April 1, 2004

Via E-Mail

National Institutes of Health (NIH)
Associate Director for Communication
Office of the Director
Building I, Room 344
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Request for Correction of Information

Dear Sir/Madam:

This request for correction of information is submitted on behalf of the American Chemistry Council's Naphthalene Panel (Panel) pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001[1] (the Information Quality Act), and the implementing guidelines issued by the Office of Management and Budget (OMB Guidelines),[2] the National Institutes of Health (NIH), U.S. Department of Health and Human Services (HHS) (NIH Guidelines),[3] and the HHS (HHS Guidelines).[4] The Naphthalene Panel consists of producers and users of naphthalene.[5] The National Toxicology Program (NTP) is an agency of the HHS and is therefore subject to OMB's Guidelines, the HHS Guidelines, and the NIH Guidelines (collectively, the "Guidelines").

The Panel seeks, pursuant to the OMB, NIH, and HHS Guidelines, correction of information disseminated by NTP. As discussed in detail below, the Panel requests:

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1 44 U.S.C. 3516 note.

2 *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information by Federal Agencies*, 67 Fed. Reg. 8452 (Feb. 22, 2002), available at www.whitehouse.gov/omb/fedreg/reproducible2.pdf.

3 *Guidelines for Ensuring the Quality of Information Dissemination to the Public*, available at http://www.hhs.gov/infoquality.

4 *Guidelines for Ensuring the Quality of Information Dissemination to the Public*, available at http://www.hhs.gov/infoquality/part1.html**.** *See also* MEMORANUMDUM FOR PRESIDENT'S MANAGEMENT COUNCIL (http://www.whitehouse.gov/omb/inforeg/pmc_graham_100402.pdf), From John D. Graham, re: Agency Draft Information Quality Guidelines (June 10, 2002) at Attachment, Section V.

5 Panel member companies are International Tar Association, Koppers Industries, and Recochem, Inc.

(i) correction of the Background Document for Naphthalene,[6]
(ii) correction of the Summaries of the RG1 and RG2 meetings,[7]
(iii) rescission of the RG2 meeting with regard to naphthalene and for NTP to hold a new RG2 meeting,
(iv) rescission of the vote of the November 19, 2002, NTP Report on Carcinogens (RoC) Subcommittee meeting with regard to naphthalene, and
(v) reconsideration of naphthalene by a new RoC Subcommittee at a future meeting in accordance with the Guidelines' requirements.[8]

If this relief is not granted, the Panel requests that NTP staff, NIH's Office of Communications and Public Liaison (OPCL), and the NTP Executive Committee undertake a comprehensive pre-dissemination review of the entire record of the listing proceeding as it relates to naphthalene, before any recommendation is made concerning listing naphthalene in the Eleventh RoC by the NTP Director.[9] This review would involve ensuring that information relied upon and developed in making a recommendation meets the basic standard of quality under the Guidelines, including the elements of objectivity, utility, and integrity.[10]

NIH's Guidelines require that a petition for correction contain several substantive components. These include: a description of the specific material that is proposed for correction, the reasons why the disputed information does not comply with the OMB or NIH Guidelines and is in error, an explanation of how the petitioning party is affected by the error, and suggested recommendations for what corrective action(s) should be taken. The Panel is adversely affected by the errors described in that the NTP Draft Background Document for Naphthalene (Background Document), and the RG1 and RG2 review summaries contain incorrect information. The information that has been disseminated by NTP, and continues to be disseminated, wrongly characterizes the cancer potential of naphthalene, thereby stigmatizing naphthalene and inviting enhanced regulatory and consumer scrutiny of naphthalene and products containing naphthalene. An unwarranted listing of naphthalene resulting from these errors, as well as from the inappropriate conduct and vote of the NTP RoC Subcommittee, would unnecessarily cause greater economic harm through, at a minimum, increased costs of regulatory compliance and possible loss of market share, to the producers and users who comprise the

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6 Included as Attachment B. Available at http://ntp-server.niehs.nih.gov/NewHomeRoc/roc11Bkgrnd2002.html.

7 Included as Attachments A and C, respectively. Available at http://ntp-server.niehs.nih.gov/NewHomeRoc/roc11Bkgrnd2002.html.

8 68 Fed. Reg. at 3033-3036.

9 *See* NIH Guidelines, Introduction before Section I, and Section I.2; OMB Guidelines Sections III.1 and 2 (67 Fed. Reg. at 8458-8459).

10 OMB Guidelines, 67 Fed. Reg. at 8459 (1st col.); NIH Guidelines (Introduction preceding Section I).

Panel. Each of the remaining components of the required request for correction is discussed below.

## I. THE RoC LISTING PROCESS

The RoC is a Congressionally mandated report prepared biennially that contains a list of substances that are believed to pose a potential hazard to human health. According to NTP, the Reports serve as "meaningful compilations of 1) the cancer data available for the listed substances in human and/or animals, 2) on the potential for exposure to these substances, and 3) on the regulations required by Federal agencies to limit exposures to these substances or exposure circumstances." [source - http://ntp-server.niehs.nih.gov/NewHomeRoc-WhatisRoc.html.]

Listing in the RoC is not an academic exercise devoid of real world consequences. Listing in the RoC means a substance will be regulated more stringently, and will be perceived thereafter as a carcinogen. For example, under OSHA's Hazard Communication Standard, substances listed in the RoC must be identified as carcinogens in material safety data sheets (MSDS). Additionally, an RoC listing can, and often does, invite a determination by the California Environmental Protection Agency that the substance may be a carcinogen for purposes of Proposition 65 pursuant to the state statute's authoritative bodies listing mechanism, as an NTP RoC listing is considered an authoritative body for purposes of Proposition 65.[11] Many other adverse inferences flow from the listing of a substance in the RoC, not the least of which is the intangible, but real nonetheless, commercially damaging stigma that is associated with substances believed to cause or contribute to cancer. This stigma can and often does lead to product liability claims, diminished sales, product substitution by downstream users of the substance, and related commercial damage.

The RoC listing process itself consists of several distinct phases. Briefly stated, the process is as follows:

- Chemical nominations undergo review by two NIEHS/NTP RoC review committees. The first, Review Group (RG) 1, is composed of senior scientists from the NIEHS/NTP staff. The RG1 first reviews the Background Document and determines if it is adequate for use in reviewing the nomination. The RG1 reviews the nomination and makes a recommendation for listing or delisting in the RoC.
- The *NTP Executive Committee's Interagency Working Group for the RoC* (RG2) consists of government scientists designated to act on behalf of the NTP Executive Committee, which consists of the heads of the government agencies that participate in

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[11] These real-world regulatory consequences are the reasons why two different federal courts have held RoC listings to be judicially reviewable. *See* Tozzi v. Dept. of Health & Human Servs., 271 F.3D 301, 310-11 (D.C. Cir. 2001); Synthetic Organic Chemical Mfr.s Ass'n v. Dept. of Health & Human Servs., 720 F. Supp. 1244 (W.D. La. 1989).

the NTP[12]. RG2 conducts a second review of the nomination, and assesses whether relevant information for a nomination is available for listing in or delisting from the RoC. The RG2 reviews the original nomination, and all public comments received on the nomination, and provides comments and makes its recommendation for listing or delisting. Notably, it does not revise the Background Document or review public comments received on the Background Document.

- The third step in the RoC process is an external scientific peer review of the nomination by a standing committee of the NTP Board of Scientific Counselors (the RoC Subcommittee). The RoC Subcommittee reviews nominations in a public meeting at which the public is given the opportunity (for the first time) to make brief oral presentations. Upon completion of its review, the RoC Subcommittee provides comment and makes its recommendation regarding listing or delisting the nominated substance in the RoC. Again, however, the Background Document is not revised to reflect any of these proceedings.
- The fourth step consists of publication of a third and final request for comments in the Federal Register after the reviews by the RG1, RG2, and the RoC Subcommittee have been completed.
- The recommendations of RG1, RG2 and the RoC Subcommittee and all public comments received are presented to the NTP Executive Committee for review and comment. The NTP Executive Committee reviews the information on the nominations and provides its opinion for listing or delisting them in the RoC.
- Next, the NTP Director receives the recommendations for listing, along with all public comments received during the process. The NTP Director reviews the information and makes a recommendation to the Secretary, HHS regarding whether to list, delist, or not list the nominated substance in the RoC. The NTP prepares a final draft of the RoC based on the NTP Director's recommendations and submits the draft report to the HHS Secretary. Upon approval of the RoC, the Secretary submits it to the U.S. Congress as a final document. The submission of the RoC to Congress constitutes publication of the report and it becomes available to the public at that time. The NTP publishes in the Federal Register a notice of the availability of the latest edition of the RoC.

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[12] Agencies represented on the NTP Executive Committee are: Agency for Toxic Substances and Disease Registry (ATSDR), Consumer Product Safety Commission (CPSC), Environmental Protection Agency (EPA), Food and Drug Administration (FDA), National Center for Environmental Health of the Centers for Disease Control and Prevention (NCEH/CDC), National Institute for Occupational Safety and Health/CDC (NIOSH/CDC), Occupational Safety and Health Administration (OSHA), National Cancer Institute of the National Institutes of Health (NCI/NIH), and National Institute of Environmental Health Sciences/NIH/NIEHS/NIH).

The naphthalene listing process is well along. The final public comment period expired in March 2003. The matter is likely now before the NTP Executive Committee for review and comment. No final recommendation by the NTP Director to the HHS Secretary whether to list naphthalene has been announced.

Panel member companies, and others, have been and continue to be significantly adversely affected by the dissemination of the erroneous and biased information that characterizes the naphthalene listing process thus far. Panel member companies will continue to be harmed if this information is not promptly withdrawn and corrected. As evidenced by the brief summary of the process set forth above, the RoC listing process is iterative. Each successive phase of the process builds upon the information extracted from the preceding phase. The Panel believes, and demonstrates below, that the very foundation of the information construct NTP has built for naphthalene in the RoC listing process - the Background Document - fails to meet the standard for quality demanded under the IQA. The Background Document is the "document of record" in the listing process. It and all other documents for which the Panel seeks correction or withdrawal as described in this petition are documents that contain "influential scientific" information as this term is defined in the Guidelines and hence are subject to a particularly rigorous standard of quality. This standard has not been met in naphthalene's case.

The failure of the NTP to meet the IQA requirements for quality in preparing the Background Document cannot be isolated to any discrete phase of the listing process. The essentiality of the Background Document to the successive phases of the listing process, the fact that the Background Document is never revised to reflect any of the deliberations or comments upon it, and the Background Document's failure to meet IQA information quality standards, mean the entire naphthalene listing record is contaminated and utterly incapable of informing the judgment of the NTP Director for purposes of making a recommendation to list or not list naphthalene in the RoC. As with the fruit of the poisonous tree, no final decision resulting from this poisoned process can be free of taint.

It is for this reason the Panel believes the best and only appropriate solution for these IQA shortcomings is for the NTP to start over the listing process for naphthalene. Alternatively, if this relief is not granted, the Panel requests that NTP staff, NIH's OPCL, and the NTP Executive Committee engage in a well-defined process of pre-dissemination review of the entire naphthalene record to ensure that the shortcomings described below are remedied so the IQA standard of data quality can be met before the NTP Director makes its recommendation to the Secretary of the Department of Health and Human Services.[13]

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[13] To its credit, NTP recently solicited comments on the current RoC process and possible ways to improve it. (68 Fed. Reg. 67692, Dec. 3, 2003). ACC submitted comments on January 30, 2004 that recommend NTP replace the current process with a new one modeled closely on that followed by NTP's Center for the Evaluation of Risks to Human Reproduction (CERHR). The Panel submits that adoption of the CERHR process would

## II SUMMARY OF INFORMATION FOR WHICH CORRECTION IS BEING SOUGHT IN ACCORDANCE WITH THE GUIDELINES

### A. Background Document

The Panel seeks correction of significant errors or omissions in the Background Document (Attachment B). The Background Document is "influential scientific" information that has been, and continues to be, disseminated by the NTP within the meaning of the Guidelines. Background documents are prepared by the NTP after an independent search of the literature and must be prepared according to a specific format set forth in the NTP's listing and delisting procedures for the NTP's RoC. Among other requirements, background documents must contain a summary of any information relating to human studies of carcinogenicity, experimental carcinogenesis, genotoxicity, and other data relevant to evaluation of carcinogenicity and its mechanisms, and the data used to prepare these sections must come from peer reviewed sources.[14] The Background Document must contain accurate summaries of information on these topics relating to naphthalene to satisfy IQA information quality standards.

The primary contributors to the Background Document are identified as NIEHS/NTP staff, including Dr. C.W. Jameson, Head, Report on Carcinogens, Environmental Toxicology Program. According to NTP Director Dr. Kenneth Olden, the Background Document "is the document of record" for all three scientific peer reviews in the RoC review process and "will remain the document of record."[15] Moreover, the Background Document has been and continues to be posted on NTP's website.

The Background Document represents the views of the NTP of the facts pertinent to naphthalene's evaluation. Accordingly, the Background Document is influential information that has been disseminated, is subject to a rigorous standard of information quality, and is, therefore, subject to the correction actions of the Guidelines.

The Panel is seeking correction of a number of significant errors and omissions in the Background Document discussed below, including many that are identified in the Panel's comments to NTP (Attachments E, F, G and H).

### B. RG1 and RG2 Summary Reports and RG2 Meeting

The RG1 (Attachment A) and RG2 (Attachment C) summary reports are lacking any detail regarding what transpired at the closed RG1 and RG2 meetings, and the Panel is seeking correction of this deficiency. These summaries, apparently prepared by NTP staff, are represented by NTP as summaries of the RG1 and RG2 discussions and recommendations, and

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go a long way toward ensuring that future RoC nominations meet the requirements of the IQA, and should reduce the number of IQA challenges received regarding RoC matters.

[14] Report on Carcinogens Listing and Delisting Procedures available at http://ntp-server.niehs.nih.gov/NewHomeRoc/ListDelistProc.html.

[15] Letter from K. Olden, Director NTP, to C. Price, Vice-President ACC, dated March 11, 2003. Included as an Attachment to Attachment H.

have been and continue to be disseminated on the NTP website. These summaries contain influential scientific information that is critical to naphthalene's evaluation in successive phases of the listing process. Accordingly, both the RG1 and the RG2 summaries are " influential scientific" information that has been disseminated and therefore subject to the correction actions of the Guidelines.

If the Eleventh RoC (or any subsequent RoC) discusses naphthalene, by necessity that document will depend crucially on the process steps that led up to its issuance. Those steps include the RG2 review meeting that occurred on October 2, 2002. The critical shortcomings in the Background Document that served as the basis for the meeting's discussions mean that the meeting itself was itself inherently flawed. Certainly the meeting summary does nothing to indicate that the participants dealt with or even recognized the problems with the Background Document identified in the prior comments of the Panel and others. The result is that any RoC based on the flawed RG2 meeting will embody the same flaws and thus will not meet IQA quality standards. The RG2 meeting thus should be rescinded and reconducted with an adequate Background Document.

Moreover, all future RoCs (as well as the Tenth) are subject to the IQA's predissemination review requirements, since they have been or will have been issued after October 1, 2002.[16] Those requirements, as expressed in the OMB and NIH Guidelines, are that agencies "shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination."[17] Any future RoC discussion of naphthalene that is based on the current proceedings will fail to have met those requirements, since the process NTP has followed thus far clearly cannot be described as ensuring the quality, pre-dissemination, of that document. (Indeed, the process is more certain to ensure its lack of quality.) For this reason as well, the RG2 meeting needs to be rescinded and properly reheld.

The Panel is seeking correction of the RG1 review summary and the RG2 review summary, if not rescinded, in accordance with the above. The Panel is also seeking rescission of the RG2 findings and recommendations on naphthalene and a reconvening of the RG2 meeting after the Background Document is corrected.

**C. NTP RoC Subcommittee Proceeding**

The Panel is also seeking correction of the irregular and highly prejudicial manner in which information was distributed by the Chairman of the NTP RoC Subcommittee at the public Subcommittee meeting on November 19, 2002, without affording the members of the Subcommittee and the public an opportunity to review this information. It is also seeking correction of the bias and lack of objectivity that was introduced into the Subcommittee meeting

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16 OMB Guidelines, 67 Fed. Reg. at 8459; NIH Guidelines, at beginning of Section II; HHS Guidelines, at Section D.3.

17 OMB Guidelines, 67 Fed. Reg. at 8459 (Section III.2); NIH Guidelines at introductory section preceding Section I.

proceedings, as well as the Subcommittee vote on the recommendation of naphthalene for listing as a result of this irregular and inappropriate introduction of new data. While the NTP RoC Subcommittee is composed of experts from the public and private sector and provides external peer review, its proceedings and conclusions, and the publication of its results, are subject to the OMB, NIH, and HHS Guidelines, and their corrective procedures on several grounds:

- The NIH Guidelines include among the NIH information covered by the OMB Guidelines "open meetings' proceedings and minutes." While the NIH Guidelines refer to "NIH Information" covered by the Guidelines and elsewhere state that the information must "represent our view," the RoC Subcommittee proceedings are conducted under the *imprimatur* of NTP/NIH, the recommendations of the Subcommittee and the votes are made in a proceeding open to the public, and subsequently published in the *Federal Register* (thus disseminated), and the recommendations play a highly influential role in the final decision by the NTP Director on whether to list a chemical for listing.

  Moreover, NTP should review the NTP RoC Subcommittee meeting proceedings to ensure that the NTP RoC Subcommittee meeting was conducted in accordance with procedures consistent with the objectivity, absence of bias, and other requirements of the Guidelines. NTP has authority to stop any further dissemination of the results of the proceedings if the procedures do not meet these standards.[18] Failure to stop the further dissemination of the outcome of the Subcommittee meeting and the vote, including its publication, indicate that the proceedings at a minimum represent NTP's view that the proceedings and results were conducted in a fair, objective, and unbiased manner, and that the recommendations and proceedings are worthy of the full consideration of the Executive Committee and the NTP Director. As a consequence, the NTP RoC Subcommittee proceedings and recommendations are subject to the OMB and NIH Guidelines at least with regard to whether the procedures followed were consistent with the goals and intent of the IQA and the OMB and NIH Guidelines.

- As discussed earlier, if the Eleventh RoC (or any subsequent RoC) discusses naphthalene, by necessity that document will depend crucially on the process steps that led up to its issuance. The meeting of the NTP

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[18] The NIH Guidelines correction procedures (Section VI.1) indicate that the material proposed for correction includes the presentation and mode of delivery. Moreover, the Office of Information and Regulatory Affairs (OIRA) explanation of the Information Quality Guidelines provide that an agency disseminates information where the agency has the authority to review and approve the information before release. June 10, 2002, Memo, attachment at 2, *citing* OMB Guidelines at 67 Fed. Reg. 8454, Feb. 22, 2002.

RoC Subcommittee is the single most important step in that process after the initial issuance of the Background Document. As discussed more fully below, the legitimacy of that meeting is irrevocably clouded by the highly irregular and improper conduct of its chair. Even more so than in the case of the RG2 meeting, the RoC Subcommittee meeting was so profoundly flawed that any RoC based on it will inevitably be colored by the same flaws and thus will not meet IQA quality standards. As a result, the RoC Subcommittee meeting should be rescinded and reconducted appropriately.

Moreover, all future RoCs (as well as the Tenth) are subject to the IQA's predissemination review requirements, since they have been or will have been issued after October 1, 2002. Those requirements, as expressed in the OMB and NIH Guidelines, are that agencies "shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination."[19] Thus, even if the RoC Subcommittee's recommendations and proceedings are not considered to represent NTP's view and therefore do not fall within the definition of "information" subject to the Guidelines, those recommendations and proceedings should be an essential part in the creation of any future RoC that discusses naphthalene. Any RoC that is based on the RoC Subcommittee proceedings will fail to have met those requirements, since that meeting cannot possibly be characterized as ensuring the quality, pre-dissemination, of that document. Rather, the proceedings only guarantee that its quality will be questioned. For this reason as well, the RoC Subcommittee meeting needs to be rescinded and properly reheld.

The transcript of the NTP RoC Subcommittee meeting of November 19, 2002 is included as Attachment D. As discussed below, the Panel is seeking rescission of the vote of the NTP RoC Subcommittee at the November 19, 2002, meeting with respect to naphthalene and a reconvening of that meeting, following correction of the other matters discussed above.

## III. SUMMARY OF GROUNDS FOR CORRECTION UNDER THE GUIDELINES APPLICABLE TO THE INFORMATION DISSEMINATED OR DEVELOPED BY NTP FOR NAPHTHALENE

The bases for seeking correction of information subject to the OMB, NIH, and HHS Guidelines include the following:

- Lack of objectivity, both in substance (with regard to accuracy, reliability, and lack of bias) and presentation (with regard to presentation in a clear,

[19] OMB Guidelines, 67 Fed. Reg. at 8459 (Section III.2); NIH Guidelines at introductory section preceding Section I.

complete, and unbiased manner).[20] The information is "highly influential" scientific information, as defined in the Guidelines, and the information must:

- Meet heightened requirements for transparency and, if applicable, reproducibility; and
- Satisfy certain requirements in the Safe Drinking Water Act (SDWA), as applicable, such as: (1) use "the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer reviewed studies when available"; (2) use "data collected by accepted methods or best available methods"; and (3) be comprehensive, informative, and understandable.[21]

- Lack of utility in terms of usefulness of the information to its intended uses, including the public.[22]

## IV. SPECIFIC CORRECTIONS REQUESTED AND BASES UNDER THE GUIDELINES

### A. Requested Corrective Action for Background Document

It is important that the Background Document satisfy the Guidelines for a number of reasons:

- The Background Document contains a broad range of information on naphthalene, including not only toxicological data, but also information concerning human exposure and environmental occurrence, that may be relied upon and used by consumers and the general public. The fact that NTP may also post on its website public comments on the Background Document does not negate the fact that the Background Document is, and is likely to be read as, a stand-alone document expressing the current views of the NTP.

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20 HHS Guidelines Section A, D.2.D.4: NIH Guidelines, Introduction, Section V.2.a. and VII; OMB Guidelines, 67 Fed. Reg. at 8453, 8459.

21 HHS Guidelines Section I.D. 4.g; NIH Guidelines, Section V.2.d and VII; OMB Guidelines, 67 Fed. Reg. at 8457-8458, 8460 (col. 2).

22 OMB Guidelines, 67 Fed. Reg. at 8459; HHS Guidelines, Section D.2.b. Both Guidelines specify that in assessing usefulness of information, the agency must consider the uses of the information not only from the perspective of the agency but also from the perspective of the public. When transparency of information is relevant for assessing the information's usefulness from the public's perspective, "the agency must take care to ensure that transparency has been addressed in its review of the information."

- The Background Document, as stated by NTP Director Olden, is the "document of record" for all three scientific peer reviews and "will remain the document of record." Accordingly, satisfaction of the requirements of the Guidelines is necessary to ensure that the three scientific peer review groups are presented with a complete and unbiased document with which to work. Given that the starting point for discussion during the three peer review meetings is the Background Document, lack of objectivity and utility of that document can only taint the entire review process.

The Background Document fails to meet requirements for objectivity both in substance, with regard to accuracy, reliability, completeness, and lack of bias, and in presentation. Further, the Background Document constitutes "influential scientific" information as defined in the Guidelines, in that dissemination of the document will and does have a clear and substantial impact on important public policies or important private sector decisions.[23] This is evidenced by the fact that the Background Document is the "document of record" in the review of whether naphthalene should be included in the *RoC*, which the NIH Guidelines describe as "[o]ne of our most visible publications," and the fact that the public may be expected to use and rely upon the information contained within it, as discussed above. Accordingly, the document is subject to a particularly high degree of transparency and the data and studies described therein are subject to requirement of reproducibility by third parties.

Moreover, the document must satisfy certain requirements of the SDWA, as applicable, including in particular use of "the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer reviewed studies when available" and constitute information that is "comprehensive, informative, and understandable."[24] The Background Document fails to meet these standards.

Finally, as detailed below, the Background Document fails to meet the requirement of "utility" both because it is not sufficiently reliable and transparent for public use or for use by the scientific peer review groups.

To satisfy these deficiencies, NTP must withdraw the Background Document from NTP's website and call for its withdrawal from any other agency's website and cease any further dissemination of the document until the document is revised to address, at a minimum the following matters:[25]

- **Page 21**: To satisfy the objectivity requirement and avoid the possibility of any inaccurate inferences being made, the Background Document should explain in detail why the three-decades old East German reports of

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23 OMB Guidelines, 67 Fed. Reg. at 8460 (col. 3 (#9)); NIH Guidelines at Section VII.

24 HHS Guidelines at Section I.D. 4.g; NIH Guidelines at Sections V.2.d, VII; OMB Guidelines, 67 Fed. Reg. at 8457-8458, 8460 (col. 2).

25 Page numbers refer to page numbers in the Background Document.

the health effects observed in tar distillation workers, Wolf (1976, 1978) as cited in NTP (1992) and (2000), can fairly be construed as evidence of carcinogenicity in humans. In so doing, it should explain how it overcomes the analyses by other authoritative bodies cited in the Panel's October 2, 2002, comments to NTP (Attachment F) and the confounding factors and other deficiencies in those studies described in the October 2, 2002, Comments.[26] The discussion of these reports should also incorporate additional comments and correct misleading and incorrect descriptions of the Wolf studies made by NTP in its reports on naphthalene, as discussed in the Panel's March 24, 2003, comments to NTP (Attachment H).[27]

- **Pages vi, 27, 31, 53**: To avoid misleading implications, which would violate the objectivity requirements, the Background Document should clarify the meaning of its terminology in referring to the "carcinogenicity" of naphthalene in mice and rats in several places. It should explain that the NTP Technical Report on the mouse study made a finding of "some evidence" of carcinogenicity in mice based on increases in *benign* tumors only under the criteria used by NTP only for individual studies. Similarly, it should explain that a finding of "clear evidence" of carcinogenic activity in rats was made by the NTP rat bioassay on naphthalene only with respect to male rats and only under the criteria used by NTP for individual studies. To eliminate additional incorrect implications, the Background Document should clearly explain the meaning of the conclusions reached in the individual NTP reports, as explained in those reports, that "the actual determination of risks to humans from chemicals found to be carcinogenic in laboratory animals requires a wider analysis that extends beyond the purview of these studies."[28] Finally, while the criteria for listing in the *RoC* are set out at the beginning of the report, it would avoid confusion to the general public to state, when discussing individual bioassays, that a listing based on a finding of "reasonably anticipated to be a human carcinogen" must be considered on the weight of the evidence as set forth in the listing criteria.

- While the purpose of the Background Document is not to reach conclusions as to whether naphthalene meets the RoC listing criteria, but

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26 *See* Attachment F: Comments of the Naphthalene Panel on Draft August 26, 2002, Draft Report on Carcinogens Background Document for Naphthalene (Oct. 2, 2002) at 5, 9-11 (Oct. 2, 2002, Comments).

27 *See* Attachment H: Letter to Dr. C.W. Jameson, NTP, from C. Price, ACC, March 24, 2003.

28 *See* NTP Rat Study on Naphthalene at 8.

rather to summarize the available relevant scientific literature, to satisfy both the "utility" and objectivity requirements the document should set forth certain information that would enable the scientific review groups to better evaluate whether naphthalene meets the RoC listing criteria. These include the following information from the Panel's September 24, 2001, comments to NTP (Attachment E)[29] as well as its March 24, 2003 comments (Attachment H):

- As concluded by EPA in the Integrated Risk Information System (IRIS) file on naphthalene, "An inhalation unit risk estimate for naphthalene was not derived because of the weakness of the evidence (observations of predominant benign respiratory tumors in mice at high dose only) that naphthalene may be carcinogenic in humans."[30] The single alveolar/bronchiolar carcinoma observed among the high dose female mice cannot legitimately be considered together with the benign lung tumors, and the NTP mouse study cannot be considered to have caused an increase in benign and malignant tumors combined. The Background Document should note that the mouse is more susceptible to the pulmonary toxicity of naphthalene than other species, calling into question the relevance of the mouse tumors to human health.
- The reasons that the rat nasal cavity tumors cannot be considered to be increased to an "unusual degree."[31]
- The reasons as to why anatomical, physiological, and metabolic differences between rats and humans raise substantial questions as to the relevance of the rat nasal tumors to humans, as discussed in the October 2, 2002, Comments.[32] The Background Document should also discuss that there is no convincing relevant evidence that naphthalene acts through mechanisms indicating it would

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29 *See* Attachment E, Comments of the Naphthalene Panel on Call for Public Comment on 16 Substances, Mixtures and Exposure Circumstances Proposed for Listing in the Report on Carcinogens, Eleventh Edition, 66 Fed. Reg. 38430 (Sept. 24, 2001) at 4.

30 IRIS Substance File for Naphthalene at Section II.C.

31 *See* Comments of September 24, 2001 (Attachment E) and March 24, 2003 (Attachment H).

32 *See* Comments of October 2, 2002 (Attachment F) and March 24, 2003 (Attachment H).

likely cause cancer in humans, for the reasons discussed in the March 24, 2003, Comments.[33]

- **Pages 27-30 (Section 4.2.1)**: To satisfy the objectivity requirements of accuracy and completeness, as well the requirement for utility, this section should not only include the discussion from the September 24, 2001, Comments referenced above with regard to rat nasal tumors, but should also explain in greater detail that cell proliferation is a potentially important mechanism for the development of nasal tumors in rats exposed to naphthalene, as explained in Section III.C of the October 2, 2002, Comments.

- **Pages 33-38 (Section 5)**: To satisfy the objectivity requirements with regard to completeness and a balanced discussion, the SDWA requirements to include the best available science and supporting studies, including peer reviewed studies when available, and the utility requirements as they pertain to the public and the various review groups and decision-makers, the section on genotoxicity should discuss the additional genotoxicity studies identified in the October 2, 2002, Comments at pages 10-11 and in a recent publication by Schreiner (2003)[34], including in particular the standard *in vivo* studies that are described. Further, the Background Document, in both Section 5 and in the Executive Summary, should state either that available data strongly support the conclusion that naphthalene is not genotoxic or that the vast majority of genotoxicity tests on naphthalene indicate that naphthalene is not genotoxic.

- To meet the objectivity requirements with regard to accuracy and completeness, the SDWA requirements noted above, and the utility requirements, the Background Document should discuss in detail, drawing from the March 24, 2003, Comments (Section 1.5), the grounds for believing that naphthalene does not belong to a well-defined, structurally-related class of substances whose members are listed in a previous *RoC* as either known to be a human carcinogen or reasonably anticipated to be a human carcinogen.

- Outdated and incorrect information in the Background Document on production, exposure, use, and environmental fate of naphthalene should be corrected as discussed in the October 2, 2002, Comments.

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33 March 24, 2003, Comments (Attachment H) at [10-14].

34 Schreiner, C.A. (2003). Genetic Toxicity of Naphthalene: A Review. *Journal of Toxicology and Environmental Health*, Part B, 6:161-183.

- To satisfy better the requirements of objectivity, with regard to completeness and transparency, as well as utility, the Background Document should be corrected to avoid misunderstanding the integrated toxicology data, including data demonstrating that observed toxic and metabolic effects relevant to the tumorigenic process are species-specific, and data regarding the relevance of laboratory animal responses for extrapolating to humans, as discussed in the Panel's October 2, 2002, Comments[35] and other comments submitted by the Panel.[36]
- The Background Document should include summaries of any scientific data meeting the SDWA standards, as adapted in the HHS Guidelines, that either RG2 or the NTP RoC Subcommittee intends to discuss in any repeat meetings that are held pursuant to this correction request. It should also correct any factual errors or omissions that were noted by RG1 and then subsequently by RG2.

**B. Requested Correction of the RG1 and RG2 Review Summaries and of the RG2 Proceedings**

Both the RG1 and the RG2 summary reports fail to meet the requirements for objectivity, both in substance with regard to completeness, and in presentation (with regard to presentation in a clear and complete manner). Moreover, the RG1 and RG2 review summaries constitute "influential scientific" information because they, like the Background Document, when disseminated will and do have a clear and substantial impact on important policies or important private sector decisions. The RG1 and RG2 recommendations and findings are considered by the NTP Director in determining whether to list naphthalene in the *RoC*, particularly since the Background Document is never revised to reflect the points they consider. Further, the public may be expected to use and rely upon the information in the RG1 and RG2 summary reports. Accordingly, these documents are required to have a particularly high degree of transparency and are subject to the SDWA requirements of comprehensiveness and informativeness.

The RG1 and RG2 summary documents fail to meet these as well as the utility requirements. The RG1 review summary fails to provide a detailed analysis of the key issues that led RG1 to make its recommendation. It does not explain how the nasal tumors in the rats satisfy the *RoC* listing requirements and why NTP's mouse study should be considered at all. Nor does it explain how RG1 concluded that the anatomical, physiological, and metabolic differences between rats and humans are not sufficient to rule out the relevance of the rat and mouse tumors to humans.

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35 October 2, 2002, Comments at Section III.B.

36 *See, e.g.,* March 24, 2003, Comments (Attachment H) at 10-16; September 24, 2001, Comments at 3-8.

The RG2 summary review similarly fails to explain how each of the two groups in the split vote reached their respective recommendations.

Moreover, the RG2 proceeding was subject to the pre-dissemination review requirements, as discussed above. The fact that it was provided with a flawed and incomplete Background Document as the primary basis for its review and recommendation establishes by definition that it failed to consider, use, or integrate the best available science and supporting studies, including peer reviewed studies, with respect to mechanism and genotoxicity.

The RG1 review summary and the RG2 review summary (if not rescinded), should be revised to correct the deficiencies described above. In addition, the RG2 findings and recommendations with regard to naphthalene should be rescinded and a new RG2 meeting convened, after preparation of a corrected Background Document.

**C. Requested Correction of the NTP RoC Subcommittee Proceedings**

The NTP RoC Subcommittee proceedings at a minimum represent NTP's view that the proceedings, including the meeting, the vote, and the publication of the Subcommittee's recommendation, were conducted in an objective, fair, unbiased manner, that the deliberations were transparent, and that the proceedings otherwise satisfied the requirements of the Guidelines, including those for pre-dissemination review. Indeed, the publication of the results of the Subcommittee vote and NTP's moving forward with the RoC listing procedures further indicate that the NTP believes that the recommendations and proceedings of the Subcommittee are worthy of the full consideration of the Executive Committee and the NTP Director. Therefore, the Panel is seeking correction of proceedings in the NTP RoC Subcommittee meeting on the grounds that it was conducted in a highly irregular manner that resulted in its failure to satisfy any of these requirements.

Moreover, as in the case of the Background Document and the RG1 and RG2 summary reports, the Subcommittee proceedings constitute "influential" scientific information and therefore are subject to a particularly rigorous degree of pre-dissemination review and a particularly high level of transparency. The Subcommittee meeting is the last of the three scientific review group meetings before all the recommendations and other relevant materials are provided to the NTP Executive Committee and the NTP Director. The Subcommittee meeting and its recommendation carry particularly significant weight in the RoC review process because the Subcommittee is the last of the three scientific review groups and because it is the only one of the scientific review groups that conducts an external peer review open to the public and which allows for consideration of public comments submitted prior to its proceedings. Accordingly, the proceedings and the Subcommittee's recommendations will have a clear and substantial impact on important public policies (*i.e.*, the decision on whether to list naphthalene in the RoC), which in turn will have a clear and substantial impact on important public sector decisions.[37]

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[37] OMB Guidelines, 67 Fed. Reg. at 8460 (col. 3 (#9)); NIH Guidelines at Section VII.

The primary violation of the Subcommittee's proceedings with respect to the Guidelines' requirements for objectivity, transparency, and utility originate from the highly irregular and prejudicial step taken by the Chairman of the Subcommittee, of temporarily stepping down as Chairman during the Subcommittee's meeting to present a highly technical presentation on naphthalene that included new information[38] that apparently had neither been shared prior to the meeting with the Subcommittee members, nor made part of the public record by NTP prior to, during, or since the meeting. Substantively, the new information presented by the Chairman to the Subcommittee during its deliberations, which appears to have significantly influenced the Subcommittee vote, included categorically incorrect statements regarding a class of chemicals known as "polycyclic aromatic hydrocarbons" (PAHs), which the Chairman asserted to include naphthalene.

For example, the Chairman argued that naphthalene belongs to the class of chemicals known as PAHs which, he stated, are "known carcinogens." It is well known, however, that the toxicological categorization of naphthalene as a PAH is unusual in the scientific community, and that it is inaccurate and scientifically indefensible to state categorically that all PAHs are "known carcinogens." The International Agency for Research on Cancer (IARC) has expressly addressed these issues. Volume 32 of the *IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans* discusses the carcinogenicity data on 42 PAH compounds. Following the Preamble, IARC's scientists state that "only condensed aromatic hydrocarbons and aza arenes with three or more rings are considered" in their review of PAHs and heterocyclics that have been tested for carcinogenicity[39] and that occur in the environment. More importantly, it is well known that the classification of PAHs is disputed. Although it is true that 15 or so PAHs are considered as known experimental or animal carcinogens, and several are considered to be human carcinogens, many others are not considered carcinogenic at all. Anthracene, fluoranthene, 1-methylchrysene, and pyrene are examples of PAHs that have been evaluated for carcinogenicity and are considered not carcinogenic by IARC, NTP, and the U.S. Environmental Protection Agency (EPA).[40] There is no information, moreover, regarding toxicological categorization of naphthalene as a PAH in any of the nomination or background materials presented by NTP in support of the nomination of naphthalene to the RoC.[41]

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38 Transcript, November 19, 2002, at 74-75 and 100-101.

39 Although the NTP bioassays on naphthalene were not completed until after publication of IARC Volume 32 in 1983, at least three independent cancer bioassays and one cell transformation assay on naphthalene were published at the time of the IARC review. Included in that Monograph are reviews on a number of PAH compounds with less experimental data available than that for naphthalene in 1983.

40 *See* EPA's IRIS documents for these chemicals, available online at http://www.epa.gov/iris/.

41 Other highly influential information newly introduced by the Chairman, on the day of the meeting, included information on alternative metabolic pathways and unsubstantiated

The presentation of such highly technical data to the Subcommittee members on the very day of the meeting, and the failure to make such information available to the public in advance of the meeting, did not allow the Subcommittee (or any interested party) sufficient time meaningfully to review the new information, confirm its accuracy, and evaluate its relevance to the listing of naphthalene. Nevertheless, the Subcommittee appeared to accept the statements of the Chairman at face value. Subcommittee members almost certainly afforded the unreviewed information and remarks considerably more weight and deference than would otherwise be the case because the presenter was, in fact, was Chairman of the Subcommittee, despite his attempt to state otherwise solely for the purpose of introducing his remarks. Similarly, the public, including the Panel, was denied any opportunity to comment on the new information and bring to the attention of the Subcommittee the flaws in the information and its lack of relevance.

Accordingly, since the Subcommittee was denied advance access to the full record considered by the Subcommittee, the purpose of the Subcommittee proceedings to conduct a meaningful external peer review was denied. This purpose was also compromised by the inability of the public, including the Panel, to comment on the newly introduced, and highly material, information. As a result, the proceedings and recommendation of the Subcommittee lacked objectivity both in substance, with regard to accuracy, reliability and bias, and in presentation (*i.e.*, in that the presentation of the new information and the deliberations on that information were not made in a clear and unbiased manner).

Moreover, the Subcommittee proceedings and vote fail to meet the rigorous standards of transparency applicable to "influential" scientific information. This follows not only from the fact that the reasoning of the Subcommittee in making its vote was not explicit, but also because the reasoning process was undoubtedly compromised by the last minute introduction of highly material information by the Subcommittee Chairman. The proceedings also failed the transparency test because the introduced materials included highly material information, such as information on metabolic pathways, which, during his presentation, the Chairman was unable to show even to the Subcommittee. In addition, during the proceedings the Chairman provided materials to the Subcommittee that were not made available to members of the public attending the meeting, let alone the general public, and discussed research results, apparently from his laboratory, and which, though said to have been published, were not provided to the Subcommittee and which were not identified by reference.[42]

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statements concerning the presence of naphthalene as a component of "urban air pollution" as reasons for listing naphthalene. *See, e.g.,* March 24, 2003 Comments (Attachment H) at 16-18 ; Transcript, November 19, 2002 (Attachment D) at 100-101.

[42] The citations later provided to the Panel by K. Olden (letter of Jan. 27, 2003) were: Flowers-Geary *et al.*, 1996; McCoull *et al*., 1999; Penning *et al*., 1999; Yu *et al*., 2002. These references were discussed in the Panel's comments of March 24, 2003 (Attachment H).

Further, the information introduced to the Subcommittee after the public comment period violates the requirements of the SDWA, applicable to "influential" scientific information, as discussed above, to use the best available science and supporting studies conducted in accordance with objective scientific practices, including peer reviewed studies when available. Because of the manner in which the information was introduced, it was impossible to verify if the studies discussed met these requirements. Clearly other information for which no documentation could be provided did not meet these standards.

It should be noted that the recommendations and other findings of the Subcommittee are not subject to the presumption of objectivity for data and analytical results that have been subjected to formal, independent peer review that is provided by the Guidelines.[43] To meet the requirements for such presumption, the peer review must meet the criteria recommended by OMB-OIRA to the President's Management Council, which among other criteria requires that peer reviews be conducted in an open and rigorous manner.[44] As discussed above, the Subcommittee proceedings were not conducted in a transparent manner and therefore by definition are not entitled to a presumption of objectivity. In any event, any such presumption of objectivity can be rebutted and to claim such a presumption in the case at hand is not warranted by any interpretation of the transcript (Attachment D).

Finally, the Subcommittee proceedings fail to meet the Guidelines' requirement for utility from the perspective of both NTP and the public. Clearly, proceedings and recommendations that emanate from such proceedings that are not objective, not transparent, and that are strongly influenced by bias do not serve the objective of making a RoC listing decision that is sound scientifically and free from bias. Such proceedings also fail to satisfy the utility criteria by not allowing for public access to ensure improvement of overall quality of the recommendation.[45]

Because the NTP RoC Subcommittee proceedings occurred after October 1, 2002, they were subject to the pre-dissemination review requirements of the Guidelines. Under this review process, it was NTP's obligation to review the integrity of the Subcommittee meetings and their compliance with the Guidelines' requirements. For the reasons discussed above, NTP, if it had properly reviewed the proceedings, could only conclude that the Subcommittee proceedings did not meet these requirements. Accordingly, NTP should have announced proactively that the Subcommittee meeting would be repeated, after ensuring that all material information, including the updated Background Document, was made available to the Subcommittee members and the public in advance. At the same time, NTP should have negated the vote of the November 19, 2002, Subcommittee meeting. The Panel has made this request in previous correspondence with NTP. The Panel believes that, under the IQA, NTP is obligated to

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43 OMB Guidelines, 67 Fed. Reg. at 8459; HHS Guidelines, Part I.D.2.c.

44 *Id.*

45 NIH Guidelines at Introduction, Section VII; OMB Guidelines, 67 Fed. Reg. at 8456-57, 8460.

correct the substantial and highly prejudicial flaws of the November 19, 2002, Subcommittee meeting by taking precisely these measures.

## V. CONCLUSION

For the reasons discussed above, the November 19, 2002, RoC Subcommittee meeting on naphthalene was conducted in a manner that violated the Information Quality Act and the implementing OMB, HHS, and NIH Guidelines. Moreover, the Background Document does not satisfy the standards of the OMB, HHS, and NIH Guidelines applicable both to disseminated information and to information that is integral to key steps of NTP's development of disseminated information. Similarly, the RG1 and RG2 review summaries fail to meet the requirements for objectivity both in substance (with regard to completeness) and in presentation (with regard to presentation in a clear and complete manner), as well as the requirements for utility. Moreover, the fact that RG2 was provided with a flawed and incomplete Background Document as the primary basis for its review and recommendation, very shortly before its meeting, establishes by definition that RG2 failed to consider, use, or integrate the best available science and supporting studies in its deliberations, and therefore violated the pre-dissemination review requirements under the Guidelines.

The best and only appropriate solution to these violations is for NTP to rescind the November 19, 2002, vote of the RoC Subcommittee on the listing of naphthalene, rescind the RG2 review summary, withdraw the Background Document from NTP's website and otherwise cease dissemination of that document, correct the Background Document so that it comports with the OMB, NIH, and HHS Guidelines, make the corrected document publicly available, and arrange for repeats of the RG2 and NTP RoC Subcommittee meetings that comport with the OMB, NIH, and HHS Guidelines, to be held after issuance of the corrected Background Document. NTP should also correct the RG1 and, if not rescinded, the RG2 review summaries to provide the necessary detail to satisfy the objectivity and utility requirements.

Alternatively, if this remedy is not granted, the Panel requests that NTP staff, NIH's OPCL, and the NTP Executive Committee engage in a well-defined process of pre-dissemination review of the entire naphthalene record with regard to the data quality standards under the NIH, OMB, and HHS Guidelines before the NTP Executive Committee makes its recommendation to the NTP Director.

If you seek additional information, please contact Dr. Anne P. LeHuray at (703) 741-5630 or *anne_lehuray@americanchemistry.com*.

Sincerely yours,

/s/

Courtney M. Price
Vice President, CHEMSTAR

cc: John D. Graham, Ph.D., OIRA, OMB
Elias A. Zerhouni, M.D., Director, NIH
Alex M. Azar II, Esquire, General Counsel, HHS
Kenneth Olden, Ph.D., Director, NTP
Mr. Lou Rozier, Office of the Director, NIEHS
Naphthalene Panel Members

American Chemistry Council
Naphthalene Panel

Request for Correction of Information

Pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (the Information Quality Act)

# Index of Attachments

Hard copies of Attachments are included in the hard copy submission. For the electronic submission, links to the Attachments are provided.

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| Attachment B | Draft Report on Carcinogens Background Document for Naphthalene 26 August 2002. http://ntp-server.niehs.nih.gov/NewHomeRoc/roc11Bkgrnd2002.html |
| Attachment C | NTP Executive Committee Working Group for the Report on Carcinogens – RG2 [dated October 2, 2002]. http://ntp-server.niehs.nih.gov/NewHomeRoc/roc11Bkgrnd2002.html |
| Attachment D | Condensed Transcript, National Institute of Environmental Health Sciences, National Toxicology Program (NTP), Board of Scientific Counselors, Report on Carcinogens (ROC) Subcommittee Meeting, November 19, 2002. Available on NTP's web site as an attachment to the Panel's March 2003 comments (see Attachment H). http://ntp-server.niehs.nih.gov/newhomeroc/roc11naphthalene.html |
| Attachment E | Comments of the Naphthalene Panel on July 24, 2001, Call for Public Comment on 16 Substances, Mixtures and Exposure Circumstances Proposed for Listing in the Report on Carcinogens, Eleventh Edition, 66 Fed. Reg. 38430 (Sept. 24, 2001) at 4. http://ntp-server.niehs.nih.gov/newhomeroc/roc11naphthalene.html |
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| Attachment H | Comments of the Naphthalene Panel in response to the Call for Public Comments on 10 Nominations in January 22, 2003 Federal Register [submitted March 24, 2003]. http://ntp-server.niehs.nih.gov/newhomeroc/roc11naphthalene.html |

American Chemistry Council

Naphthalene Panel

Request for Correction of Information

Pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (the Information Quality Act)

# Attachment A

# Review Summary of the National Institute of Environmental Health Sciences (NIEHS/NTP) RoC Review Committee (RG1)

Date: 10 June 2002

(available at http://ntp-server.niehs.nih.gov/NewHomeRoc/roc11Bkgrnd2002.html)

American Chemistry Council

Naphthalene Panel

Request for Correction of Information

Pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (the Information Quality Act)

# Attachment B

# Draft
# Report on Carcinogens
# Background Document
# for Naphthalene

## 26 August 2002

(available at http://ntp-server.niehs.nih.gov/NewHomeRoc/roc11Bkgrnd2002.html)

American Chemistry Council

Naphthalene Panel

Request for Correction of Information

Pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (the Information Quality Act)

# Attachment C

# NTP Executive Committee Working Group for the Report on Carcinogens – RG2

Review Date: 2 October 2002

(available at http://ntp-server.niehs.nih.gov/NewHomeRoc/roc11Bkgrnd2002.html)

American Chemistry Council

Naphthalene Panel

Request for Correction of Information

Pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (the Information Quality Act)

# Attachment D

# Condensed Transcript

# National Institute of Environmental Health Sciences

# National Toxicology Program (NTP)

# Board of Scientific Counselors

## Report on Carcinogens (ROC) Subcommittee Meeting

Date: 19 November 2002

American Chemistry Council

Naphthalene Panel

Request for Correction of Information

Pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (the Information Quality Act)

# Attachment E

# Comments of the Naphthalene Panel on the Nomination of Naphthalene for Possible Listing in the Report on Carcinogens

Submission Date: 24 September 2001

American Chemistry Council

Naphthalene Panel

Request for Correction of Information

Pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (the Information Quality Act)

# Attachment F

# Comments of the Naphthalene Panel on the Draft Background Document

Submission Date: 2 October 2002

American Chemistry Council

Naphthalene Panel

Request for Correction of Information

Pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (the Information Quality Act)

# Attachment G

# Comments of the Naphthalene Panel on the Release of the RG2 Review

Submission Date: 4 November 2002

American Chemistry Council

Naphthalene Panel

Request for Correction of Information

Pursuant to Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (the Information Quality Act)

# Attachment H

# Comments of the Naphthalene Panel in response to the Call for Public Comments on 10 Nominations in January 22, 2003 Federal Register

Submission Date: 24 March 2003