



The New, Enhanced IRIS



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Overview

About IRIS

Objectives and features of the Enhanced IRIS

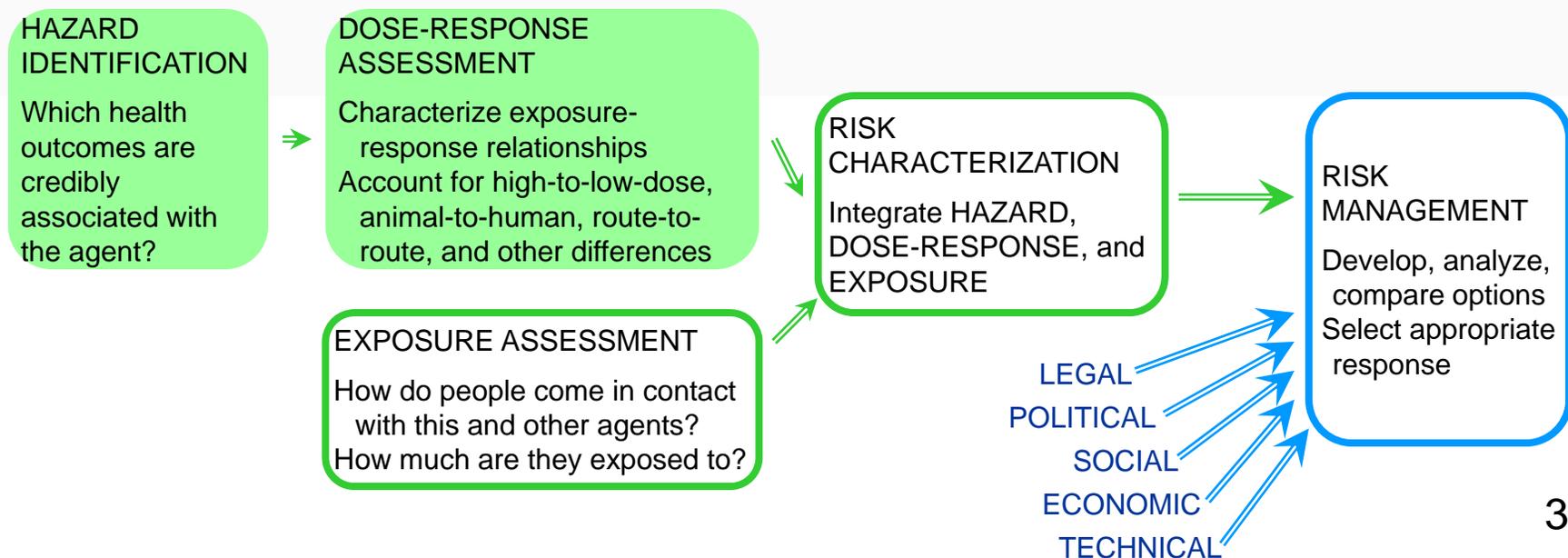
NRC review of the Enhanced IRIS



About IRIS

IRIS assessments critically review the publicly-available peer-reviewed scientific studies to

- Identify adverse health outcomes
- Characterize exposure-response relationships





Objectives of the Enhanced IRIS

To improve the fundamental science

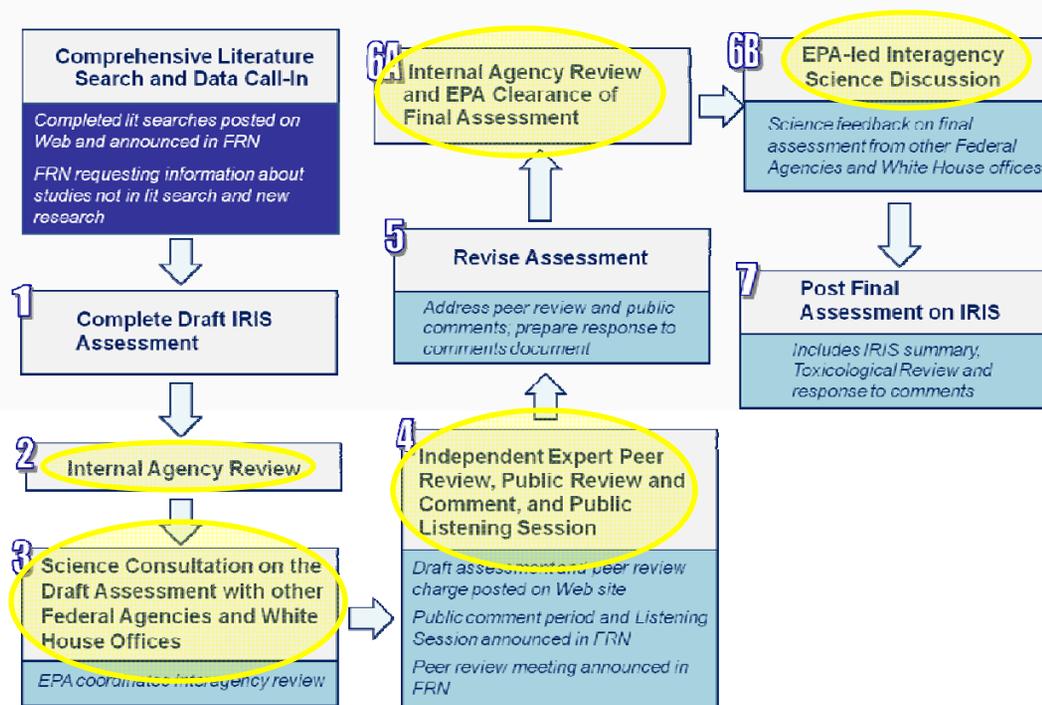
- by implementing principles of systematic review
- by strengthening peer review

To increase productivity to better meet stakeholder needs

To increase transparency so issues are identified and debated early

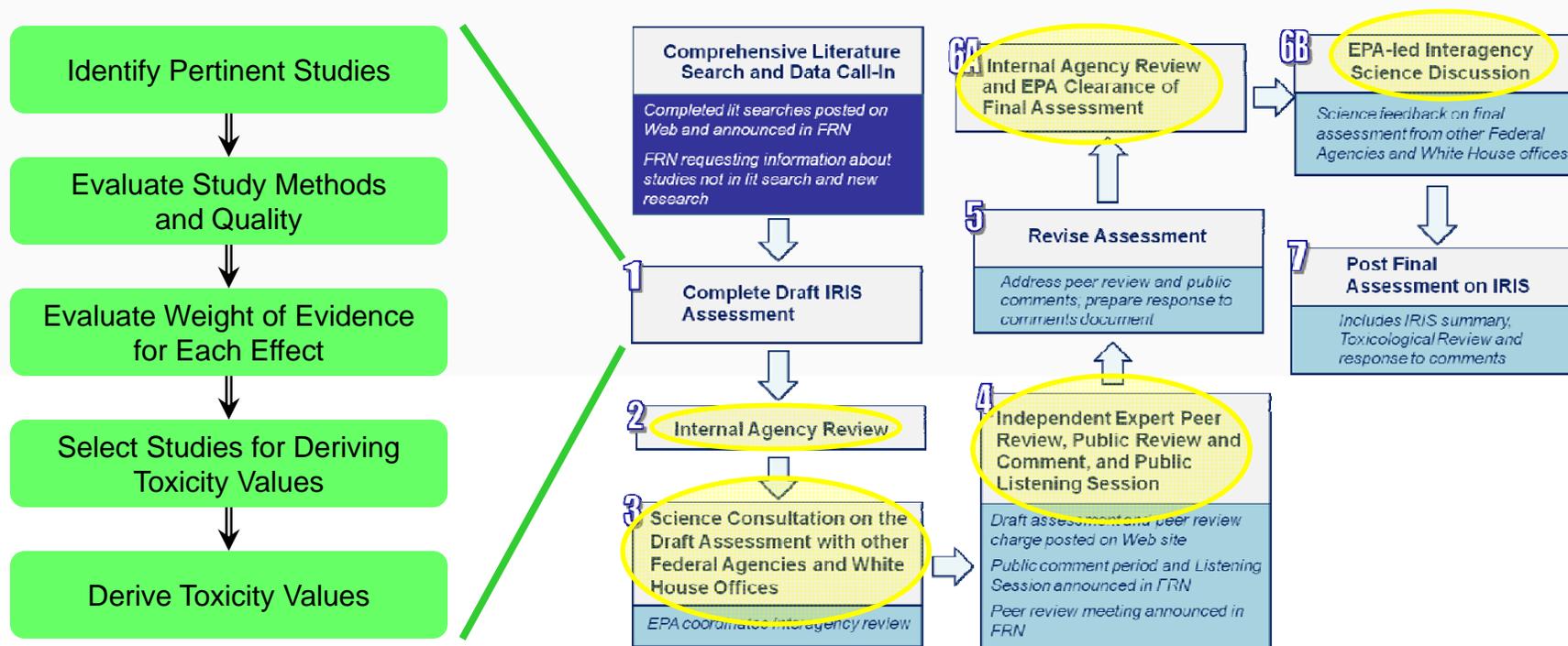


IRIS Means Multi-level Comment and Peer Review



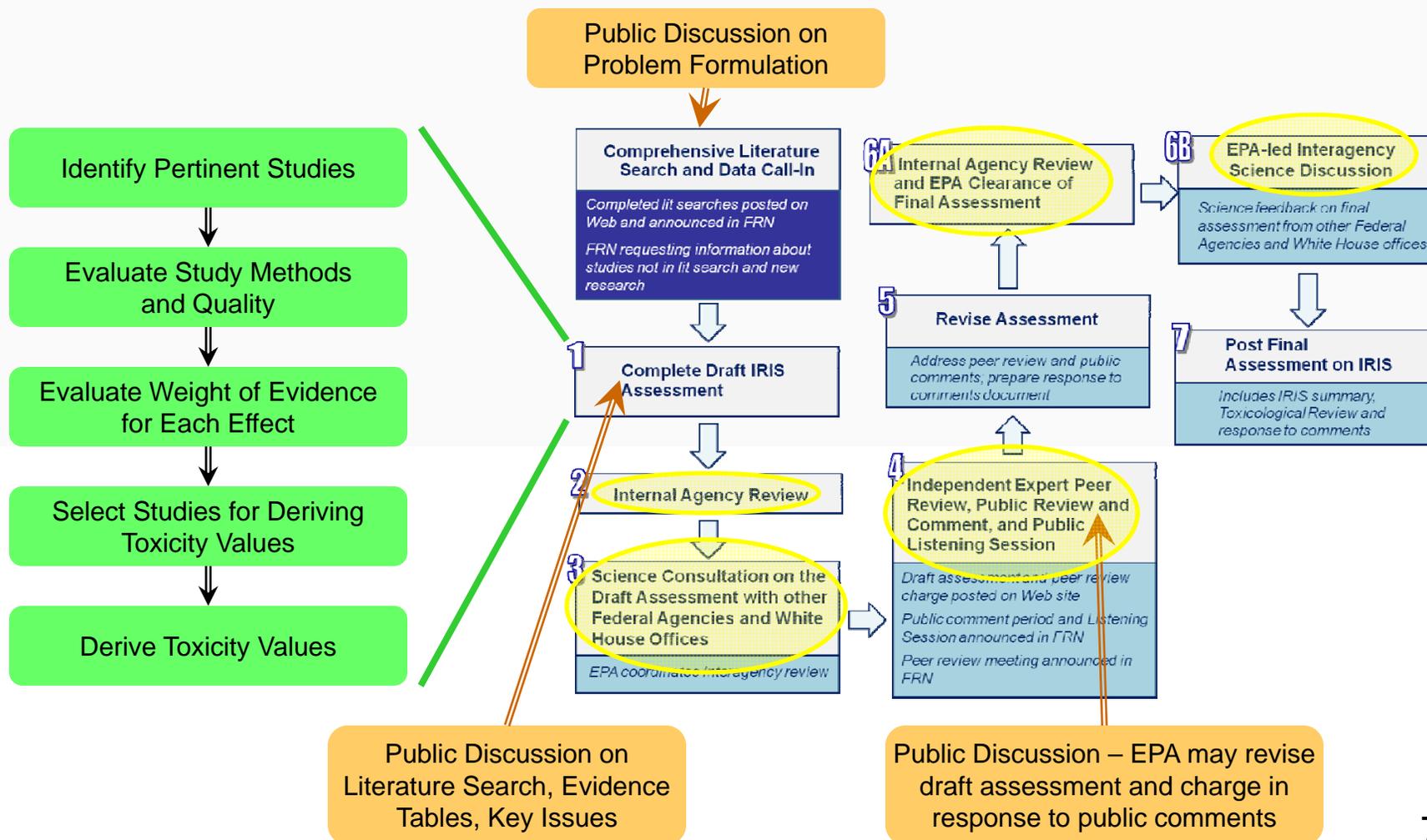


The Enhanced IRIS Means Systematic Review





The Enhanced IRIS Means Public Engagement



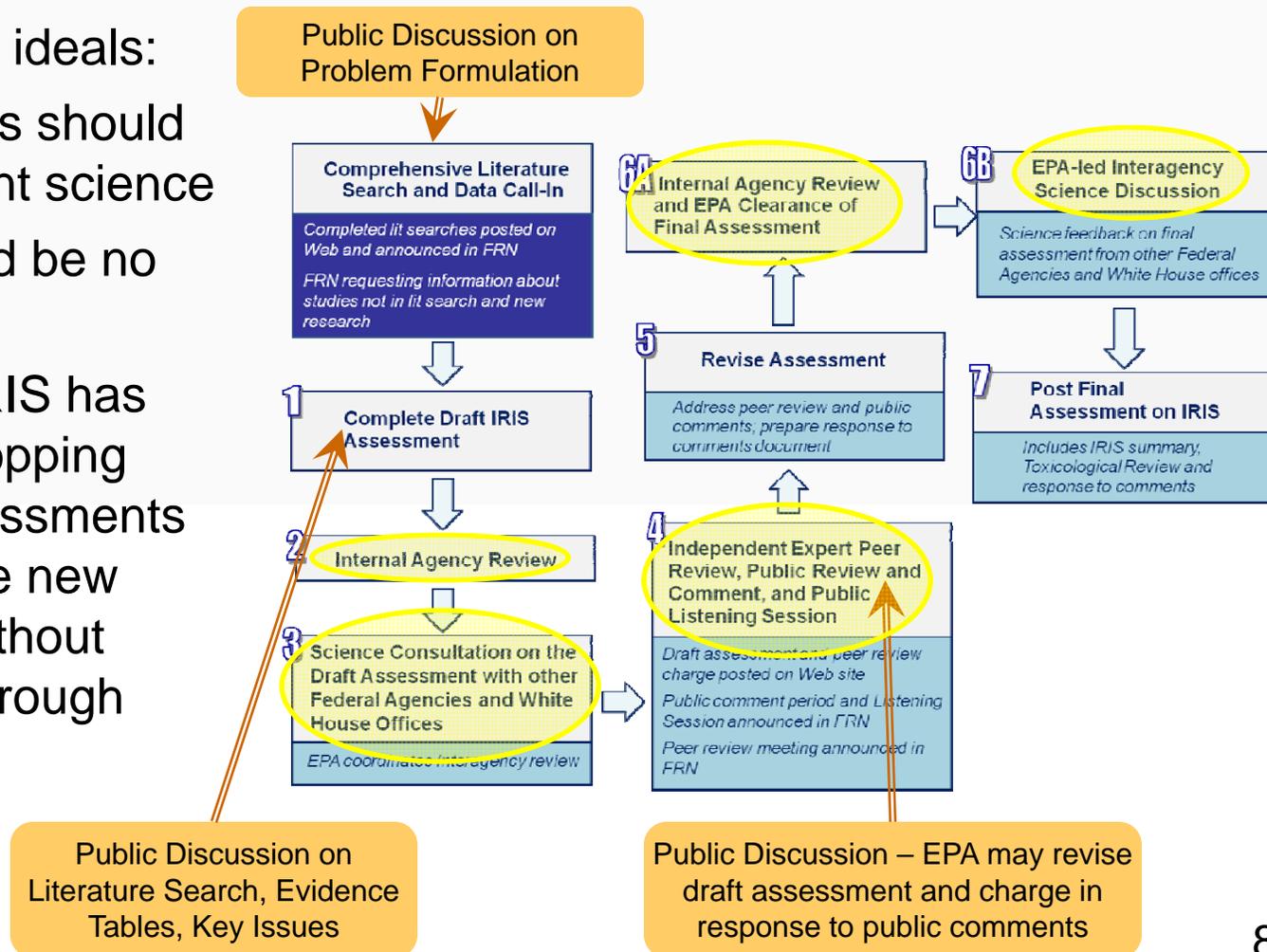


The Enhanced IRIS Means “Stopping Rules” to Bring Assessments to Completion

Two conflicting ideals:

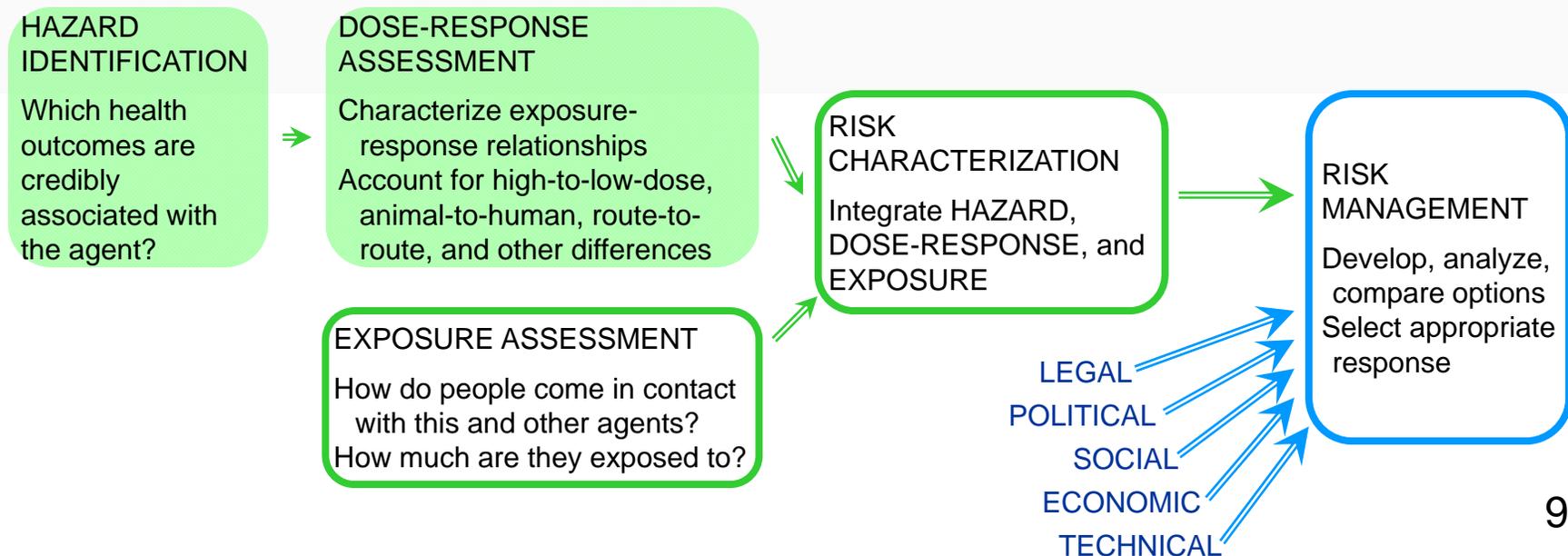
- Assessments should reflect current science
- There should be no undue delay

Accordingly, IRIS has developed “Stopping Rules” so assessments can incorporate new publications without cycling back through earlier steps





The Enhanced IRIS Means New Scientific Content





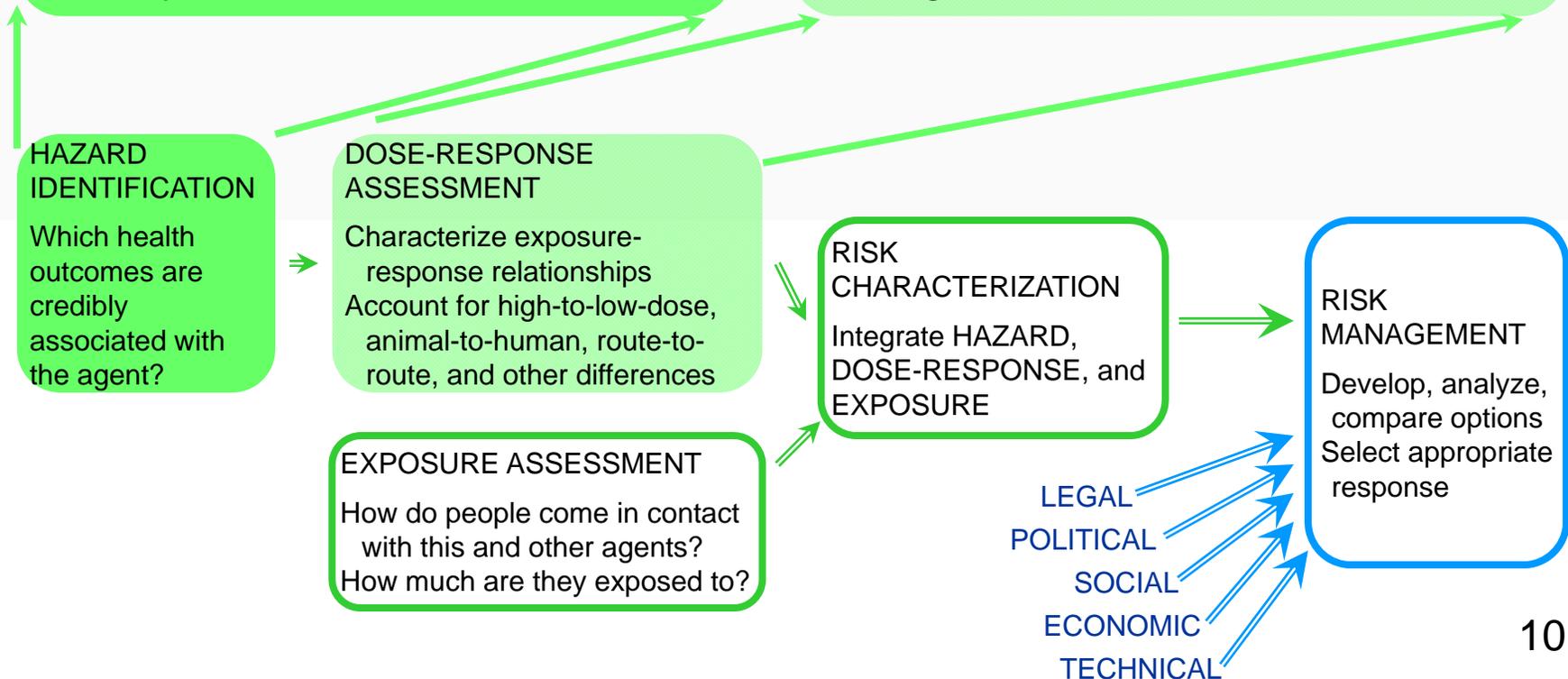
The Enhanced IRIS Means New Scientific Content

The HAZARD IDENTIFICATION section identifies all credible health hazards

- A workshop in Aug 2013 explored evidence-integration frameworks
- Another workshop in Oct 2014 will address this topic

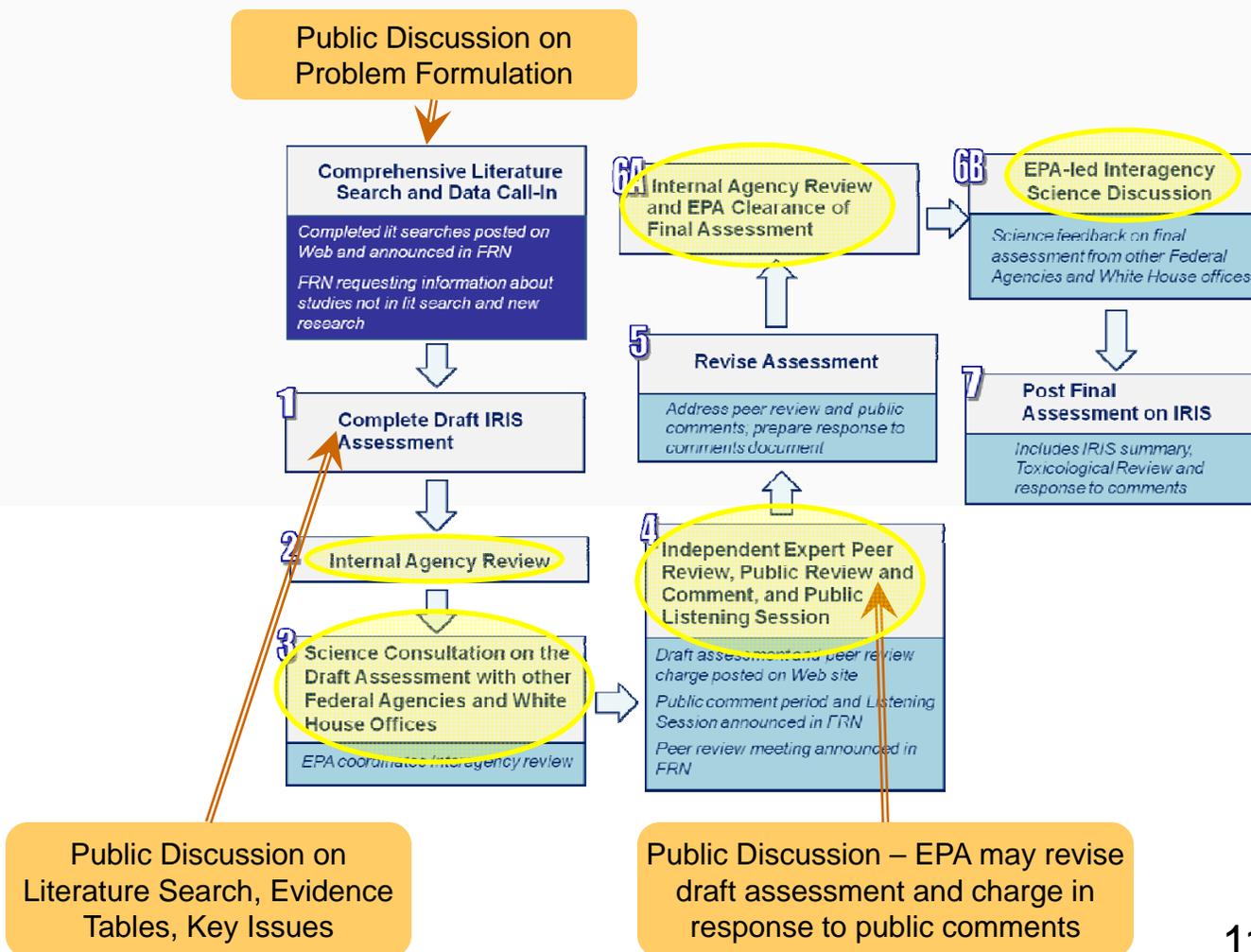
The DOSE-RESPONSE ASSESSMENT explores toxicity values for each credible health hazard

- This will facilitate subsequent cumulative risk assessments that consider the combined effect of multiple agents acting at a common site or through common mechanisms



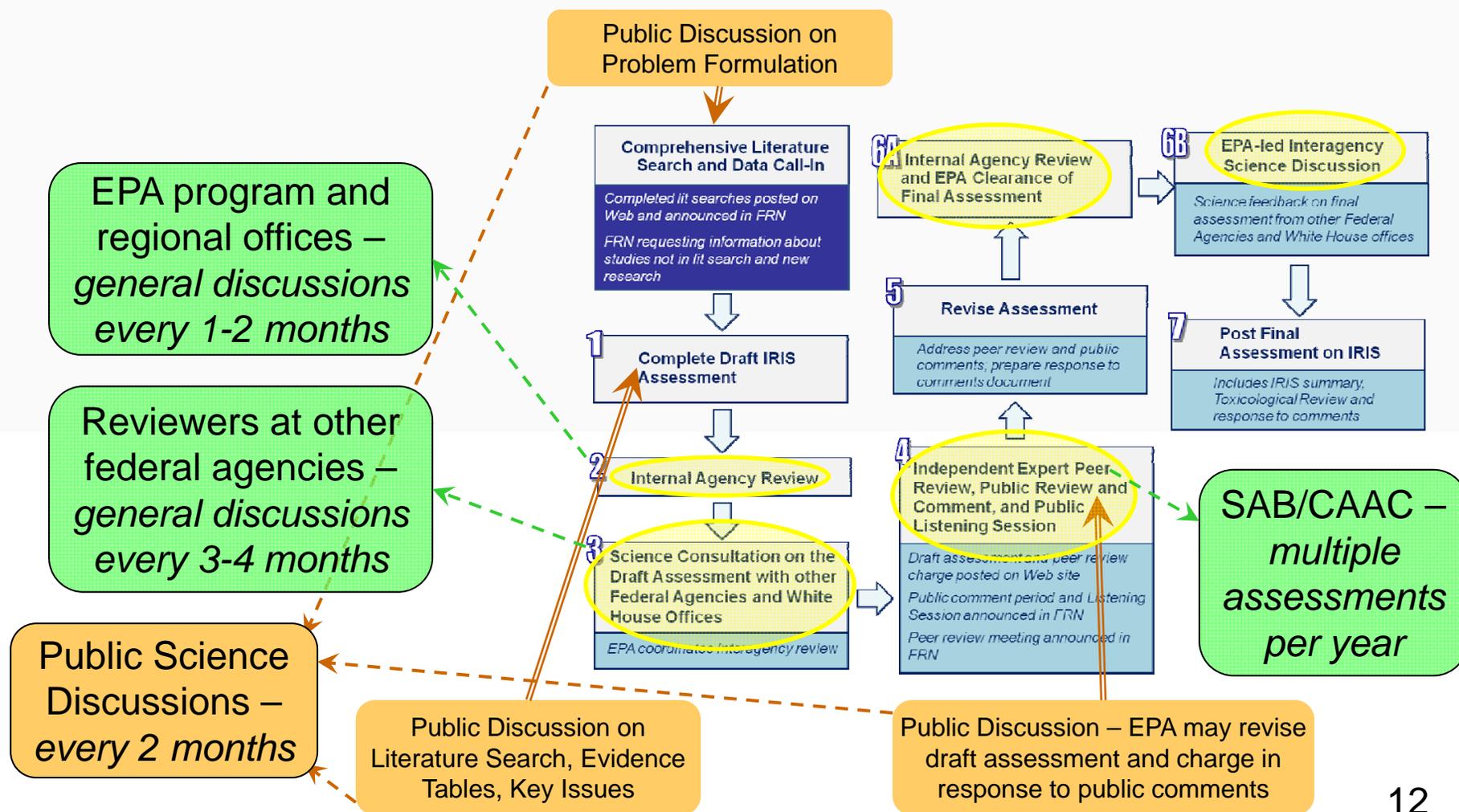


The Enhanced IRIS Means Frequent Discussions with Multiple Stakeholder Groups





The Enhanced IRIS Means Frequent Discussions with Multiple Stakeholder Groups





The Enhanced IRIS Means Improved Peer Review

The SAB *Chemical Assessment Advisory Committee* should provide

- Consensus recommendations
- Consistent recommendations across assessments
- Scientific advice on cross-cutting issues

Frequent reviews by a continuing committee will provide regular feedback on progress and implementation of the NRC's recommendations



The Enhanced IRIS Was Recently Reviewed by the National Research Council

“Overall, the committee finds that substantial improvements in the IRIS process have been made, and it is clear that EPA has embraced and is acting on the recommendations in the NRC formaldehyde report. The NRC formaldehyde committee recognized that its suggested changes would take several years and an extensive effort by EPA staff to implement. Substantial progress, however, has been made in a short time, and the present committee’s recommendations should be seen as building on the progress that EPA has already made.” [NRC 2014, p 9]

“ . . . the IRIS program has moved forward steadily in planning for and implementing changes in each element of the assessment process. The committee is confident that there is an institutional commitment to completing the revisions of the process even as the program continues through the current transition phase and is closely watched by both stakeholders and Congress.” [p 129]



The NRC Considered Assessments of Ammonia, TMBs, and Benzo[a]pyrene (released later)

“In general, EPA has been responsive to the recommendations from the NRC formaldehyde report. As discussed in Chapter 1, the timing of the publication of the IOM standards was such that EPA could not have been expected to have incorporated the standards into its assessments to date. Nevertheless, comparison of statements made in the draft preamble and draft handbook with the 2011 IOM standards demonstrates that EPA has not only responded to the recommendations made in the NRC formaldehyde report but is well on the way to meeting the general systematic review standards for identifying and assessing evidence.

“Thus, [Table 4-1] is useful primarily for pointing out where further standardization might be helpful, not as a test and demonstration of whether IOM standards have been met. . . .

“In addition, the subset of documents reflected in the table does not represent all the materials available. Because EPA’s transition to a systematic process for reviewing the evidence is evolving, . . . some elements that appear undeveloped in Table 4-1 have been addressed in materials released more recently.” [p 52]



Timeline of the NRC Review and the Trimethylbenzene Assessment

- Apr 2011: NRC releases *Formaldehyde* report
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- June 2012: IRIS releases draft TMB assessment for public comment and peer review
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- July 2013: EPA announces Enhancements to IRIS
- Aug 2013: IRIS revises TMB assessment to address public comments, releases it for peer review
- Aug 2013: IRIS releases draft Benzo[a]pyrene assessment for public comment
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- May 2014: NRC releases its review of the IRIS process
- June 2014: SAB/CAAC meets to peer-review the draft TMB assessment



The New, Enhanced IRIS

Improved science	<ul style="list-style-type: none">- Systematic review- Toxicity values for all credible health hazards- Strengthened peer review
Increased transparency	<ul style="list-style-type: none">- Clear, concise, systematic assessments- Opportunities for public engagement- Continuing relationships with stakeholders
Increased productivity	<i>We must make the Enhanced IRIS work by completing more assessments in less time</i>

IRIS will continue to evolve as we receive public input and peer review advice – Thank you!