Report on Carcinogens Concepts

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NTP Board of Scientific Counselors Meeting
April 11, 2016
The Report on Carcinogens (RoC) is a science-based, public-health document

- Congressional mandate directs the Secretary, Health and Human Services (HHS) to publish a list of carcinogens
- NTP prepares the RoC for the Secretary, HHS using a four-part process and established listing criteria
  - Scientific input
  - Opportunity for public comments
  - Peer review of scientific information

- Select Candidate Substances
  - Concept document
- Evaluate cancer hazards
  - Protocol
  - RoC Monograph
    - Cancer hazard evaluation component
  - Substance profile
- Peer review draft monographs
  - Compilation of substance profiles

Anyone can nominate a substance to the RoC

On an ongoing basis the NTP requests information on nominated substances

<table>
<thead>
<tr>
<th>Substance</th>
<th>FR notice</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>H. pylori</td>
<td>Jan 2012</td>
<td>0</td>
</tr>
<tr>
<td>Di-tri-HAAs</td>
<td>Oct 2015</td>
<td>0</td>
</tr>
</tbody>
</table>

The NTP uses this information and input from its interagency partners to identify substances to propose for formal review

Living list of nominations

BSC = Board of Scientific Counselors; FR = Federal register; HAAs = haloacetic acids
NTP conducts scoping and problem formulation activities

- Scoping
- Problem Formulation
- Literature Searches
- Select substance/research question
- Refine
- Protocol Development

Iterative process

Scientific and public input
- Technical advisors, webinars, public forums
NTP is proposing two substances for review

Draft concept is a planning and communication tool

- Background information
  - Human exposure
  - Concerns for carcinogenicity
  - Key questions or relevant issues
  - Scoping/problem formulation activities
- Rationale and public health significance
- Objective (or literature-based research question)
- Proposed approach for monograph development

BSC = Board of Scientific Counselors; FR = Federal register; HAAs = haloacetic acids
Different approaches proposed for the two substances

Approach for monograph development is tailored to the nature and complexity of the individual substance.

Concept document provides a mechanism to communicate and receive early input on the specific approach.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Approach</th>
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<tbody>
<tr>
<td>Di- and tri-haloacetic acids</td>
<td>Potential evaluation of a class</td>
</tr>
<tr>
<td><em>H. pylori</em></td>
<td>Builds on IARC assessments</td>
</tr>
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Next steps

- NTP considers comments on draft concepts from the Board of Scientific Counselors and public
- If selected by NTP Director, the Office of the RoC
  - Finalizes the concept documents
  - Establishes a webpage and posts relevant materials
  - Initiates protocol (if needed) and monograph development

Invite nominations
  - Interagency review
  - Public comment: FR notice

Develop draft concept
  - Public comment

Draft concept reviewed by NTP BSC

NTP Director

Select candidate substance
• Comment on the **merit** of the proposed project relative to the mission and goals of the NTP.

• Comment on the **clarity and validity of the rationale** for the proposed evaluation.

• Comment on the **strategy and approach** proposed to meet the stated objectives of the evaluation. Are the objective and approach for the cancer evaluation reasonable and clearly articulated? Are you aware of other scientific issues that need to be considered?

• Rate the **overall significance and public health impact** of this evaluation as low, moderate, or high.

• Provide any other comments you feel NTP staff should consider in developing this evaluation.