Good afternoon, I am pleased to appear before you today to present testimony on the Report on Carcinogens. I am Linda Birnbaum, Director of the National Institute of Environmental Health Sciences (NIEHS), part of the National Institutes of Health (NIH), and Director of the National Toxicology Program (NTP). The NTP is an interagency program headquartered at the NIEHS. The NIEHS and NTP are part of the U.S. Department of Health and Human Services.

The Report on Carcinogens is an informative, science-based public health document, required biennially under the Public Health Service Act[1] and approved and published by the Secretary of Health and Human Services. The Secretary has delegated responsibility for preparation of the Report on Carcinogens to the NTP.

The Report on Carcinogens identifies agents, substances, mixtures, or exposure circumstances, collectively known as "substances," that are considered cancer hazards for people living in the United States. It is not a risk assessment document. A listing in the Report indicates a potential hazard for cancer, but does not estimate cancer risks that individuals may face when encountering listed substances in their daily lives. Many factors, including the amount and duration of exposure and an individual's susceptibility to a substance, affect whether a person will develop cancer.

Reducing exposures to cancer-causing substances is important to protect public health. The Report provides health regulatory and research agencies, scientific and medical communities, and the public with information they can use to make decisions about exposures to cancer-causing substances. The Report is not a regulatory document.

The Public Health Service Act stipulates that the Report list substances in one of two categories defined by statute: *known to be carcinogens* or *reasonably anticipated to be*

[1] Section 301(b)(4) of the Public Health Service Act, as amended

carcinogens. The Report lists a wide-range of substances including, metals, pesticides, drugs, natural and synthetic chemicals, and biological agents such as certain viruses. For each listed substance, the Report includes a substance profile that provides information from cancer studies that provide justification for the listing and information about use, production, potential sources of exposure, and any current Federal regulations to limit exposures.

Each edition of the Report is cumulative a

under review. We drew upon the scientific expertise of Federal agencies including NIH, the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, the U.S. Environmental Protection Agency, the Consumer Product Safety Commission, and the Department of Labor's Occupational Safety and Health Administration.

The process for the 12th Report included many opportunities for public input. Public comments were solicited:

- on substances nominated for review;
- on the draft background documents that summarized and evaluated all relevant publicly available, peer-reviewed scientific literature from human, experimental animal, and mechanistic studies, as well as information on exposure, chemical and physical properties, use, and production;
- on the external scientific expert panel's recommendation on whether to list the substances; and
- on the draft substance profiles that ultimately appear in the Report.

The public also had an opportunity to provide oral testimony at external, scientific expert panel meetings and at meetings of the NTP Board of Scientific Counselors. All public comments were posted on a website and distributed to the expert advisory groups for consideration in their deliberations.

Beginning with the 3rd Report in 1983, the NTP has used established criteria to evaluate the scientific evidence on each substance under consideration to determine whether to recommend listing the substance as *known* or *reasonably anticipated carcinogen,* or to not list it in the Report. The Report on Carcinogens listing criteria have been reviewed and revised

periodically since they were developed. The current criteria, approved by the Secretary of Health and Human Services in 1996, were the product of a thorough and public review.[2]

The listing criteria specify the level of evidence that must be met in order for a substance to be listed in the Report in either category. For a substance to be listed in the *known* category, there must be sufficient evidence from studies in humans that indicates a causal relationship between exposure to the substance and human cancer. In brief, for a substance to be listed in the *reasonably anticipated* category, the level of evidence can be based on one of three scenarios:

1) limited evidence of carcinogenicity from studies in humans or

2) sufficient evidence of carcinogenicity from studies in experimental animals or

3) evidence that a substance is a member of a class of substances already listed in the Report or that it causes biological effects known to lead to the development of cancer in humans.

The conclusion to list a substance in the Report is based upon scientific judgment with NTP giving consideration to all relevant data and to input from the advisory groups and the public.

If new scientific information becomes available once a substance is listed, it can be nominated for re-review including to upgrade the listing from *reasonably anticipated* to *known carcinogen*, to refine identification of the listed substance, or to remove the substance from the Report.

The NTP is now moving forward with preparation of the 13th Report. We have maintained rigorous, independent, external peer review and multiple opportunities for public

[2] National Toxicology Program Fiscal Year 1996 Annual Plan. U.S. Department of Health and Human Services. NIH Publication No. 96-4168.

input in the review process. To enhance transparency and efficiency and to better enable us to complete the Report with the statutory biennial timeframe, we have added the following steps:

- making more transparent how the NTP reaches its conclusions concerning the listing recommendation for a substance under review by combining the scientific information, its assessment, and the listing recommendation in a single document,
- providing more flexibility in the approaches the NTP might use to obtain external scientific and public input during a substance's evaluation, and
- separating the substances under review from a specific Report edition so that the list of substances is dynamic and the review process is continuous between editions.

We sought public input on the proposed review process for the 13th Report through solicitation of written comments and a public listening session. Taking into consideration public comments, we proposed these revisions to the NTP Board of Scientific Counselors in December 2011 at a public meeting. The NTP Board of Scientific Counselors endorsed the changes.

We finalized the Report review process in January 2012, posted it to the Report website, and announced its availability in the Federal Register.[3] We are now beginning work on the 13th Report.