From: George Woodall
To: Stan Durkee; John Vandenberg
Cc: Bill Russo; Bob Hetes; Douglas Mckinney; Michel Stevens; Michele Aston; Robert Fegley; Robert Mcgaughy; Tim Benner; Tim Watkins; William Petersen
Subject: Re: Outstanding Issues with Draft Ethylene Oxide Residual Risk Assessment
Date: 08/03/2004 09:24 AM

Stan,

(b) (5)

I can provide copies (perhaps in scanned PDF files) of the documents that were faxed to me, if you so desire. Let me know if there is any additional information that you may need.

Best regards,
George

George M. Woodall, Ph.D
Toxicologist
National Center for Environmental Assessment (B243-01)
US Environmental Protection Agency
Research Triangle Park, NC 27711

Phone: (919) 541-3896
Fax: (919) 541-0245
E-mail: woodall.george@epa.gov
▼ George Woodall

George Woodall

To: Stan Durkee/DC/USEPA/US
cc: Bill Russo/RTP/USEPA/US@EPA, Bob

08/02/2004
03:14 PM

Hetes/RTP/USEPA/US@EPA, Douglas Mckinney/RTP/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Michel Stevens/RTP/USEPA/US@EPA, Michele Aston/RTP/USEPA/US@EPA, Robert Fegley/DC/USEPA/US@EPA, Robert Mcgaughy/DC/USEPA/US@EPA, Stan Durkee/DC/USEPA/US@EPA, Tim Benner/DC/USEPA/US@EPA, Tim Watkins/RTP/USEPA/US@EPA, William Petersen/RTP/USEPA/US@EPA
Subject: Re: Outstanding Issues with Draft Ethylene Oxide Residual Risk Assessment

Stan,

(b) (5)

George

▼ Stan Durkee

Stan Durkee

07/26/2004
05:29 PM

To: Bill Russo/RTP/USEPA/US@EPA, Douglas Mckinney/RTP/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Tim Watkins/RTP/USEPA/US@EPA, Stan Durkee/DC/USEPA/US@EPA, Robert Mcgaughy/DC/USEPA/US@EPA, Michel Stevens/RTP/USEPA/US@EPA, Bob Hetes/RTP/USEPA/US@EPA, Michele Aston/RTP/USEPA/US@EPA, George Woodall/RTP/USEPA/US@EPA, William Petersen/RTP/USEPA/US@EPA, Robert Fegley/DC/USEPA/US@EPA, Tim Benner/DC/USEPA/US@EPA
cc:
Fax to:
Subject: Outstanding Issues with Draft Ethylene Oxide Residual Risk Assessment

NOTE TO: Ethylene Oxide Residual Risk Review Team:

Please see Bob's note (Attachment 2, second note below) noting the results of his meeting with OAQPS managment on three outstanding issues with the draft ethylene oxide residual risk assessment:

(b) (5)

Thanks for your cooperation.

Stan

Attachment 1

Deirdre Murphy

To: Mark Morris/RTP/USEPA/US@EPA
cc:
Subject: ETO - NIOSH values basis

07/02/2004
04:20 PM

Hi Mark,
I found the basis for my thinking the NIOSH values are based on analytical capabilities. See blue sentence below in Appendix A of the NIOSH pocket guide on their web site.
Deirdre
p.s. REL = Recommended Exposure Limit

NIOSH POCKET GUIDE TO CHEMICAL HAZARDS
APPENDICES

A B C D E F G

APPENDIX A
NIOSH Potential Occupational Carcinogens

New Policy

For the past 20 plus years, NIOSH has subscribed to a carcinogen policy that was published in 1976 by Edward J.

Fairchild, II, Associate Director for Cincinnati Operations, which called for "no detectable exposure levels for proven carcinogenic substances" (Annals of the New York Academy of Sciences, 271:200-207, 1976). This was in response to a generic OSHA rulemaking on carcinogens. Because of advances in science and in approaches to risk assessment and risk management, NIOSH has adopted a more inclusive policy. NIOSH recommended exposure limits (RELs) will be based on risk evaluations using human or animal health effects data, and on an assessment of what levels can be feasibly achieved by engineering controls and measured by analytical techniques. To the extent feasible, NIOSH will project not only a no-effect exposure, but also exposure levels at which there may be residual risks. This policy applies to all workplace hazards, including carcinogens, and is responsive to Section 20(a)(3) of the Occupational Safety and Health Act of 1970, which charges NIOSH to ". . .describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience."

The effect of this new policy will be the development, whenever possible, of quantitative RELs that are based on human and/or animal data, as well as on the consideration of technological feasibility for controlling workplace exposures to the REL. Under the old policy, RELs for most carcinogens were non-quantitative values labeled "lowest feasible concentration (LFC)." [Note: There are a few exceptions to LFC RELs for carcinogens (e.g., **RELs for asbestos, formaldehyde, benzene, and ethylene oxide are quantitative values based primarily on analytical limits of detection or technological feasibility**). Also, in 1989, NIOSH adopted several quantitative RELs for carcinogens from OSHA's permissible exposure limit (PEL) update.]

Under the new policy, NIOSH will also recommend the complete range of respirators (as determined by the NIOSH Respirator Decision Logic) for carcinogens with quantitative RELs. In this way, respirators will be consistently recommended regardless of whether a substance is a carcinogen or a non-carcinogen.

Old Policy

In the past, NIOSH identified numerous substances that should be treated as potential occupational carcinogens even though OSHA might not have identified them as such. In determining their carcinogenicity, NIOSH used the OSHA classification outlined in 29 CFR 1990.103, which states in part:

Potential occupational carcinogen means any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species as the result of any oral, respiratory or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration. This definition also includes any substance which is metabolized into one or more potential occupational carcinogens by mammals.

When thresholds for carcinogens that would protect 100% of the population had not been identified, NIOSH usually recommended that occupational exposures to

carcinogens be limited to the lowest feasible concentration. To ensure maximum protection from carcinogens through the use of respiratory protection, NIOSH also recommended that only the most reliable and protective respirators be used. These respirators include (1) a self-contained breathing apparatus (SCBA) that has a full facepiece and is operated in a positive-pressure mode, or (2) a supplied-air respirator that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode in

combination with an auxiliary SCBA operated in a pressure-demand or other positive-pressure mode.

Recommendations to be Revised

The RELs and respirator recommendations for carcinogens listed in this edition of the Pocket Guide still reflect the old policy. Changes in the RELs and respirator recommendations that reflect the new policy will be included in future editions.

Attachment 2

----- Forwarded by Stan Durskee/DC/USEPA/US on 07/26/2004 05:02 PM -----

Robert Fegley

07/23/2004
02:43 PM

To: Durkee.Stan@EPAMAIL.EPA.GOV@EPA
cc: Tim Benner/DC/USEPA/US@EPA, George Woodall/RTP/USEPA/US@EPA, Dave Guinnup/RTP/USEPA/US@EPA
Fax to:
Subject: Ethylene oxide discussion

Here is a summary of my discussion with Dave Guinnup regarding the ethylene oxide sterilizer assessment. Dave has taken a look at this and agrees with the summary here.

ORD has three sets of concerns with the project as it currently stands:

(b) (5)

(b) (5) [redacted]

Thanks,

Bob

PS Stan, please share this summary with others on the workgroup (such as other ORD folks, OECA, OPEI and OGC). Dave will be talking with others in OAQPS as well.

Robert Fegley,
Air Media Manager
Office of Science Policy
Office of Research and Development
USEPA
Washington DC

202/564-6786