

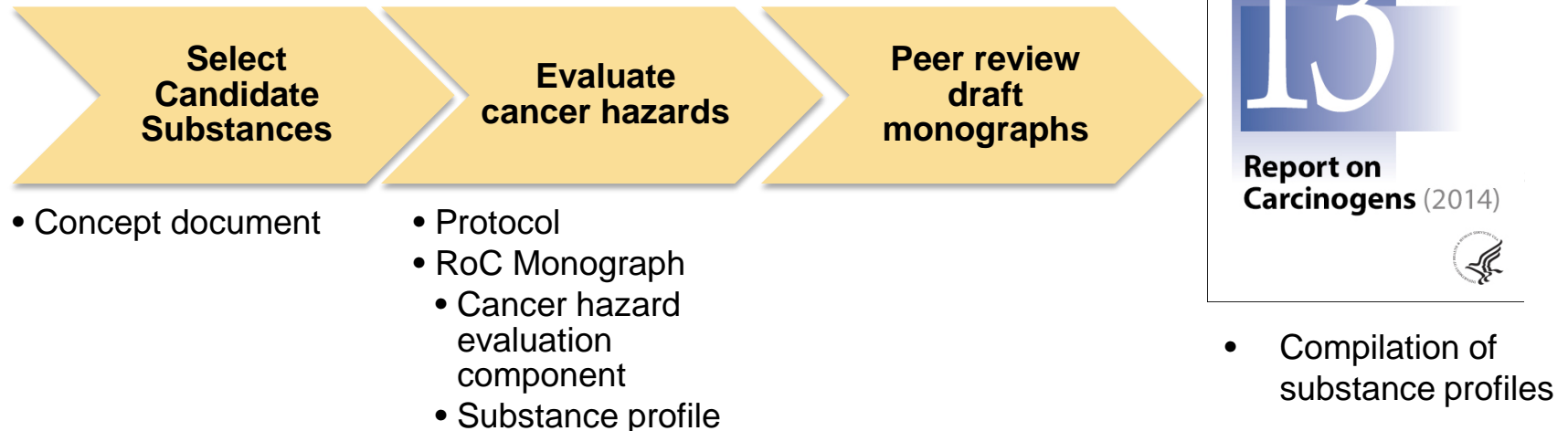
# Report on Carcinogens Concepts

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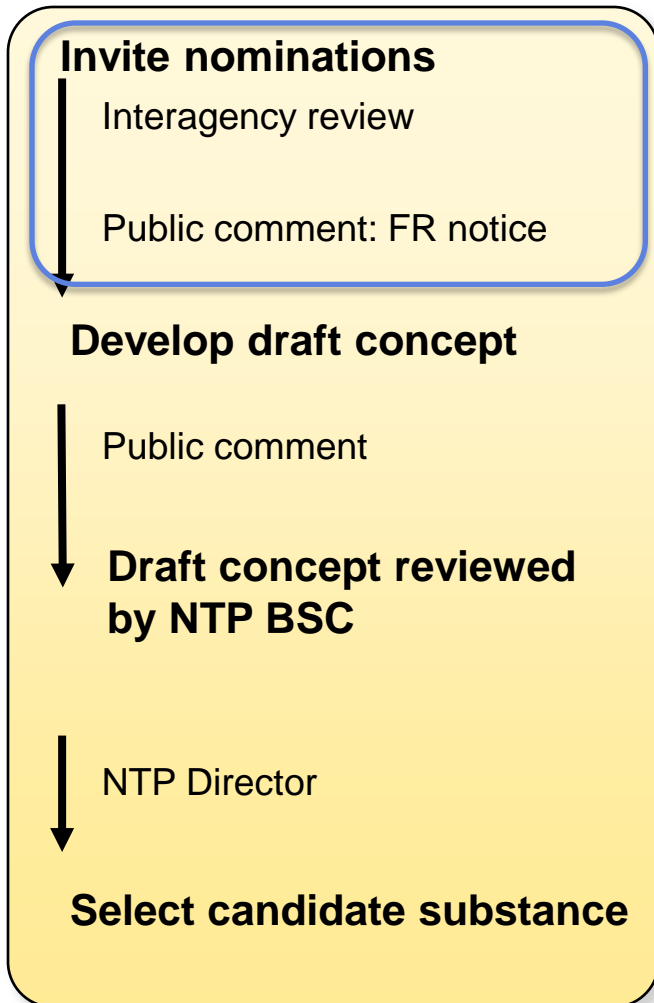
# The Report on Carcinogens (RoC) is a science-based, public-health document

- 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





## Ongoing process for selecting candidate substances



- Anyone can nominate a substance to the RoC
- On an ongoing basis the NTP requests information on nominated substances

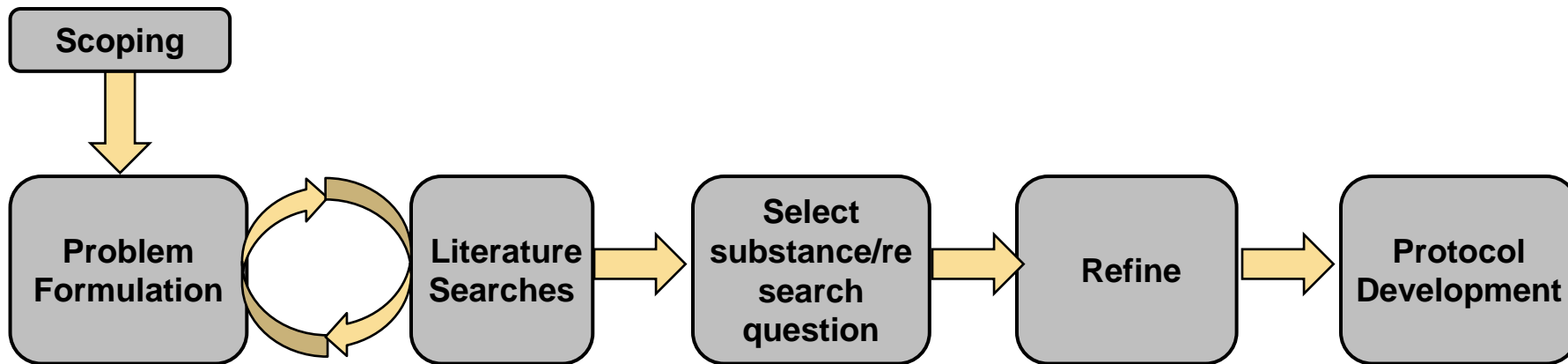
Substance	FR notice	Comment
<i>H. pylori</i>	Jan 2012	0
Di-tri-HAAs	Oct 2015	0

- The NTP uses this information and input from its interagency partners to identify substances to propose for formal review
- Living list of nominations



# Concept and protocol development

## NTP conducts scoping and problem formulation activities



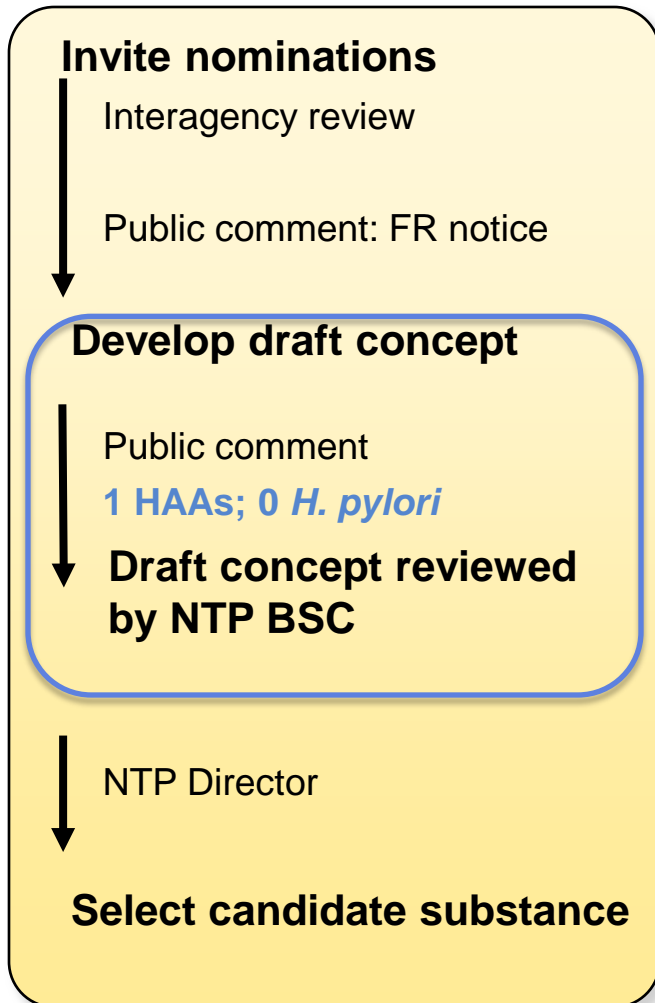
Iterative process

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



## 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

Substance	Approach
Di- and tri-haloacetic acids	Potential evaluation of a class
<i>H. pylori</i>	Builds on IARC assessments



### **Invite nominations**

Interagency review

Public comment: FR notice

### **Develop draft concept**

Public comment

**Draft concept reviewed  
by NTP BSC**

NTP Director

**Select candidate substance**

- 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



# Reviewer questions

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- 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.