DTSC Comments

September 17, 2004

Department of Toxic Substances Control

Terry Tamminen
Agency Secretary
Cal/EPA

Edwin F. Lowry, Director
700 Heinz Avenue, Suite 200
Berkeley, California 94710-2721

Arnold Schwarzenegger
Governor

FILE COPY

September 17, 2004

Mr. Iraj Javandel
Environmental Restoration Program
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COMMENTS ON CORRECTIVE MEASURES STUDY REPORT, JULY 2004 FOR THE LAWRENCE BERKELEY NATIONAL LABORATORY (LBNL), BERKELEY, CALIFORNIA, EPA ID No. CA 4890008986

Dear Mr. Javandel:

The Department of Toxic Substances Control (DTSC) has reviewed the Draft Corrective Measures Study Report for the Lawrence Berkeley National Laboratory, dated July 2004.

Mr. Michael B. Rochette of California Regional Water Quality Control Board, Dr. Calvin C. Willhite of our Human and Ecological Risk Division, and Mr. Buck King of our Geologic Services Unit have provided their comments (see Attachments). Please note that Mr. Nabil Al-Hadithy of the City of Berkeley has not sent his comments in a letter to DTSC which we have requested.

Please provide your response by October 18, 2004.

Should you have any questions, please call me at 510- 540-3932.

Sincerely,

Waqar Ahmad

Waqar Ahmad
Hazardous Substances Engineer
Standardized Permits and Corrective Action Branch

cc: Mr. Hemant Patel
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Department of Toxic Substances Control

Terry Tamminen
Agency Secretary
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700 Heinz Avenue, Suite 200
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Arnold Schwarzenegger
Governor

MEMORANDUM

TO: Waqar Ahmad
Hazardous Substance Engineer
Standardized Permitting and Corrective Action Branch
Berkeley Regional Office

FROM: Buck King, RG, CHG *BK*
Engineering Geologist
Geology, Permitting and Corrective Action Branch, Northern California
Geological Services Unit, Berkeley Regional Office

CONCUR: Brian Lewis, CEG, CHG *BK for BL*
Engineering Geologist Supervisor I
Geology, Permitting and Corrective Action Branch, Northern California
Geological Services Unit, Sacramento Regional Office

DATE: September 16, 2004

SUBJECT: Review of Draft RCRA Corrective Measures Study Report for Lawrence Berkeley National Laboratory, Berkeley, Alameda County, California
Project No. 22120/200178-48/39-HWMP

DOCUMENT REVIEWED

Draft RCRA Corrective Measures Study Report for Lawrence Berkeley National Laboratory. Prepared by Lawrence Berkeley National Laboratory. (CMS Report)

INTRODUCTION

The Northern California Geological Services Unit (GSU) of the Department of Toxic Substances Control (DTSC) has completed our review of the CMS Report dated July, 2004. The GSU has no comments on the CMS Report. If you have any questions, please contact Buck King at (510) 540-3955 or Brian Lewis at (916) 255-6532.

Department of Toxic Substances Control

Terry Tamminen
Agency Secretary
Cal/EPA

Arnold Schwarzenegger
Governor

MEMORANDUM

TO: Waqar Ahmed
Standardized Permitting and Corrective Action Branch
700 Heinz Street, Suite 300
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FROM: Calvin C. Willhite, Ph.D.
Human and Ecological Risk Division
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DATE: September 10, 2004

SUBJECT: Lawrence Berkeley National Laboratory
University of California
Berkeley, California

PCA: 22120 Site-WP: 200178-48 MPC: 39-PER

In response to a request from the Hazardous Waste Management Program to the Human and Ecological Risk Division (HERD) on July 27, 2004 for review of the "RCRA Corrective Measures Study Report for the Lawrence Berkeley National Laboratory, the following is provided. No comment is made concerning site characterization protocols, sampling locations or criteria, data quality objectives, constituent or media sampling depths, numbers of samples, specific analytical methods, quality assurance or verification. No comment concerning any aspect of site ecological risk (if any) associated with regulated materials site is offered.

INTRODUCTION

The Lawrence Berkeley National Laboratory (LBNL) has advanced to the Corrective Measures Study (CMS) phase of site discovery, evaluation and remediation. The plan for conduct of the CMS was approved by the DTSC on June 8, 2002 and the materials reviewed here followed the approved plan.

The soil and groundwater areas presented in the CMS of previously unresolved concern are those identified on the attached figure: SWMUs and AOCs Recommended for Inclusion in Corrective Measures Study, Lawrence Berkeley National Laboratory (LBNL). The present review focused primarily upon media clean-up standards (Sections 3.1-3.4, 4 and 5) and directs the reader to new, published risk assessment information for a primary risk-driver at the site.

GENERAL COMMENT

The report is well-organized and clearly presents nearly all options with estimated financial costs for each level of theoretical health risk. Each of the various options is presented with each risk level identified in the U.S. EPA acceptable risk range. While it is beyond the expertise of risk assessment to evaluate the accuracy of the range of cost estimates, it appears that the authors have identified correctly the applicable or relevant and appropriate requirements (ARARs) specified under the Solid Waste Disposal Act, the Toxic Substances Control Act, and the Clean Water Act. Identification of ARARs is important in establishing performance goals for remedial alternatives; ARARs are reiterated throughout the CMS and the ARARs proposed at LBNL have specific bearing on the Ground Water Project Tasks described in the CMS. It appears the LBNL authors have considered carefully all three ARAR types [ambient or chemical-specific ARARS that establish health- or risk-based specific chemical concentration limits in various LBNL environmental media; performance, design or action-specific ARARs that establish requirements on specific remedial activities related to management of hazardous materials released at LBNL; location-specific ARARs that establish administrative restrictions on and control of remedial activities based on the specific character of the LBNL). ARARs are so important to the CMS that, in fact, at LBNL the baseline public health risk assessment could have been satisfied by simply documenting the chemical-specific ARARs since all materials considered in the CMS have promulgated ARARs.

At page xiii, it is not clear why a well-head treatment option of site groundwater prior to its use as either industrial process water and/or landscape irrigation was not included in the present analysis? Given the clear need to conserve EBMUD drinking water and the opportunity to reduce the long-term financial costs associated with site mitigation, an explanation for rejection of those options should be included at some point in the document.

In general, risk analyses rely upon the upper 95% confidence limit on the arithmetic mean of the chemical concentration data for each material considering all site groundwater. The authors present the risk analyses and the proposed risk reductions based on well-by-well concentrations. While this approach takes into account possible "hot-spots" (see Risk Assessment Guidance for Superfund. Volume 1. Human Health Evaluation Manual (Part A; EPA/540/1-89/002 Section 4.3.2), this is not the customary approach to a site as a whole (U.S. EPA Publ. 9285-7-081, May 1992). Because the heterogeneous, fractured and complicated geology at LBNL provides physical limitations to handling site groundwater as a homogeneous "aquifer" data set, a brief explanation of the geologic and groundwater characteristics included either in Section 1.2 (Introduction) or as a brief clarification in the Executive Summary would facilitate the readers' understanding of the CMS approach used here.

At page 24 (line 11 from bottom), the document should do a much better job of explaining the site-specific features that lead one to the conclusions about "technical impracticability". This is a key concept presented in the CMS and must be clearly delineated – specifically, which area are amenable to remediation to MCLs and which areas are unlikely to meet the CMS goals – and – what features of those areas which are unlikely candidates for complete remediation to ARARs account for that failure? While Section 2 describes water yield and site geology, the authors should more directly explain the critical physical features which lead to the proposed ultimate "technical impractability". It is very important that the document be very clear on the specific factors that preclude certain area site groundwater remediation to MCLs.

SPECIFIC COMMENT

1. Page xv-xvii. Please identify the common names of the chemicals of concern (e.g., PCBs and/or specific VOCs) for each soil and groundwater unit listed in the table. At the soil units AOC 6-3 and SWMU 3-6, please either delete or modify the entry "No action" with a footnote the explanation of the CMS document section describing the completed interim measures or revise the entry to state "No further action". As written, the text is confusing and suggests that nothing was proposed, planned or has been completed.
2. Page xvi. At the column "Recommended Corrective Measure Alternative for Cleanup", the status of the various alternatives for AOC 1-9 and AOC 2-4 is confusing. The status of the various alternatives is not readily apparent and it is not clear which of the various alternatives are actually recommended?
3. Page xvii. At the column "Recommended Corrective Measure Alternative for Cleanup", the entry can be clarified by deletion of the phrase "is not a potential drinking water source" and replacement with "and groundwater characteristics do not meet SWRCB Resolution 88-63 provisions".
4. Page 8, Section 1.3.3. Please list the areas of concern and/or solid waste management units that have been the subjects of interim soil removals. As written, it appears that the all of the materials of concern may remain on-site where this in fact is not necessarily the case.
5. Page 10. It is worthwhile to point out that any hypothetical off-site exposure would be far less than that accounted for by the hypothetical on-site future residential exposure scenario. Therefore, the on-site risk assessments included in the HHRA account for off-site residential exposure scenarios.
6. Page 10. Please clarify what is meant by the term "relatively stable"?
7. Page 14; Tables 1.3.4-2 and 1.3.4-3. Please identify the primary chemical(s) encountered at each entry and please footnote the current status of that AOC or SWMU. Where the area or unit was retained in the CMS based on excess health risk, indicate the primary chemical that accounts for that risk.

8. Page 16. Please explain the ultimate fate of the treated water that has been collected for the past 12 years as "hydrauger effluent". Since this water is treated, to what total water volume over this dozen years does this correspond and have those treated waters been used for any beneficial purpose (e.g., LBNL industrial process or landscape irrigation)?
9. Page 23, line 11 from bottom. As written, the conclusion is speculation. Either replace the word "would" with "could" or replace the phrase with "there could be a possible adverse impact on private property values in neighborhoods adjacent to the Berkeley lab." There is no direct evidence for the statement as written.
10. Page 191, Section 5.0. Interim remedial measures for soil PCBs have already been completed at Area of Concern (AOC) 6 Building 88 and Solid Waste Management Unit (SWMU 3-6) Building 75 (Attachment 1). It is important that the reader recognize that the interim remedial measures for the laboratory were achieved and verification sampling found compliance with the soil polychlorinated biphenyl ARARs for all congeners consistent with unrestricted future site land use (e.g., Toxic Substances Control Act 40 CFR 761; Federal Register 59: 62788 and OSWER Directive No. 93555.4-01 FS, August 1990). It may be worthwhile to expand the presentation of this fact in the Executive Summary.

CONCLUSION

The CMS represents a clear presentation of options available to regulatory risk managers. The authors and the facility should be given public credit for their achievements in removal of soil PCBs to less than ARARs intended for unrestricted future land use – especially at Building 88. This is remarkable in light of the fact that the facility was able to accomplish removal actions in spite of the high voltage electrical and critical utility lines with concrete supports at the this AOC (Figure 1). These utility lines are located in soils where PCBs were found and are located near the Berkeley cyclotron; clearly the immediate danger to workers engaged in soil excavations could have been brought forward as obstacles that could impede these remedial measures. The facility has made remarkable progress in site PCB risk reduction and this fact should be recognized by regulatory agencies.

The CMS appendices should include an update on the carcinogenic potency of trichloroethylene (TCE), a material which accounts in large measure for the risk estimates presented for the various areas of concern and solid waste management units. Given the marked discrepancy between recent advancements in the science (Attachments 2-4) and the 20 year old risk assessments which formed the historical basis of the promulgated ARARs for TCE, to neglect considerations of these published advancements in TCE risk assessment would be to present an incomplete picture of the hazards (if any) associated with the TCE found in soil and groundwater at LBNL.

REFERENCES

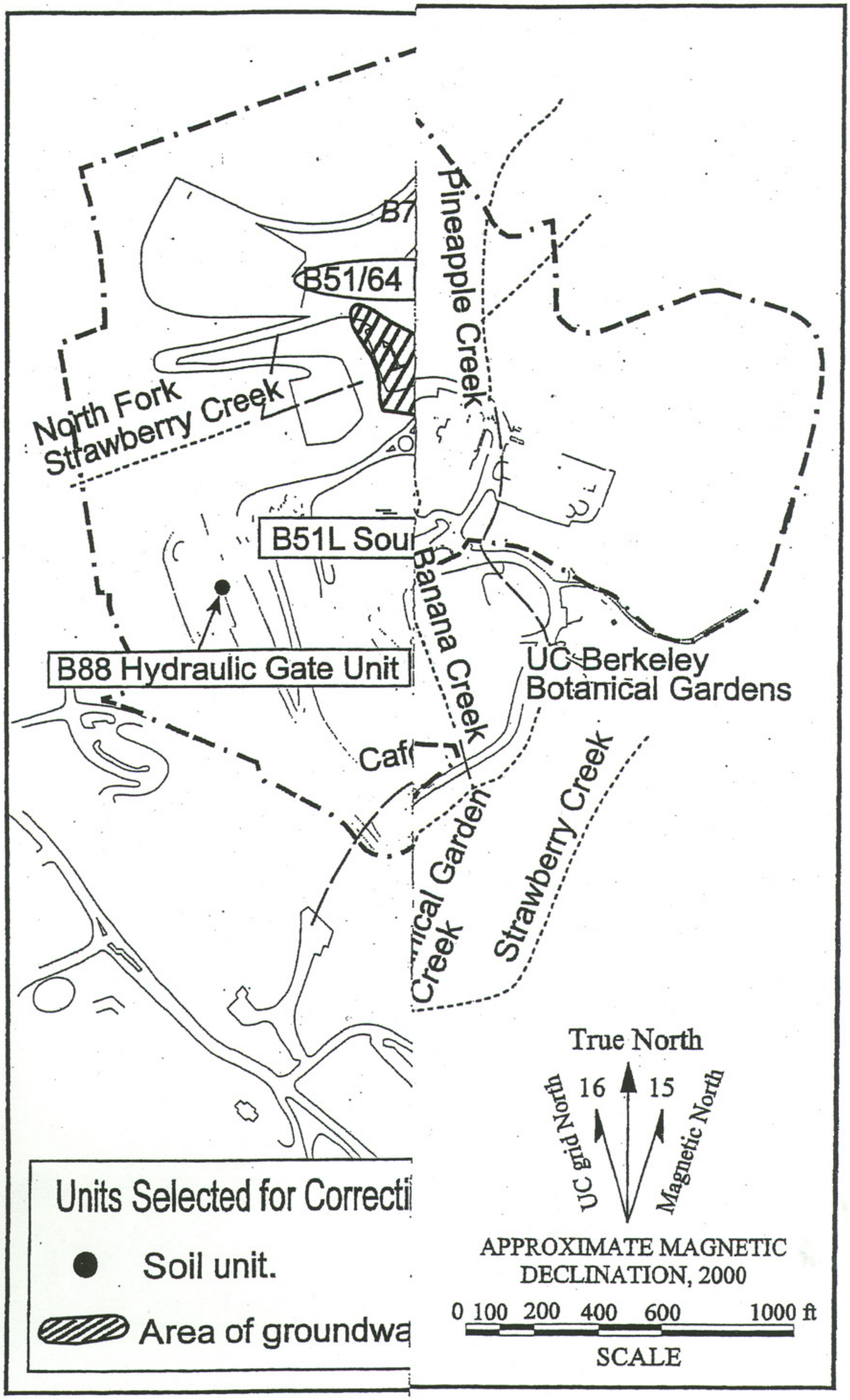
Clewell, H.J. and M.E. Andersen. 2004. Applying mode-of-action and pharmacokinetic considerations in contemporary cancer risk assessments: An example with trichloroethylene. Crit. Rev. Toxicol. 34(5): 385-445.

Kester, J.E. and H.J. Clewell. 2004. The perils and promise of modern risk assessment: the example of trichloroethylene. Clin. Occup. Environ. Med. 4: 497-512.

Ruden, C. 2001. Interpretations of primary carcinogenicity data in 29 trichloroethylene risk assessments. Toxicology 169: 209-225.

Attachments (4)

Reviewed by: David L. Berry, Ph.D.
Senior Toxicologist



SWMUs and AOCs Recentional Laboratory (LBNL)

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Applying Mode-of-Action and Pharmacokinetic Considerations in Contemporary Cancer Risk Assessments: An Example with Trichloroethylene

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ABSTRACT: The guidelines for carcinogen risk assessment recently proposed by the U.S. Environmental Protection Agency (U.S. EPA) provide an increased opportunity for the consideration of pharmacokinetic and mechanistic data in the risk assessment process. However, the greater flexibility of the new guidelines can also make their actual implementation for a particular chemical highly problematic. To illuminate the process of performing a cancer risk assessment under the new guidelines, the rationale for a state-of-the-science risk assessment for trichloroethylene (TCE) is presented. For TCE, there is evidence of increased cell proliferation due to receptor interaction or cytotoxicity in every instance in which tumors are observed, and most tumors represent an increase in the incidence of a commonly observed, species-specific lesion. A physiologically based pharmacokinetic (PBPK) model was applied to estimate target tissue doses for the three principal animal tumors associated with TCE exposure: liver, lung, and kidney. The lowest points of departure (lower bound estimates of the exposure associated with 10% tumor incidence) for lifetime human exposure to TCE were obtained for mouse liver tumors, assuming a mode of action primarily involving the mitogenicity of the metabolite trichloroacetic acid (TCA). The associated linear unit risk estimates for mouse liver tumors are 1.5×10^{-6} for lifetime exposure to 1 μg TCE per cubic meter in air and 0.4×10^{-6} for lifetime exposure to 1 μg TCE per liter in drinking water. However, these risk estimates ignore the evidence that the human is likely to be much less responsive than the mouse to the carcinogenic effects of TCA in the liver and that the carcinogenic effects of TCE are unlikely to occur at low environmental exposures. Based on consideration of the most plausible carcinogenic modes of action of TCE, a margin-of-exposure (MOE) approach would appear to be more appropriate. Applying an MOE of 1000, environmental exposures below 66 μg TCE per cubic meter in air and 265 μg TCE per liter in drinking water are considered unlikely to present a carcinogenic hazard to human health.

KEYWORDS: Cancer risk assessment, Mode-of-action, Pharmacokinetics, Trichloroethylene

I. INTRODUCTION

Assessing the potential risk associated with human exposure to carcinogenic environmental contaminants represents an uncomfortable admixture of scientific evaluation and political policy, with the potential for enormous impact on both the public health and the economic well-being of the nation. A difficult challenge facing cancer risk assessors today is to realistically consider the implications of the chemical's mechanism(s) of carcinogenicity in developing a risk assessment approach for

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CLINICS IN OCCUPATIONAL AND ENVIRONMENTAL MEDICINE

The perils and promise of modern risk assessment: the example of trichloroethylene

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Trichloroethylene (TCE; C_2HCl_3) is on the Agency for Toxic Substances and Disease Registry/US Environmental Protection Agency (EPA) Top 20 CERCLA priority list of hazardous substances (http://www.atsdr.cdc.gov/clist.html#list). It is present at 852 of 1430 Superfund sites and was selected in 1988 as the primary contaminant for the first subregistry of the Agency for Toxic Substances and Disease Registry's national exposure registry [1]. Because of the environmental prevalence of TCE, the fact that the toxicologic criteria for its systemic and carcinogenic effects have been "under review" by the EPA since the late 1980s has complicated assessments of potential human health risk for more than 15 years. Given the rapid evolution in understanding of molecular mechanisms of toxic action in recent years, the EPA's long-anticipated draft "Trichloroethylene Health Risk Assessment: Synthesis and Characterization" (TCE HRA) [2] was viewed by many as a critical test of the EPA's resolve to incorporate the best available science into its toxicity assessments, a goal articulated through several iterations of the EPA's guidelines for carcinogen risk assessment [3–5].

The EPA's re-evaluation of TCE health risks was conducted according to a new procedure in which recognized outside experts were commissioned by the EPA and other parties to document the literature and analyze key scientific questions, forming a consensus on major issues on which the EPA would rely in completing the HRA. Consensus was built through a joint EPA/government/industry effort that included two "Williamsburg meetings" [6], at which the opinions of experts on TCE and risk assessment were solicited. Subsequently, papers by several EPA scientists and outside experts, several of whom had been involved in the consensus process, were published together as "state-of-the-science" (SOS) papers in an *Environmental Health Perspectives* supplement in May 2000 [7,8]. Despite these efforts, the Agency's draft TCE HRA [2] immediately provoked fundamental criticism of its underlying assumptions and

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Toxicology 169 (2001) 209–225

TOXICOLOGY

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Interpretations of primary carcinogenicity data in 29 trichloroethylene risk assessments

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Abstract

This paper explores to what extent interpretations of individual primary carcinogenicity data differ between different risk assessors, and discusses possible reasons for such differences as well as their impact on the overall risk assessment conclusions. For this purpose 29 different TCE carcinogenicity risk assessments are used as examples. It is concluded that the TCE risk assessors surprisingly often interpret and evaluate primary data differently. Two particular reasons for differences in data interpretation are discussed: different assessments of statistics, and different assessments of whether the results obtained in bioassays have toxicological relevance. Differences in the interpretation and evaluation of epidemiological data are also explored and discussed. © 2001 Elsevier Science Ireland Ltd. All rights reserved.

Keywords: Primary carcinogenicity data; Trichloroethylene; Risk assessments; Regulatory toxicology

1. Introduction

Health risk assessments of chemicals are being made on national, regional and international basis. Often different risk assessors come to different conclusions about the magnitude, and even the nature, of risks. Little attempt has been made in the past to describe and understand the reasons for these differences. In-depth studies of the crucial issues of scientific uncertainty and interpretative practices require toxicological training and should be made within the community of toxicologists. A deeper understanding of the risk assessment process may help increasing the transparency and reliability of risk assessments so that they better serve the needs of risk managers and the public.[1]

This is the second report from a case study in which the chlorinated solvent trichloroethylene (TCE) is taken as a model substance for a detailed study of how risk assessments of chemicals are performed by different risk assessors. TCE has been chosen as a model substance for this study

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[1] These issues are also currently being addressed by the International Programme on Chemical Safety (IPCS) in their project aiming at global co-ordination and harmonization of the risk assessment process (see www.who.int/pcs/).

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