



THE REPORT ON CARCINOGENS: UNDERSTANDING A VITAL PUBLIC HEALTH DOCUMENT

What is the Report on Carcinogens and why is it of interest to lawmakers?

The [Report on Carcinogens](#) is a scientific report mandated by the Public Health Service Act of 1978 to be issued biennially by the Department of Health and Human Services. The Report rigorously evaluates substances, including industrial chemicals and pesticides and exposure circumstances such as radiation, for their potential to cause cancer in people. Substances are evaluated and may be listed in one of two categories: *known to be a human carcinogen* or *reasonably anticipated to be a human carcinogen*. The National Toxicology Program (NTP), an interagency program housed at the National Institute of Environmental Health Sciences, manages the extensive process used to prepare each edition of the Report, the [12th](#) of which was issued in June 2011. The NTP was established in 1978 to coordinate research across US agencies. As such, the NTP integrates input from across the federal agencies as part of the process for developing the report.

Why is the Report necessary?

The Report provides public health officials, occupational health and safety professionals, medical clinicians and American businesses critical, objective information on the strength of the scientific evidence for the carcinogenicity of specific substances. This information is vital for the protection the health and safety of all people in the U.S. The Report is not a regulatory document but is used by other agencies in establishing regulations that protect human health. While there are additional scientific bodies around the world that issue similar scientific assessments of carcinogens, including the [International Agency for Research on Carcinogens \(IARC\)](#) of the United Nation's World Health Organization, the NTP's Report on Carcinogen is the only assessment of carcinogens conducted by the U.S. government and as such, provides assurances of public participation and input by American researchers, industry, public interest advocates and individuals.

Is the process for preparing the Report scientifically sound and transparent?

The nomination and review of substances by the NTP is a [multi-year process](#) that involves multiple rounds of external peer review, expert advisory reviews, and opportunities for public input. In preparation for the most recent report, the 12th Report on Carcinogens, the NTP established three scientific advisory groups, which included an external expert panel as well as two governmental review groups drawn from across the federal agencies.

At each step in the process—the nomination of substances, the review of the literature, the draft of the report—there was opportunity provided for public comment. For example, in the review of styrene included in the 12th Report, the Styrene Information and Research Council, a consortium of styrene manufacturers, provided public comments at every opportunity in the process—six times between 2004 and 2011.

Throughout its history, the NTP has made changes and improvements in the process for developing and issuing the Report, including efforts to integrate scientific advances in our understanding of the biological effects of substances to which people may be exposed. Prior to the development of the most recent 12th Report, the NTP held a public meeting to get input that was used to [revise the process](#) for the Report in order to enhance the scientific rigor and adhere with guidance from the Office of Management and Budget's Peer Review Bulletin. The outcome of this revision was the inclusion of additional peer review of both the background documents used in the assessment and the draft of the substance profiles.

If the National Academy of Sciences (NAS) is reviewing the listing of formaldehyde and styrene, shouldn't NTP wait to issue the next report?

Throughout its history, the NTP has demonstrated its ability to continuously improve the process for the Report on Carcinogens while upholding both its Congressional mandate to periodically issue revisions and updates to the report and its responsibility to the American people to provide sound guidance on carcinogens to support cancer prevention. Considerable background work is involved in preparing a Report due to the extensive review of the existing scientific literature on each substance, multiple external and interagency peer reviews, review of public comments that are solicited throughout the process, and external expert engagement. If the NTP were to wait until the NAS completes its assessment, this would effectively delay the 13th and the 14th Reports by at least 2-3 years.

Delaying the Report until the NAS completes its review would only serve to undermine the law and the public's and businesses' right to know about carcinogenic hazards. While the NAS is reviewing the listing of formaldehyde and styrene specifically, this should not call into question the entire process of the Report on Carcinogens or the need to continue assessments of other substances. If recommendations for improving the process based on these specific chemicals were to emerge from the NAS review, the NTP would, as it has in the past, integrate them into the ongoing process. This allows for continued assessment and dissemination of information on carcinogens as mandated by the law and demanded by the public.

To argue that the NTP should wait until the completion of the NAS review presumes that the Report process itself is inherently flawed and will need dramatic overhaul. There is no scientifically sound reason to assume this to be the case. As in the past and with other issue areas, the NAS report will provide an additional perspective and, potentially, recommendations for improvements with respect to the listings of formaldehyde and styrene in the 12th Report. This represents an additional peer review of the outcomes of a process that has already undergone extensive review, public input and rigorous evaluation of the literature. If the additional review necessitates changes to these listings, the Report process provides ample means to make the changes.