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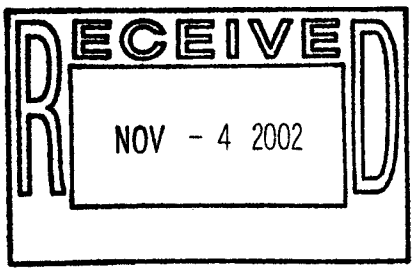
November 4, 2002



Via E-Mail and FedEx

Dr. C.W. Jameson
National Toxicology Program
Report on Carcinogens
79 Alexander Drive
Building 4401, Room 3118
P.O. Box 12233
Research Triangle Park, NC 27709

Re: National Toxicology Program (NTP) Executive Committee
Working Group for the Report on Carcinogens - RG2
Naphthalene Review (October 2, 2002)

Dear Dr. Jameson:

The Naphthalene Panel (Panel) of the American Chemistry Council submits these supplemental comments to NTP regarding the nomination of naphthalene for listing in the 11th *Report on Carcinogens* (*RoC*).[1] On October 2, 2002, NTP's Executive Committee Working Group for the RoC, sometimes known as "RG2," reviewed data and other information relating to the naphthalene nomination. The RG2 review resulted in a tie vote, with the conclusion, "...the Director NTP will be informed that the RG2 could not make a majority recommendation for either listing or not listing naphthalene in the RoC."[2] The Panel submits these comments in support of the second motion, "Recommend that naphthalene not be listed in the RoC because the relevant data are insufficient to list as *reasonably anticipated to be a human carcinogen*."

The Panel also wishes to express its disappointment that, in its haste to nominate and consider the potential listing of naphthalene, NTP has made inadequate allowances for stakeholder involvement in the listing process. For this reason the Panel respectfully requests

[1] Federal Register July 24, 2001 (Vol. 66, No. 142) pages 38430-38432; Federal Register: March 28, 2002 (Vol. 67, No. 60) page 14957; Federal Register: May 24, 2002 (Vol. 67, No. 101) pages 36621-36622; Federal Register: September 20, 2002 (Vol. 67, No. 183) pages 59301 – 59303.

[2] *RG2 Review Summary Document for Naphthalene*, available on-line at http://ntp-server.niehs.nih.gov/NewHomeRoc/roc11Bkgrnd.html.

that naphthalene not be taken up for consideration at the November 19-20, 2002, meeting of the NTP Board of Scientific Counselors Report on Carcinogens Subcommittee (NTP RoC Subcommittee), but rather be deferred for later consideration by that Subcommittee in 2003. The Panel bases this request on due process considerations as well to promote an appropriate evaluation of the scientific basis of the naphthalene nomination.

The September 20, 2002, *Federal Register* notice (67 Fed. Reg. 59301-59303) announcing the November 19-20, 2002, meeting of the NTP RoC Subcommittee designated naphthalene as one of ten chemicals nominated for listing in the *RoC* that was "[t]entatively scheduled" for review at that meeting. The *Federal Register* notice also indicated that all ten chemicals "have completed review by the RG1 and the RG2." In fact, RG2 review of naphthalene had not been completed on the date the notice was published. Rather, the RG2 report was not posted on NTP's website and publicly announced until October 18, 2002, nearly a month after the notice of the NTP RoC Subcommittee meeting. Further, the RG2 report indicates an RG2 review date of October 2, 2002, which also follows and is inconsistent with the September 20, 2002 notice. Accordingly, on procedural grounds alone, because of the misstatement of the status of the RG2 review of naphthalene in the September 20, 2002, notice, naphthalene should not be taken up for consideration at the November 19-20, 2002, meeting. This is particularly apt in light of the fact that the notice indicates that naphthalene was only "tentatively scheduled" for the November meeting.

The tie vote by the RG2 review committee is, in the Panel's view, further evidence that the consideration of naphthalene for potential listing in the 11th RoC was premature. The speed at which the listing has occurred is at the expense of appropriate consideration of the scientific and legal bases for listing, resulting in an apparently rushed *Draft Report on Carcinogens Background Document for Naphthalene, 26 August, 2002*[3] (see the Panel's October 2, 2002 comments) as well as in lack of consensus among RG2 reviewers. If naphthalene is reviewed at the November 19-20 meeting, the Panel as well as other interested parties will be given an extremely short amount of time to evaluate and analyze the implications of the RG2 recommendations and to take those recommendations into account in written comments. The RG2 found the issues concerning the listing of naphthalene to be highly complicated and controversial. Not only did the RG2 have a highly unusual, if not unprecedented, split vote on the listing of naphthalene in the *RoC* (4 votes in favor and 4 votes against), the Chair of the RG2 chose to abstain from casting a tie-breaking vote as a result of "the difficulty the RG2 had with this nomination."[4] Given these complexities and based on fairness and due process considerations, interested parties should be provided far more time to address the issues raised by the RG2 than is afforded by the November 4, 2002, deadline for submission of written comments.

The Panel also believes that even if it were given an extension beyond November 4, 2002, to supplement its comments for consideration at the November 19-20 meeting, it would have insufficient time to address completely the issues raised by the RG2 recommendation.

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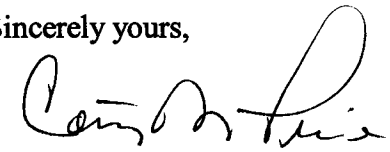
[3] The *Draft Background Document* is available on-line at http://ntp-server.niehs.nih.gov/NewHomeRoc/roc11Bkgrnd.html.

[4] The language quoted is taken from the *RG2 Review Summary Document for Naphthalene.*

Further, a later supplemental submission of comments might impair the ability of the members of the NTP RoC Subcommittee to give those comments their full consideration. The Panel is confident that a deferral of naphthalene to a later Subcommittee meeting would enable the NTP RoC Subcommittee, the Panel and other interested parties time to evaluate this controversial matter that would be useful to in considering the basis for listing or not listing naphthalene in the RoC.

For further information, please call the Naphthalene Panel Manager, Dr. Anne LeHuray at (703) 741-5630 or e-mail at: anne_lehuray@americanchemistry.com.

Sincerely yours,



Courtney M. Price
Vice President, CHEMSTAR