Report on Carcinogens Concepts

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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

The Report on Carcinogens (RoC) is a science-based, public-health document


Transmit & publish RoC

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.

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

Living list of nominations.

Completed steps:
Ongoing process for selecting candidate 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>

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

Invite nominations
  Interagency review
  Public comment: FR notice

Develop draft concept
  Public comment
  1 HAAs; 0 H. pylori
  Draft concept reviewed by NTP BSC
  NTP Director
  Select candidate substance

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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<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>
</tbody>
</table>
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

**Flowchart:**

- **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.