IRIS for Environmental Public Health

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IRIS Public Stakeholder Meeting November 13, 2012





Thoughts on the IRIS Process

Streamlining

Transparency

Timely completion and staying up-to-date

How I use the IRIS database

Community environment health

- Evaluation and development of new risk assessment methods
 - Cumulative risk: multiple chemicals and multiple endpoints
- Value-added: Summary and synthesis of available studies

Figure 2. May 2009 IRIS Assessment Development Process³

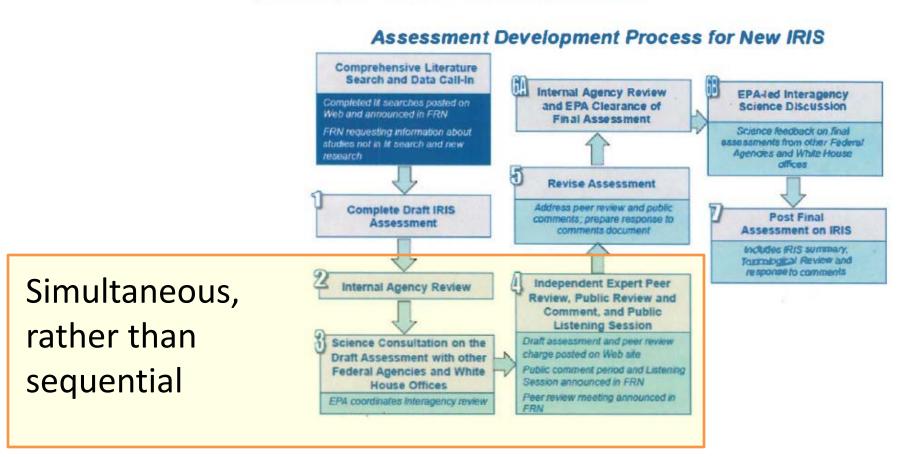


Figure Source: EPA's Integrated Risk Information System Program Progress Report and Report to Congress

Figure 2. May 2009 IRIS Assessment Development Process³

Assessment Development Process for New IRIS Comprehensive Literature Search and Data Call-in •Value added? Internal Agency Review EPA-led Interagency Completed It searches posted on and EPA Clearance of Science Discussion Web and announced in FRN Final Assessment Increase Science feedback on final FRN requesting information about assessments from other Federal studies not in lit search and new Agencies and White House transparency offices Revise Assessment Address peer review and public Complete Draft IRIS Post Final comments; prepare response to Assessment comments document Assessment on IRIS broudes IRIS summary, Torringgeal Review and re sponse to comments Independent Expert Peer Internal Agency Review Review, Public Review and Comment, and Public Listening Session Draft assessment and peer review Science Consultation on the charge posted on Web site Draft Assessment with other Public comment period and Listening Federal Agencies and White Session announced in FRN **House Offices** Peer review meeting announced in EPA coordinates Interagency review

Figure Source: EPA's Integrated Risk Information System Program Progress Report and Report to Congress

Timely AND Up-to-date

- Toxicity Evaluation Program Comparison Project Topics
 - Transparency
 - Treatment of confidential business information
 - Peer review/public comment
 - Process and Presentation
 - Chemical selection/coverage
 - Accessibility/ease of location
 - Rigor
 - Data sufficiency criteria
 - Methods for development of toxicity values
 - Updating of toxicity assessments

Programs and Mandates

	Mandate	Source of Authority
IRIS	Assess toxicity of substances relevant to EPA mandates	Various*
ОРР	Review and approve applications for new pesticides to ensure safety and efficacy	FIFRA, 7 U.S.C. §136a
CDER	Review and approve applications for new human drugs to ensure safety and efficacy	FFDCA, 21 U.S.C. §355
CVM	Review and approve applications for new animal drugs to ensure safety and efficacy	FFDCA, 21 U.S.C. §360b
ATSDR	Assess toxicity of substances commonly found at Superfund sites	CERCLA, 42 U.S.C. §9604

^{*}Unlike other programs, IRIS was not created by statute

Emerging Themes

- Variations in transparency and public participation
 - Opportunities for public involvement
 - Use and treatment of CBI

- Rigor and timeliness
 - Reviews
 - Updates

Striking the balance

- Science never stops and neither do the community questions, the spills and releases, the hurricanes...
- Timely assessments are needed to do the work and make the decisions "on the ground"
- Regular updates are needed
 - Example: ATSDR's Toxicological Profiles process