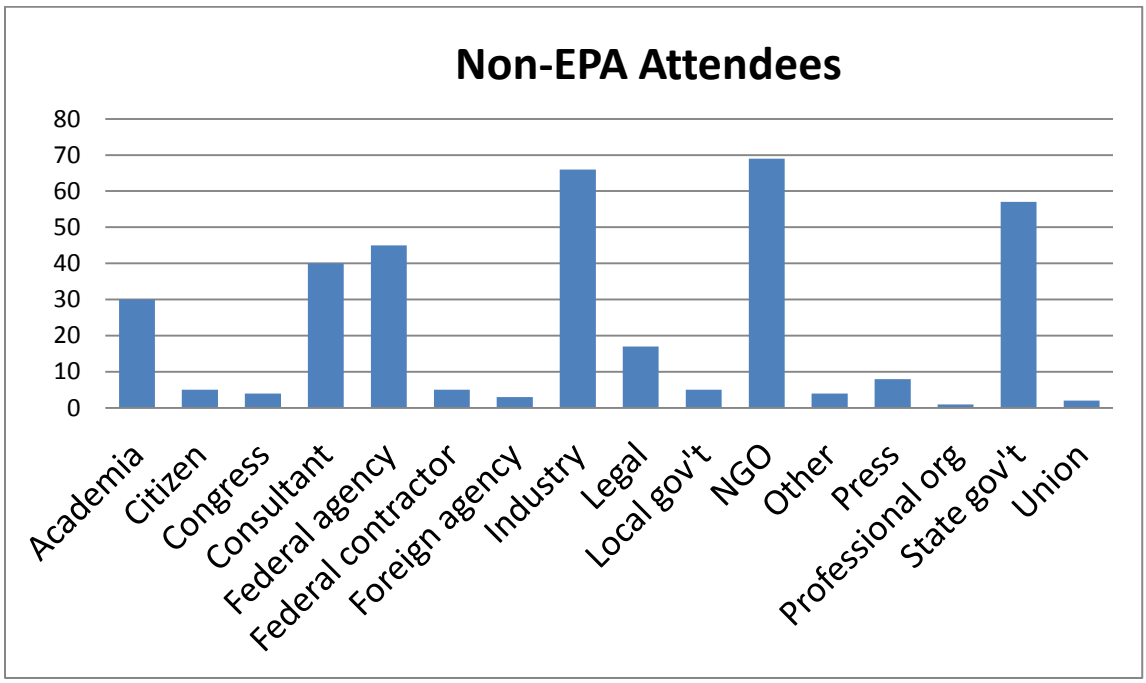


Figure 2. *Stakeholder organizations represented at the meeting, by sector*



Overview of Comments Received During the IRIS Public Stakeholder Meeting

The IRIS Program heard from dozens of stakeholders during the open forum portion of the public meeting. While a wide variety of comments were made, in general they could be grouped into approximately a dozen categories. Table 1 provides some additional information on each category of comment.

Table 1. *Categories of Stakeholder Comments and Additional Details*

Category	General Description and Additional Details
Chemical Specific Comments	Several commenters asked questions about specific chemicals. For example, one stakeholder noted that the dioxin assessment was delayed by multiple reviews and industry concerns.
Conflict of Interest Issues	Some stakeholders noted their concern about the definition of "conflict of interest." Other stakeholders suggested that one's affiliation can be a bias but should not necessarily be considered a conflict of interest.
Communication	Some stakeholders commented on communication issues. For example, some suggested that EPA needs to be more effective in alerting the public about events. Others commented that EPA should use plain language instead of relying on jargon.
Objectivity	Several stakeholders commented about EPA's objectivity. For example, stakeholders asked how IRIS will ensure objectivity in evaluating studies and making decisions. Some suggested that chemical manufacturers should not be considered public participants in the same way that health agencies are.
Peer Review	Stakeholders made a variety of comments about peer review. For example, it was suggested that EPA should include experts with sufficient experience in risk assessment on peer review panels. Others suggested that the public should have more time to interact at peer review meetings. Some said that the IRIS Program could ask EPA's Science Advisory Board (SAB) staff to look at how EPA responded to peer review comments when revising assessments. Others said there is not enough time for the public to provide comments and for EPA to evaluate merit of the comments and conduct additional analyses.
Process	There were multiple comments about the IRIS process. For example, some commented that EPA should develop and adopt stopping rules to end delayed processes. Stakeholders also suggested that EPA should develop and adopt starting rules for stronger, upfront public engagement. Other wanted to know when the public will see assessments that have gone through peer review, and they wanted to know how these assessments will look.
Science Issues	Several stakeholders commented on specific science issues (not captured elsewhere in this table). For example, some commented on the use of default factors and suggested this weakens conclusions. Some noted that the metrics used are "old school" and asked if EPA has considered updating metrics to compare chemicals using alternatives assessment. Others asked about increasing the role of biomonitoring data in IRIS assessments.
Stakeholder Engagement	Several commented on the topic of stakeholder engagement. Some asked that EPA keep a record of stakeholder meetings so remote participants can read and better understand the issues. Others said that the IRIS Program needs to acknowledge the structural difference between the regulated community and the exposed public. Others said that EPA needs to level the playing field for different stakeholders. Some suggested that the IRIS Program should identify communities vulnerable to the chemicals undergoing assessment and reach out to them. Others said that better engagement will come from documents that are more clear and concise and where there are fewer, but strategically timed, points of interaction and greater participation through webinars. Some asked EPA to consider holding several smaller local and state public engagement sessions about IRIS.
Systematic Review	The topic of systematic review was mentioned several times by stakeholders. It was noted that systematic review is good and will solve a lot of problems, but EPA will still need scientific judgment. Some wanted to know how EPA plans to address data limitations when synthesizing data and developing toxicity values. Others asked about study quality considerations and data gaps.
Throughput	Throughput within the IRIS Program was a frequent theme of stakeholder comments. Some suggested that not all IRIS assessments are created equal and that certain chemicals move faster and more controversial ones take longer. Others said greater transparency around deadlines is needed. One stakeholder suggested that EPA pilot a program where industry develops the assessment. Some commented that doing systematic review earlier in the process and engaging stakeholders to provide input on missing studies could help fill data gaps. Some suggested that a default approach could allow states to decide if they need to wait for new information from an updated IRIS assessment or not. Others asked how EPA is planning to use data from the REACH program. Others said lack of resources is an issue and suggested that EPA consider if only a robust summary on a particular substance might meet stakeholder needs. One stakeholder said transparency cannot be a code word for endless delays.
Transparency	Several individuals commented about transparency in the IRIS Program. Some suggested that minutes of meetings with stakeholders and documents submitted during these meetings should be publicly available.
Trust	Several stakeholders commented on the issue of trust. Some commented that studies conducted by industry must be considered for IRIS assessments. Others said that until we see evidence that industry is serious about addressing risk of chemicals rather than fighting EPA action, lack of trust remains an issue. Others commented that the IRIS Program's past policies of not engaging with industry is part of the issue of lack of trust.
Webinar	Several suggested that IRIS develop a better process for providing more equal comment time to in-room and webinar participants.
Weight of Evidence	Several stakeholders wanted to know when they can expect to see criteria for weight of evidence and implementation of systematic review in the IRIS Program.

Summary of Stakeholder Feedback from Webinar Polls

Several webinar polls were conducted during the open forum session of the IRIS public stakeholder meeting. These polls were conducted to help with outreach and communication efforts for future public engagement in the IRIS Program. Figure 3 shows the results of a webinar poll asking participants how they heard about the IRIS public stakeholder meeting; Figure 4 shows the results of a poll asking participants how they would like to engage with the IRIS Program in the future; and Figure 5 shows webinar poll results in response to a question about whether or not participants' questions were addressed in this meeting.

Figure 3. *Webinar poll results for "How did you hear about this meeting?"*

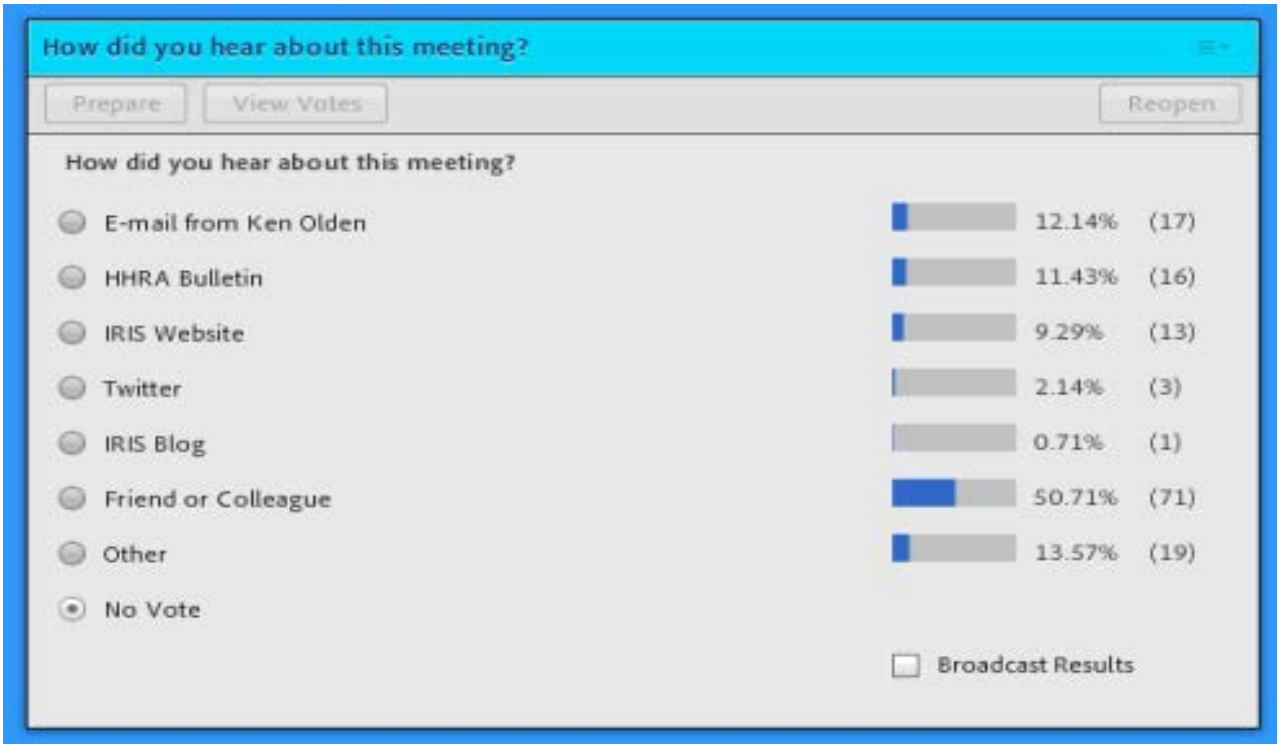


Figure 4. *Webinar poll results for "How would you like IRIS to engage the public more?"*

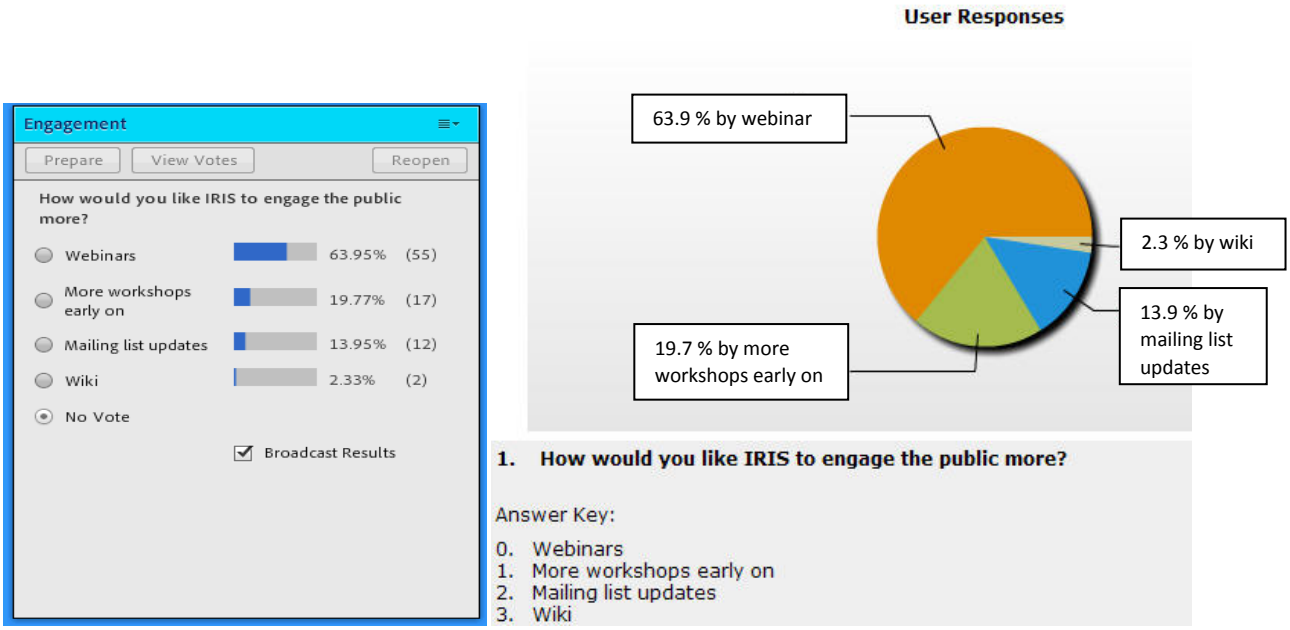
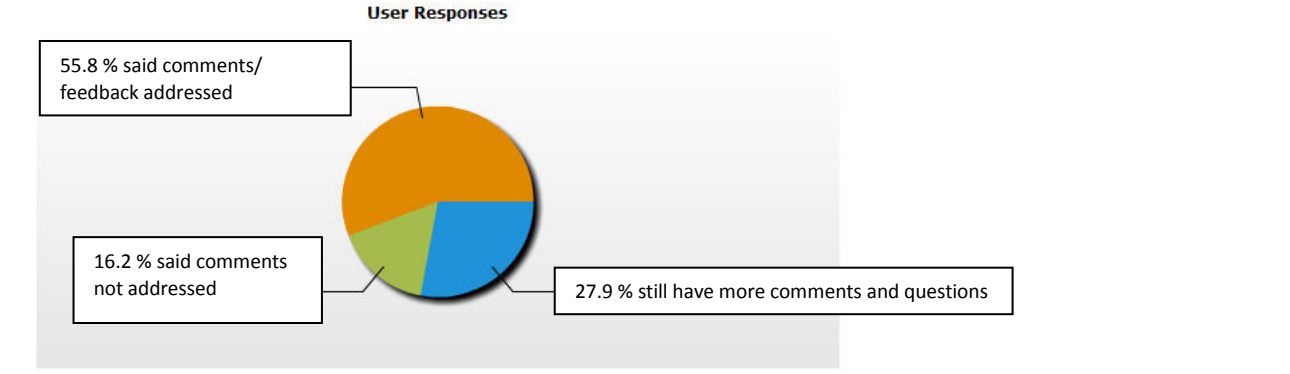


Figure 5. *Webinar poll results for "Did this meeting address your comments….?"*



3. Did this meeting ….

Answer Key:

0. Address your comments/feedback
1. Not address your comments
2. You still have more comments and questions

User Responses

Choice	Correct Answer	# Selected	% Selected
0	✗	24	55.8%
1	✗	7	16.3%
2	✗	12	27.9%
	Total:	**43**	**100%**

Next Steps

The November 13, 2012, IRIS public stakeholder meeting was intended to be the beginning of an ongoing dialogue with stakeholders. The IRIS Program is currently considering ways to engage stakeholders in the future – both about the IRIS Program in general and about specific IRIS health assessments. Additionally, because of the overwhelming respond to this meeting, the IRIS Program is planning additional town hall and stakeholder meetings. To enhance communication with stakeholders, the IRIS Program added all of the November 13 attendees to the Human Health Risk Assessment research program monthly bulletin[2], which will include updates about activities in the IRIS Program. Additionally, based on feedback from stakeholders on November 13, the IRIS Program created a new IRIS listserv[3]. EPA will use this listserv to regularly update stakeholders about opportunities to engage in the IRIS Program in general; opportunities to engage with the IRIS Program about specific IRIS health assessments; the availability of newly released draft and final assessments; general updates about the IRIS Program; and other news and events. Additionally, the IRIS Program plans to use the IRIS website (www.epa.gov/iris) more aggressively as a vehicle for communicating with the public.

EPA's IRIS Program is committed to engaging stakeholders in a meaningful way, and the Program welcomes comments and input from all stakeholders.

[2] To be added to the distribution list for the HHRA monthly bulletin, please sign up at: https://public.govdelivery.com/accounts/USAEPA/subscriber/new?topic_id=USAEPAORD_8

[3] To be added to the IRIS listserv, please sign up at: https://public.govdelivery.com/accounts/USAEPA/subscriber/new?topic_id=USAEPA_517