**A Look at State-Level Risk Assessment in the United States: Making Decisions in the Absence of Federal Risk Values**

1. **ABSTRACT**

State environmental agencies in the United States are charged with making risk management decisions that protect public health and the environment while managing limited technical, financial, and human resources. Meanwhile, the federal risk assessment community that provides risk assessment guidance to state agencies is challenged by the rapid growth of the global chemical inventory. When chemical toxicity profiles are unavailable on the U.S. Environmental Protection Agency’s Integrated Risk Information System (IRIS) or other federal resources, each state agency must act independently to identify and select appropriate chemical risk values for application in human health risk assessment. This practice can lead to broad interstate variation in the toxicity values selected for any one chemical, and calls into question the scientific credibility of health risk assessments based on these values.

Within this context, this paper describes the decision-making process and resources used by U.S. states in the absence of federal guidance. The risk management of trichloroethylene (TCE) in the U.S. serves as a useful case study to demonstrate the need for a collaborative approach toward identification and selection of chemical risk values. The regulatory experience with TCE is contrasted with collaborative risk science models, such as the European Union’s efforts in risk assessment harmonization. Finally, we introduce State Environmental Agency Risk Collaboration for Harmonization (SEARCH), a free online interactive tool designed to help create a collaborative network among state agencies to provide a vehicle for efficiently sharing information and resources, and for the advancement of harmonization in risk values used among U.S. states.

**Keywords:** State, collaboration, database, harmonization, chemical

1. **INTRODUCTION**

U.S. Federal and State environmental agencies are currently at a breaking point. The General Accounting Office estimates that 80,000 to 100,000 chemicals are currently in use and approximately 700 new chemicals are introduced into commerce each year. (1)  As a result, the rate of chemical use and production has surpassed the federal scientific community’s ability to provide detailed guidance for quantitative risk assessment in the form of safe dose estimates (e.g., reference doses) and cancer risk values (e.g., slope factors). (2,3) These risk values are an essential tool used by State environmental agencies in conducting health risk assessments associated with chemicals in the environment, such as in addressing air and water contamination, hazardous waste site remediation decisions, and assessing the safety of products.(4) This paper discusses the role of United States Environmental Protection Agency (EPA) in developing federal chemical risk guidance, and explores the approaches employed by States when such federal guidance is unavailable. We then examine the use and effectiveness of collaborative approaches to risk assessment in Europe as a possible model for U.S. inter-state cooperation. Finally, in an effort to facilitate additional collaboration among state environmental agencies, we introduce a free online interactive tool designed to help meet the needs of state agency and community risk assessors. The State Environmental Agency Risk Collaboration for Harmonization (SEARCH) tool is intended to facilitate communication and foster collaboration among state risk assessors, by providing access to shared information and resources among state risk assessors.

1. **THE Federal-State Relationship in Risk Assessment**

Most contaminated sites and emission permitting systems throughout the United States are regulated and managed by State-level agency programs. In selecting cleanup levels and regulatory values, most States rely upon U.S. EPA Integrated Risk Information System (IRIS) database as their primary source of human health risk values.(5,6) IRIS provides qualitative and quantitative data on the adverse health effects of chemical exposure.(5) It contains oral reference doses (RfDs) and inhalation reference concentrations (RfCs) to estimate noncarcinogenic effects of chemicals, as well as oral slope factors, and inhalation unit risks used to estimate carcinogenic risk. Risk managers use this data to make decisions and set regulatory limits to protect public health.(7)

However, IRIS is currently facing many challenges. After the U.S. Government Accountability Office (GAO) conducted an examination of the federal risk assessment process in 2008, GAO reported that EPA is experiencing a backlog of approximately 70 chemical assessments and estimated that more than 287 IRIS assessments are now outdated. (1) GAO cited numerous reasons for the limited level of productivity, some of which are related to the federal process itself, and others that relate to the chemical risk information that is deemed necessary to issue a robust assessment. Since GAO published this report, EPA has implemented several reforms to improve the federal risk assessment process, such as increasing funding and staffing, and restoring EPA’s independence in the process so that risk assessments can no longer be delayed due to federal interagency reviews (34). However, the other reasons GAO cited for significant delays cannot be readily resolved through these recent reforms. For example, GAO reported that congressional action has delayed some chemical assessments until new information is available because of the significant economic impact the assessment would have on industry. Additionally, as the scientific complexity of risk assessments grow, EPA must also follow increasingly complex risk assessment guidelines and often use methods and models that are still in development or are being implemented for the first time. Further, GAO stated that EPA’s management decision to include a comprehensive and quantified uncertainty analysis in each assessment has significantly contributed to delaying the process because of the complexity of the analysis. GAO questioned the value of a detailed quantified uncertainty analysis and in support of this view, it quoted the U.S. National Academies (consisting of the National Academy of Science, National Academy of Engineering, Institute of Medicine, and National Research Council), which stated that “there is serious danger that agencies will produce ranges of meaningless and confusing risk estimates, which could result in risk assessment of reduced rather than enhanced quality and objectivity (34).”

Thus, in an effort to maintain the highest quality risk data, the IRIS chemical assessment process has slowed to a point that threatens its ability to provide data for the majority of chemical risk assessments that are needed by states. While IRIS is recognized as a high quality source of toxicity information for U.S. state and private-sector risk assessors, the program is currently overwhelmed by the significant number of chemicals currently in use in the U.S. It is estimated that approximately 80,000 chemicals are currently used in the U.S.(1), whereas IRIS contains risk values for about 550 chemical assessments(5). A contributing factor to this discrepancy is that under the current Toxic Substances Control Act(8), if human exposure to a chemical is not expected, collection of toxicology data may not be viewed as necessary to ensure public safety(8). The absence of sufficient toxicity data to develop a quantitative dose-response relationship precludes IRIS evaluation.

1. **IRIS and the case of Trichloroethylene**

Trichloroethylene (TCE) is an industrial solvent and degreaser and is a common contaminant in air, soil, surface and groundwater, identified in over 1,500 hazardous waste sites regulated under the major environmental U.S. laws, including the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act(9). The history of the TCE assessment at EPA provides a good illustration of the issues currently facing EPA and IRIS. TCE is known to adversely affect human health; it has been shown to have adverse, non-carcinogenic health effects on multiple target organs, including the nervous system, liver, kidneys and immune system. In addition, developmental effects have been reported following TCE exposure.(10) The carcinogenicity of TCE has been assessed by the International Agency for Research on Cancer (IARC)and the National Toxicology Program (NTP).(11,12)  TCE has been classified as “probably” and “reasonably anticipated to be” carcinogenic to humans, respectively, by these two organizations based on their respective classification systems (13). U.S. EPA has not reached consensus on the carcinogenicity of TCE.

U.S. EPA’s TCE risk assessment has been the subject of much controversy. Despite the fact that TCE is a common contaminant, US EPA has not updated its original 1989 TCE assessment and currently does not have a finalized IRIS Toxicological Review for TCE. The timeline for EPA’s TCE assessment, as reported by GAO, is shown in Table I. (1)

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| --- | --- | --- | --- | --- | --- |
| **Table I. Timeline of Events for Trichloroethylene (TCE) Toxicological Profile** | | | | | |
|  |  |  |  |  |  |
| 1989 | EPA withdraws TCE Toxicological Review from IRIS | | | | |
| 2001  2002 | National Center for Environmental Assessment (NCEA) releases draft TCE health risk assessment  Environmental Protection Agency’s (EPA) Science Advisory Board reviews the draft TCE assessment | | | | |
| 2006 | National Academy of Science (NAS) releases report recommending new TCE data be incorporated and NCEA's assessment be reissued | | | | |
| 2009 | EPA issues Draft Toxicological Review of TCE | | | | |
|  |  |  |  |  |  |

In 1989, the TCE non-cancer and cancer risk values were withdrawn from IRIS for further review. In 2001, EPA’s National Center for Environmental Assessment (NCEA) released a draft TCE health risk assessment that proposed a range of non-cancer values; however the 2001 draft did not offer guidance on how to apply the proposed range of values. This lack of guidance was noted as a major concern by State agency risk assessors. (14) The 2001 draft assessment also characterized TCE as “highly likely to produce cancer in humans.” In 2002, EPA’s Scientific Advisory Board (SAB) peer reviewed the draft assessment and concluded that the weight of evidence for TCE carcinogenicity suggested that the appropriate classification for TCE was on the continuum between “highly likely to be carcinogenic to humans” and “known to be carcinogenic to humans”. (15) The National Academy of Sciences(16) reviewed the TCE assessment in 2006 and concluded that the weight of evidence of TCE carcinogenicity had strengthened since EPA issued its 2001 draft assessment(17), but did not recommend a cancer classification. NAS did recommend that new data be incorporated into the assessment and that the assessment be finalized. In November 2009, EPA issued a revised draft toxicological review of TCE that is currently undergoing external review. (18)

The case of TCE illustrates how the extensive IRIS review process can delay the development of regulatory values for chemicals of environmental concern. Until EPA finalizes its 2009 TCE assessment, States will have to use other approaches for evaluating and managing risk due to TCE exposure. Given the limited extent to which IRIS provides comprehensive coverage of risk values for the universe of chemicals of interest, State risk assessors cannot always rely on this database to fulfill their data needs. As a result, chemicals without easily accessible risk values may not be fully considered by States during the risk assessment process.

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1. **How States Make Decisions When No Federal Guidance is Available**

In the absence of federal guidance on risk values, U.S. States turn to other sources of toxicity and risk information, or they work independently to derive their own risk values. The Interstate Technology and Regulatory Council (ITRC) proposed a hierarchy for selecting human health toxicity values based on the merit of the underlying toxicity data and the quality of peer review.(6) Originally prescribed in Risk Assessment Guidance for Superfund(19), the tiered hierarchy was revised by ITRC as follows:

* Tier 1—EPA’s Integrated Risk Information System (IRIS) values. The chemicals listed in

IRIS have undergone peer review and are continuously re-reviewed.

* Tier 2—EPA’s Provisional Peer-Reviewed Toxicity Values (PPRTVs). The Office of Research and Development/National Center for Environmental Assessment/Superfund Health Risk Technical Support Center develops PPRTVs on a chemical-specific basis when requested by EPA’s Superfund program for use in site-specific risk assessments. PPRTVs are developed in a shorter period of time, and although these assessments undergo external peer review, their development does not include a multi-program consensus review as is done with the IRIS assessments.
* Tier 3—Other Toxicity Values. This tier includes additional EPA/non-EPA sources of toxicity information. Priority should be given to sources of information that are most current, peer-reviewed, transparent, and publicly available. Example sources include the California Environmental Protection Agency (CalEPA) toxicity values, the Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk levels, and Health Effects Assessment Summary Tables (HEAST) values. (6)

While there was general agreement on the use of the ITRC tiered approach, not all States have adopted the ITRC approach, instead opting to establish their own hierarchy. In addition, many States with the technical and financial resources choose to independently derive their own risk values (e.g., California Environmental Protection Agency, Texas Commission on Environmental Quality). Not surprisingly, one of the main factors determining how states handle risk management decisions is the availability of in-house capabilities, which are affected by shrinking state environmental agency budgets. In March 2010, the Environmental Council of the States (ECOS) issued a green report entitled Impacts on Reduction in FY 2010 on State Environmental Agency Budgets. The report summarized data collected from 37 out of 50 states that responded to a survey regarding the extent of the financial impact on their environmental programs. ECOS reported that across the country, 2,112 environmental positions have been eliminated or are being held vacant due to budget cuts, and 20 states have reduced or eliminated programs (hazardous waste programs are among those facing reductions).(20)  One effect of limited resources is that many States do not have a toxicologist or technically trained staff, which makes it difficult for them to produce their own risk values. Figure 1 shows the proportion of States with risk assessment capability.

**Figure 1. State Agencies with Risk Assessment Capability**

The impact of limited time and resources on risk management decisions is most apparent when states must make decisions regarding chemicals that are not included in IRIS. The variety of approaches can sometimes result in the use of a wide range of toxicity values across the U.S. Differences in state-selected risk values, whether due to political or scientific reasons, can lead to questioning of the scientific credibility of the organization or the risk assessment process. Additionally, broad discrepancies between neighboring states can elicit public concern and protest from citizens doubting the degree to which public health is protected.(21) Also, within State agencies there can be political pressure to have risk values no more stringent than neighboring states, driven by the perception that strict environmental regulations can deter new businesses. These issues become apparent when looking at the ways that States have chosen to regulate TCE in the absence of U.S. EPA risk values.

1. **States and the case of Trichloroethylene**

In the years since 1989 when U.S. EPA withdrew its TCE risk values, U.S. States have continued to address ongoing clean-up decisions regarding TCE. To provide insight into how states have approached the situation, the Indiana Department of Environmental Management (IDEM) conducted a survey in 2007 of officials within State environmental agencies of all fifty states. Results of the survey revealed large disparities in toxicity values that were being used for TCE risk management decisions. Table IIshows a summary of State TCE toxicity information that lists reference doses and slope factors for inhalation and oral routes of exposure, and appropriate references based on responses to the 2007 survey. Table III presents summary statistics for the inhalation Reference Dose (RfDi), the oral Reference Dose (RfDo), Inhalation Slope Factor (SFi), and Oral Slope Factor (SFo). Tables IV and V provide individual source and value rankings for the RfDi, RfDo, SFi, and SFo. In summary, results of the survey indicated that reference dose values used differed by three orders of magnitude; slope factors differed by two orders of magnitude.

IDEM’s survey also revealed that States use a variety of sources for risk values when conducting risk assessments. Instead of using one of the of risk values from the hierarchy discussed above, States used a variety of alternative sources of risk values, particularly in situations where federal guidance is absent, in the process of changing, or is out-dated by newer science developments. In the case of TCE, some States continue to use the risk values proposed in EPA’s 2001 draft assessment, other States have developed their own toxicity values, and still other States continue to rely on older guidance documents when proceeding with site remediation and closure. Based on the 2007 survey for the TCE inhalation slope factor, 49% of states were using the 2001 draft EPA values(17); 25% were using old IRIS-based values (including values that had been withdrawn); 18% of the states were using Cal EPA values; and approximately 6% were using State-derived values. In the case of TCE, bordering States often selected widely differing values. For example, Wisconsin selected an inhalation cancer risk value (SFi) of 0.4 mg/kg-day and Illinois selected an inhalation value of 0.006 mg/kg-day, resulting in a 67-fold difference between the neighboring States.

Based on their interviews with other State officials, IDEM concluded that one of the main factors which influenced decisions regarding TCE risk values was the varying degrees of technical, financial, and human resources. Some States, such as Indiana and New Jersey, invested resources into the development of risk values, while others deferred to regional federal entities for guidance due to lack of resources. Scientific disagreements were also observed. For example, differences of opinion between the Division of Hazardous Waste Management and the Division of Emergency and Remedial Response within the Ohio EPA regarding which toxicity information to use, resulted in the use of different risk values between the two divisions.

TCE is not unique. Other common contaminants, such as naphthalene, dioxin, and perchloroethylene, have experienced similar delays in the development of an IRIS value, resulting in a wide-variety of State approaches for these chemicals. Given the likelihood that States will continue to make their own decisions regarding critical risk values in the absence of EPA values, a collaborative approach among the States may provide a means to better channel limited resources for maximum impact.

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| **Table II. State Trichloroethylene (TCE) Toxicity Information and Sources** | | | | | | | | | | | | |  |  | | |  |
|  |  | |  | |  |  | | |  |  | | |  |  | | |  |
|  |  | | **RfDi** | | | **RfDo** | | | | **SFi** | | | | **SFo** | | | |
|  | **State** | | **mg/kg-day** | **Source** | | **mg/kg-day** | | **Source** | | **(mg/kg-day)-1** | | **Source** | | **(mg/kg-day)-1** | | **Source** | |
| 1 | Alabama | | 0.00567 | Ext | | 0.006 | | N(O) | | 0.007 | | Cal | | 0.013 | | Cal | |
| 2 | Alaska | | 0.01 | R10 | | 0.0003 | | R10 | | 0.4 | | R10 | | 0.4 | | R10 | |
| 3 | Arizona | | 0.011 | R9 | | 0.0003 | | R9 | | 0.007 | | R9(Cal) | | 0.013 | | R9(Cal) | |
| 4 | Arkansas | | 0.011 | R6 | | 0.0003 | | R6 | | 0.4 | | R6 | | 0.4 | | R6 | |
| 5 | California | | 0.17 | Cal | |  | |  | | 0.007 | | Cal | | 0.013 | | Cal | |
| 6 | Colorado | | 0.011 | N | | 0.0003 | | N | | 0.4 | | N | | 0.4 | | N | |
| 7 | Connecticut | |  |  | |  | |  | |  | |  | | 0.089 | | NAS | |
| 8 | Delaware | | 0.17 | Cal | |  | |  | | 0.007 | | Cal | | 0.013 | | Cal | |
| 9 | Florida | | 0.00567 | Ext | | 0.006 | | N(O) | | 0.006 | | N(O) | | 0.011 | | N(O) | |
| 10 | Georgia | | 0.01 | N | | 0.0003 | | N | | 0.4 | | N | | 0.4 | | N | |
| 11 | Hawaii | | 0.01 | R9 | | 0.0003 | | R9 | | 0.4 | | R9 | | 0.4 | | R9 | |
| 12 | Idaho | | 0.01 | N | | 0.0003 | | N | | 0.4 | | N | | 0.4 | | N | |
| 13 | Illinois | |  |  | | 0.006 | | Cal(O) | | 0.006 | | Cal(O) | | 0.011 | | Cal(O) | |
| 14 | Indiana (Comm) | | 0.01 | R3, R9 | | 0.0003 | | R3, R6, R9 | | 0.018 | | IDEM | | 0.034 | | IDEM | |
| Indiana (Res) | | 0.054 | | IDEM | | 0.1 | | IDEM | |
| 15 | Iowa | | 0.011 | R | | 0.007 | | DWS & HA | | 0.385 | | R | | 0.4 | | R | |
| 16 | Kansas | |  |  | |  | |  | | 0.006 | | N(O) | | 0.011 | | N(O) | |
| 17 | Kentucky | | 0.01 | N | | 0.0003 | | N | | 0.322 | | KDEP | | 0.322 | | KDEP | |
| 18 | Louisiana | | 0.014 | R3 | | 0.0003 | | R3 | | 0.4 | | R3 | | 0.4 | | R3 | |
| 19 | Maine | | 0.006 | I | | 0.006 | | I | | 0.006 | | I | | 0.011 | | I | |
| 20 | Maryland | | 0.01 | R3 | | 0.0003 | | R3 | | 0.4 | | R3 | | 0.4 | | R3 | |
| 21 | Massachusetts | | 0.05 | CHEM/AAL | | 0.002 | | MADEP | | 0.006 | | E | | 0.011 | | H(W) | |
| 22 | Michigan | |  |  | | 0.0017 | | Dawson | | 0.006 | | EPA(87) | | 0.01 | | NCI, NTP | |
| 23 | Minnesota | |  |  | |  | |  | | 0.006 | | E | | 0.011 | | E | |
| 24 | Mississippi | |  |  | | 0.006 | | EPA | | 0.006 | | EPA | | 0.011 | | EPA | |
| 25 | Missouri | | 0.17 | Cal | | 0.17 | | Ext | | 0.007 | | Cal | | 0.013 | | Cal | |
| 26 | Montana | | 0.01 | N | | 0.0003 | | N | | 0.4 | | R9 | | 0.4 | | R9 | |
| 27 | Nebraska | | 0.011 | N | | 0.0003 | | N | | 0.4 | | N | | 0.4 | | N | |
| 28 | Nevada | | 0.01 | R9 | | 0.0003 | | R9 | | 0.4 | | R9 | | 0.4 | | R9 | |
| 29 | New Hampshire | | 0.01 | R3 | | 0.0003 | | R3 | | 0.4 | | R3 | | 0.4 | | R3 | |
| 30 | New Jersey (Soil) | | 0.17 | Cal | |  | |  | | 0.01 | | Cal | | 0.031 | | A-280 | |
| New Jersey (Vapor) | | 0.011 | R3 | | 0.4 | | R3 | |
| 31 | New Mexico | | 0.011 | R6 | | 0.0003 | | R6 | | 0.4 | | R6 | | 0.4 | | R6 | |
| 32 | New York | | 0.011 | N | | 0.00146 | | HC | | 0.007 | | Cal | | 0.00572 | | NYS DEC | |
| 33 | North Carolina | | 0.01 | R9 | | 0.0003 | | R9 | | 0.4 | | R9 | | 0.4 | | R9 | |
| 34 | North Dakota | |  |  | |  | |  | |  | |  | |  | |  | |
| 35 | Ohio (DHWM) | | 0.006 | Ext | | 0.006 | | N(O) | | 0.006 | | W | | 0.011 | | W | |
| Ohio (DERR) | | 0.17 | Cal | | 0.5 | | Cal(99) | | 0.007 | | Cal | | 0.013 | | Cal | |
| 36 | Oklahoma | | 0.01 | R6 | | 0.0003 | | R6 | | 0.4 | | R6 | | 0.4 | | R6 | |
| 37 | Oregon | | 0.011 | R6 | | 0.0003 | | R6 | | 0.4 | | R6 | | 0.4 | | R6 | |
| 38 | Pennsylvania | | 0.143 | A | | 0.006 | | N(O) | | 0.00595 | | N(O) | | 0.011 | | N(O) | |
| 39 | Rhode Island | | 0.006 | I | | 0.006 | | I | | 0.006 | | I | | 0.011 | | I | |
| 40 | South Carolina | | 0.17 | Cal | |  | |  | | 0.007 | | Cal | | 0.013 | | Cal | |
| 41 | South Dakota | | 0.01 | R3 | | 0.0003 | | R3 | | 0.4 | | R3 | | 0.4 | | R3 | |
| 42 | Tennessee | | 0.17 | Cal | |  | |  | | 0.007 | | Cal | | 0.013 | | Cal | |
| 43 | Texas | |  |  | | 0.006 | | N(O) | | 0.006 | | N(O) | | 0.011 | | N(O) | |
| 44 | Utah | | 0.006 | I | | 0.006 | | I | | 0.006 | | I | | 0.011 | | I | |
| 45 | Vermont | | 0.01 | R9 | | 0.0003 | | R9 | | 0.4 | | R9 | | 0.4 | | R9 | |
| 46 | Virginia | | 0.01 | N | | 0.0003 | | N | | 0.4 | | N | | 0.4 | | N | |
| 47 | Washington | | 0.01 | N | | 0.0003 | | N | | 0.4 | | N | | 0.4 | | N | |
| 48 | West Virginia | | 0.01 | N | | 0.0003 | | N | | 0.4 | | N | | 0.4 | | N | |
| 49 | Wisconsin | | 0.011 | N | | 0.007 | | EPA MCL | | 0.4 | | R3 | |  | |  | |
| 50 | Wyoming | | 0.01 | R9 | | 0.0003 | | R9 | | 0.4 | | R9 | | 0.4 | | R9 | |
| **Notes:** | | |  |  | |  | |  | |  | |  | |  | |  | |
| RfC and UR converted to RfDi and SFi, respectively, assuming 70 kg individual breathing 20 m3/day of air. | | | | | | | | | | | |  | |  | |  | |
| New Jersey has different RfDi and SFi for different pathways (Soil and Vapor Intrusion). | | | | | | | | | | |  |  | |  | |  | |
| Ohio has different RfDi, RfDo, SFi, and SFo for different divisions within their agency (DHWM and DERR). | | | | | | | | | | | |  | |  | |  | |
| Indiana has different SFi and SFo for commercial and industrial settings. | | | | | | | | |  | |  |  | |  | |  | |
| Wisconsin only applies RfDo to groundwater. | | | | | | |  | |  | |  |  | |  | |  | |
|  |  |  | | |  | |  | |  | |  |  | |  | |  | |
|  | **Key:** |  | | |  | |  | |  | |  |  | |  | |  | |
|  | A | ATSDR | | |  | |  | |  | | NAS | National Academies of Science | | | |  | |
|  | A-280 | New Jersey A-280 | | | | |  | |  | | NCI | National Cancer Institute | | | |  | |
|  | Cal | California EPA (Cal/EPA) | | | | |  | |  | | N(O) | NCEA (Old Value) | | | |  | |
|  | Cal(99) | 1999 Cal/EPA | | |  | |  | |  | | NTP | National Toxicity Program (1990)(12) | | | |  | |
|  | Cal(O) | Cal/EPA (Old Value) | | | | |  | |  | | NYS DEC | New York State Dept. of Env. Conservation | | | | | |
|  | CHEM/AAL | Massachusetts Chem. Health Effects Assessment | | | | | | |  | | R | Risk Assessment Info. System | | | | |  |
|  |  | Methodology/ Allowable Ambient Level | | | | | | |  | | R3 | U.S. EPA Region III | | | | |  |
|  | Comm | Commercial Setting | | | | |  | |  | | R6 | U.S. EPA Region VI | | | | |  |
|  | Dawson | Dawson *et al*, (1993) (22) | | | | |  | |  | | R9 | U.S. EPA Region IX | | | | |  |
|  | DERR | Ohio Div. of Emergency & Remedial Response | | | | | | |  | | R9(Cal) | U.S. EPA Region IX (Cal/EPA modified) | | | | | |
|  | DHWM | Ohio Div. of Haz. Waste Mgmt. | | | | |  | |  | | R10 | U.S. EPA Region X | | | | |  |
|  | E | ECAO (NCEA Old Value) | | | | |  | |  | | Res | Residential Setting | | | | |  |
|  | EPA | 1987 U.S. EPA Value | | | | |  | |  | | RfC | Reference Concentration | | | | |  |
|  | EPA MCL | U.S. EPA Maximum Contaminant Level | | | | | | |  | | RfDi | Inhalation Reference Dose | | | | |  |
|  | Ext | Extrapolated Value | | | | |  | |  | | RfDo | Oral Reference Dose | | | | |  |
|  | DWS & HA | Drinking Water Standards & Health Advisories | | | | | | |  | | SFi | Inhalation Slope Factor | | | | |  |
|  | HC | Health Canada | | |  | |  | |  | | SFo | Oral Slope Factor | | | | |  |
|  | H(W) | HEAST Withdrawn Value | | | | |  | |  | | Soil | Soil Pathway | | |  | |  |
|  | I | IRIS | | |  | |  | |  | | UR | Unit Risk | | |  | |  |
|  | IDEM | Indiana Dept. of Env. Mgmt. | | | | |  | |  | | Vapor | Vapor Intrustion Pathway | | | | |  |
|  | KDEP | Kentucky Dept. of Env. Protection | | | | |  | |  | | W | Withdrawn Value | | | | |  |
|  | MADEP | Massachusetts Dept. of Env. Protection | | | | | | |  | |  | No Value Specified/Utilized | | | | |  |
|  | N | NCEA | | |  | |  | |  | |  |  | | |  | |  |
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| **Table III: Summary Statistics for RfDi, RfDo, SFi, and SFo** | | | | |
|  |  |  |  |  |
| **Statistic of Interest** | **RfDi** | **RfDo** | **SFi** | **SFo** |
| **mg/kg-day** | **mg/kg-day** | **(mg/kg-day)-1** | **(mg/kg-day)-1** |
| No. of States with No Value Specified | 8 | 9 | 2 | 2 |
| No. of Values | 44 | 42 | 51 | 50 |
| MEAN | 0.04 | 0.02 | 0.21 | 0.20 |
| MEDIAN | 0.011 | 0.0003 | 0.322 | 0.090 |
| Most Conservative Value | 0.00567 | 0.0003 | 0.4 | 0.4 |
| *No. of States Using Most Conservative Value* | 2 | 25 | 24 | 23 |
| *% of States Using Most Conservative Value* | ~4.6 | ~60 | ~47 | 46 |
| Least Conservative Value | 0.17 | 0.5 | 0.00595 | 0.00572 |
| *No. of States Using Least Conservative Value* | 7 | 1 | 1 | 1 |
| *% of States Using Least Conservative Value* | ~16 | ~2.4 | ~2.0 | 2.0 |
| Magnitude of Difference | ~30 | ~1700 | ~67 | ~70 |
| **NOTES:** |  |  |  |  |
| "Mean" and "Median" exclude states with no value specified. | | |  |  |
| "% of States Using" calculated by dividing "No. of States Using" by "No. of Values". | | | | |
| "Magnitude of Difference" = LOG10("Least Conservative" / "Most Conservative"). | | | | |

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| **Table IV: Oral Reference Dose (RfDo) Source and Value Rankings**   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Rank** | **Aggregated Source Category** Individual Sources and Ranks | | | **No./Total** | **% Total** | **RfDo Value** (mg/kg-day) | **Applicable States (Aggregated)** | | **1** | **New NCEA-based Sources** | | | **25/42** | **~60** | **0.0003** | AK, AR, AZ, CO, GA, HI, ID, IN, KY, LA, MD, MT, NE, NV, NH, NM, NC, OK, OR, SD, VT, VA, WA, WV, WY | |  | 1 | NCEA |  |  |  |  | |  | 2 | U.S. EPA Region IX | |  |  |  | |  | 3 | U.S. EPA Region III | |  |  |  | |  |  | U.S. EPA Region VI | |  |  |  | |  | 5 | U.S. EPA Region X | |  |  |  | | **2** | **Old IRIS-based Sources** | | | **10/42** | **~24** | **0.006** | AL, FL, IL, ME, MS, OH (DHWM), PA, RI, TX, UT | |  | 1 | NCEA (old) |  |  |  |  | |  | 2 | IRIS (old) |  |  |  |  | |  | 3 | Cal/EPA (old) |  |  |  |  | |  |  | EPA (old) |  |  |  |  | | **3** | **EPA-MCL-based Sources** | | | **2/42** | **~4.8** | **0.007** | IA, WI (groundwater) | |  | 1 | DWS & HA |  |  |  |  | |  | 2 | EPA MCL |  |  |  |  | | **4** | **1999 Cal/EPA** | |  | **1/42** | **~2.4** | **0.5** | OH (DERR) | |  | **Dawson *et al*, 1993** |  |  | **1/42** | **~2.4** | **0.0017** | MI | |  | **Extrapolation from RfDi** | | | **1/42** | **~2.4** | **0.17** | MO | |  | **Health Canada** | |  | **1/42** | **~2.4** | **0.00146** | NY | |  | **1992 MADEP** |  |  | **1/42** | **~2.4** | **0.002** | MA | | **Notes:** | |  |  |  |  |  |  | | OH uses different numbers in their Division of Hazardous Waste Mgmt. (DHWM) and Division of Emergency and | | | | | | | | | Remedial Response (DERR). | | | |  |  |  |  | | WI only applies RfDo to groundwater. | | | |  |  |  |  | | "RfDo Value" is the most representative value within an aggregated category. | | | | | | |  | | The absence of a rank indicates an equal ranking with the preceding source (e.g., U.S. EPA Region III and VI have an equal rank). | | | | | | | | |

**Table V: Inhalation Slope Factor (SFi) Source and Value Rankings**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Rank** | **Aggregated Source Category**  Individual Sources and Ranks | | | | **No./Total** | | **% Total** | | | **SFi Value** (mg/kg-day)-1 | | | **Applicable States (Aggregated)** | |
| **1** | **New NCEA-based Sources** | | | | **25/51** | | **~49** | | | **0.4** | | | AK, AR, CO, GA, HI, IA, ID, LA, MD, MT, NE, NV, NH, NJ (Vapor), NM, NC, OK, OR, SD, VT, VA, WA, WV, WI, WY | |
|  | 1 | NCEA | | |  | |  | | |  | | |
|  | 2 | U.S. EPA Region III | | |  | |  | | |  | | |
|  |  | U.S. EPA Region IX | | |  | |  | | |  | | |
|  | 4 | U.S. EPA Region VI | | |  | |  | | |  | | |
|  | 5 | U.S. EPA Region X | | |  | |  | | |  | | |
|  |  | RAIS | | |  | |  | | |  | | |
| **2** | **Old IRIS-based Sources** | | | | **13/51** | | **~25** | | | **0.006** | | | FL, IL, KS, MA, ME, MI, MN, MS, OH (DHWM), PA, RI, TX, UT | |
|  | 1 | NCEA (old) | | |  | |  | | |  | | |
|  | 2 | IRIS (old) | | |  | |  | | |  | | |
|  | 3 | ECAO memo | | |  | |  | | |  | | |
|  |  | EPA (old) | | |  | |  | | |  | | |
|  | 5 | Cal/EPA (old) | | |  | |  | | |  | | |
|  |  | Withdrawn value | | |  | |  | | |  | | |
| **3** | **California EPA** | | | | **9/51** | | **~18** | | | **0.007** | | | AL, AZ, CA, DE, MO, OH (DERR), NY, SC, TN | |
|  | 1 | | Cal/EPA | |  | |  | | |  | | |
|  | 2 | | U.S. EPA Region IX (Cal) | |  | |  | | |  | | |
| **4** | **State Sources** | | | | **3/51** | | **~5.9** | | | **varies** | | | IN (C), IN (R), KY | |
|  | 1 | | IDEM | |  | |  | | | 0.018 (C) / 0.054 (R). | | |
|  | 2 | | KDEP | |  | |  | | | 0.322 | | |
| **5** | **California EPA NJ Soil Source** | | | | **1/51** | | **~2.0** | | | **0.01** | | | NJ (Soil) | |
| **Notes:** | | | |  | |  |  | |  |  | | |  | |
| IN has developed different numbers for commercial (C) and residential settings (R). | | | | | | | | | | | | |  | |
| NJ uses different numbers for vapor intrusion and soil standards. | | | | | | | | | | | |  |  | |
| OH uses different numbers in their Division of Hazardous Waste Mgmt. (DHWM) and Division of Emergency and | | | | | | | | | | | | | | |
| Remedial Response (DERR). | | | | | | | |  | | |  |  | |  |
| "SFi Value" is the most representative value within an aggregated category. | | | | | | | | | | | | | |  |
| The absence of a rank indicates an equal ranking with the preceding source (e.g., U.S. EPA Region III and IX have an equal rank). | | | | | | | | | | | | | | |

1. **Collaborative Approaches in Europe**

In the U.S., we have limited formal structures for using collaborative approaches to risk assessment. However, international initiatives can highlight the practical application of the structure and benefits that can result from a collaborative process. In particular we draw on the experiences of the European Union (EU) and the International Programme on Chemical Safety (IPCS) as examples of movement to such collaborative models. Around the world there is call for harmonization of chemical risk assessment methods. The IPCS(23) Harmonization Project describes this as “the effort to strive for consistency among approaches and to enhance understanding of the various approaches to chemical risk worldwide,” to gain “an understanding of the methods and practices used by various countries and organizations so as to develop confidence in, and acceptance of, assessments that use different approaches.” Employing this concept of harmonization at the state level could help alleviate the data and safety gaps in U.S. chemical regulation and streamline the risk assessment process.

In 2006, the E.U. adopted new legislation addressing the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH). In essence, the Directive assigned a greater responsibility to industry to manage the risks from chemicals and to affirmatively and publicly provide safety information on each substance. The Directive also called for the progressive substitution of chemicals proven to be harmful when suitable alternatives have been identified. (24)

Prior to adopting REACH, however, the European Union had established and relied on a collaborative process to complete risk assessments. In the mid-1990’s, the Council of the European Communities enacted Council Regulation (EEC) No 793/93 and its companion regulation No 1488/94. (25, 26) Together, these regulations provided a framework for risk evaluation and control of existing substances consisting of four stages: (1) data collection, (2) priority setting, (3) risk assessment, and (4) risk reduction. The later regulation expanded on the risk assessment component; it presented Member States with the responsibility of completing risk assessments for existing substances and outlined the required components for each risk assessment report. But perhaps most relevant to the situation facing the U.S. states, each regulation contained a stipulation that Member States complete risk assessments at a “Community level,” based on the premise that a Community level risk assessment can “avoid disparities between Member States which would not only affect the functioning of the internal market but would also fail to guarantee the same level of protection of man and the environment.” (26)

These Regulations and the accompanying Technical Guidance Document established the basic framework for the preparation of a collaborative, harmonized Risk Assessment Report (RAR).(27) In summary, a Member State volunteered to act as “Rapporteur” for a substance on the priority list (the priority list is drawn up by the Commission in consultation with Member States). The Rapporteur, in conjunction with industry stakeholders, prepared a detailed draft risk assessment for the chosen substance typically within 12 months from priority list publication. Upon completion, the Rapporteur presented the draft RAR to technical experts representing other Member States for endorsement. The Scientific Committee on Toxicity, Ecotoxicity, and the Environment (CSTEE) would next conduct a peer review and give its opinion to the European Commission regarding the quality of the RAR and its conclusions.(28) The Commission then prepared a final proposal for discussion; adoption was by simple majority vote of the Committee, composed of representatives from all Member States and chaired by a representative of the Commission. Once approved, summaries of adopted RAR’s were published in the Official Journal.

The theoretical framework of the E.U. Directives’ risk assessment process was well-intentioned. While rigorous examination is beyond the scope of this paper, we offer results from two studies that evaluated the process. Munn and Hansen conducted a preliminary analysis of the risk assessment process, and focused on if and how policy influenced regulatory decisions.(28) They argued that any risk assessment process can easily be defeated by disagreements resulting from the gap between science and policy, which tends to occur when there is insufficient evidence to declare that risk posed by any substance is “acceptable” or “not acceptable.” The analysis was conducted on 22 risk assessments, six of which had undergone the entire process under Regulation 793/93, and 16 that had been reviewed by the CSTEE, but had not yet undergone the full process.(25) Munn and Hansen found that the CSTEE agreed with the majority of the conclusions of RARs submitted for review, with a few exceptions due to policy-based decisions (e.g., the precautionary principle, exposure minimization for carcinogens, avoid unnecessary animal testing), and very few disagreements resulted from differing scientific opinions.(28) Thus, even though the science-policy gap slowed down the process for a few chemicals, the authors found that the process was smooth for the majority of substances. Further, their analysis concluded that the RAR process “provide(d) a transparent account of the scientific basis for regulatory decisions made under the Regulation.”(28)

Bodar *et al*. evaluated the first group of risk assessments (41) from the priority list, focusing on the conclusions of the risk assessments. (29) Bodar *et al*. found that even though the performance of the process had been criticized by policy-makers and non-governmental organizations as being slow and ineffective, Member States had been able to complete a significant number of high quality RARs, particularly for “difficult” (i.e., of wide use or having controversial toxicity data) substances.(29) For example, the United Kingdom finalized their TCE RAR in 2004 following review and endorsement by technical experts from Member States and the CSTEE.(30) These accomplishments by the E.U. have demonstrated that a collaborative process toward risk assessment can be an effective way of completing a sensible number of risk assessments without foregoing quality across a wide and populous geographic area.

The E.U.’s pre-REACH risk assessment process provides us with a working example of a systematic interagency collaborative risk assessment process. The collaboration among Member States seen in the E.U. could serve as a model for formal cooperation between U.S. States. The adoption and adaptation of such a model could be of particular use for those substances that are commonly found in contaminated sites but do not have final IRIS assessments, such as TCE. Organized cooperation has the potential to increase the level of scientific exchange and bring substantive discussions among State assessors and can help reduce the duplication of effort that can occur when States conduct assessments independently and unaware of other’s work. At the same time, it must be acknowledged that collaborative work in risk assessment at the State level may also bring some delay, such as unresolved differences of opinion among the assessors or conflicting public comments received during mandated state public comment periods. It is also possible that States with more stringent regulation might face pressure to reduce their standards to enable agreement among the many, rather than the converse. Nevertheless, the goal is for States to agree on a harmonized approach that will allow State officials to make risk management decisions that offer scientifically sound and consistent protection for residents of every State in the absence of guidance from US. EPA. Considering the backlog of chemicals in need of health assessment, it appears that a collaborative approach among States forms a feasible, affordable strategy that could help streamline and harmonize chemical risk assessment in the U.S.

1. **Need for Collaboration in the U.S.: SEARCH**

As the ultimate authority on most site clean-up and emissions-permitting decisions, each U.S. State makes its own risk management decisions. However, these decisions can affect interstate relations, and can become problematic if neighboring states select wildly different pollution standards. In effort to keep up with the daunting workload, States sometimes form partnerships with other states or join non-profit organizations to share technical risk assessment expertise. The formation of these interstate groups helps states pool resources and move toward consensus on complex risk issues. Table VI provides a non-exhaustive list of some organizations working to facilitate interagency collaborations.

**Table VI. Organizations Facilitating Interagency Collaborations in the U.S.**

|  |
| --- |
| **Alliance for Risk Assessment (ARA)** - The ARA is a collaboration of organizations that fosters the development of technical chemical risk assessment products and services, through a team effort of specialists and organizations dedicated to protecting public health by improving the process and efficiency of risk assessment, and to increasing the capacity for developing risk values to meet growing demand. [www.allianceforrisk.org](http://www.allianceforrisk.org) |
| **Association for Environmental Health and Sciences (AEHS)** – AEHS exists to facilitate communication and collaboration among environmental health and science professionals in the areas of soil and water contamination. AEHS provides technical support, peer-review, and expert witnesses for litigation purposes.  [www.aehs.com/](http://www.aehs.com/) |
| **Environmental Council of the States (ECOS)** – ECOS is a non-profit association of U.S. state and territorial environmental agency leaders whose purpose is to improve state agency capabilities that will lead to better protection of public health and the environment.  [www.ecos.org/](http://www.ecos.org/) |
| **Federal-State Toxicology Risk Assessment Committee -** with representatives from state health and environmental agencies and EPA Headquarters and Regional personnel, fosters cooperation, consistency, and an understanding of EPA's and different States' goals and problems in human health risk assessment. <http://water.epa.gov/aboutow/waterscience/fac/fstrac/index.cfm> |
| **Interstate Technology and Regulatory Council** **(ITRC)** - The ITRC develops information resources and help break down barriers to the acceptance and use of technically sound innovative solutions to environmental challenges through an active network of diverse professionals. ITRC consists of 50 states, the District of Columbia, multiple federal partners, industry participants, and other stakeholders, cooperating to break down barriers and reduce compliance costs, making it easier to use new technologies, and helping states maximize resources.  [www.itrcweb.org/](http://www.itrcweb.org/) |
| **Multi-State Working Group (MSWG)** – MSWG is a multi-stakeholder network that works to improve environmental performance, economic sustainability, social responsibility and quality of life.  [www.mswg.org/](http://www.mswg.org/) |
| **Northeast States for Coordinated Air Use Management (NESCAUM)** – NESCAUM is a nonprofit association of air quality agencies in the Northeast, that provides scientific, technical, analytical, and policy support to the air quality and climate programs of the eight Northeast states.  [www.nescaum.org/](http://www.nescaum.org/) |
| **Northeast Waste Management Officials’ Association (NEWMOA)** - NEWMOA is an interstate association where northeastern states collaborate to identify new solutions to environmental issues related to hazardous waste, solid waste, waste-site cleanup and pollution prevention.  [www.newmoa.org/](http://www.newmoa.org/) |

Recognizing the limitations of current practices, several groups have suggested strategic improvements to U.S. State regulatory practices. For example, the Lowell Center for Sustainable Production, University of Massachusetts Lowell, published “Options for State Chemicals Policy Reform: A Resource Guide”.(31) This document explored policy options and structures that states can implement to reform the current federal chemicals management policy and regulations. Recently, EPA has also begun encouraging collaboration to promote consistency and efficiency. In a 2007 Office of Enforcement and Compliance Assurance release “Guide for Addressing Environmental Problems: Using an Integrated Strategic Approach,” EPA introduced a strategic approach to solving environmental problems in a more efficient and effective manner, promoting consistency in planning and implementation, transfer of knowledge through the sharing of lessons learned, and establishing a framework to guide planning and decision-making. EPA claimed the following benefits to such an approach:

* increased communications across different offices possibly resulting in new ideas for solving environmental problems;
* less time spent duplicating efforts;
* enhanced efficiency and effectiveness of human and financial resources; and
* more measureable results. (32)

While the EPA document was directed at addressing compliance issues, the same principles and benefits of this collaborative approach can be applied to risk assessment across U.S. State environmental agencies.

# Introducing SEARCH

The available evidence suggests that collaborative approaches will promote greater efficiencies in risk value development. Therefore, we created the State Environmental Agency Risk Collaboration for Harmonization (SEARCH). SEARCH is an internet database that identifies state agency risk assessment divisions and contact information (division address, phone number, and a link to the agency website) by State. It was developed to serve as a platform for sharing of risk assessment information, with the belief that a first and critical step toward collaboration is increasing communication among U.S. State agencies.

* 1. ***Survey of State Risk Assessors.*** Prior to designing SEARCH, we contacted state agency risk assessors from all 50 U.S. states, initially via electronic mail and subsequently (if necessary) by telephone to ensure the completion of our database. State agencies were asked to identify the division/department responsible for human health risk assessments and to provide contact information. In addition, agencies were asked for suggestions on the type of risk assessment information they would find most useful. We felt it was important to involve the agencies in the creation of SEARCH, as this tool is intended for their use. Results and suggestions from all the agencies regarding the types of information that would be helpful to them and evaluated these responses for inclusion in SEARCH were recorded and compiled.

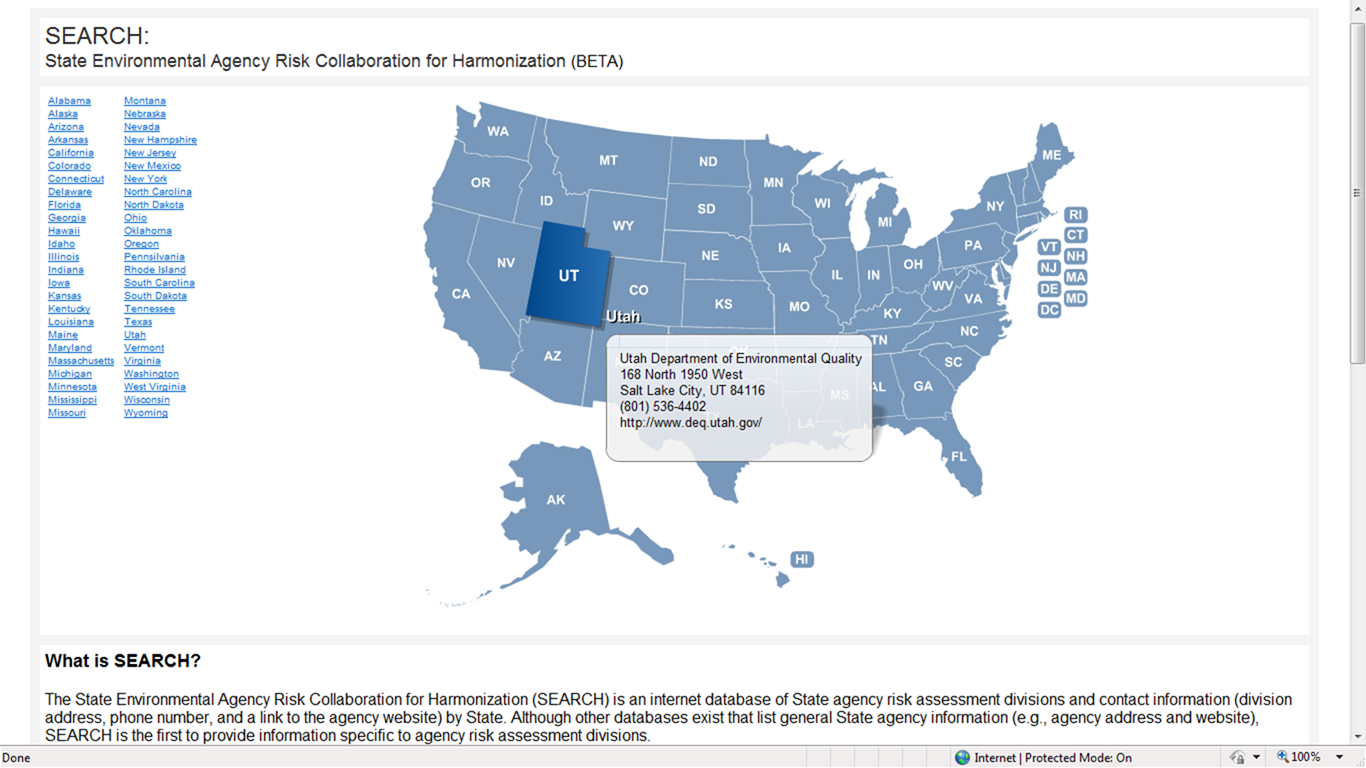
* 1. ***Results.***

Forty-one out of 50 states responded to our inquiries. The results of the survey indicate that there was no user-friendly on-line tool available that States can use to supplement the work of existing interstate membership organizations and committees. Our interviews with State risk assessors indicated that an overwhelming majority of the states would like to have a resource to provide timely information on how other states approach risk assessments in the absence of federal guidelines. When asked if they were aware of any existing database that could provide such risk information for each state, the majority of states indicated they were not aware of such a resource. Twenty-one respondents indicated that they would like SEARCH to include a list of risk values by state, and assumptions supporting those values, particularly for those substances not included in IRIS. Other suggestions from states included a regularly updated list of significant risk assessment-related actions and risk policy decisions, by state, as well as links to state-approved risk assessment guidance documents.

* 1. ***Understanding* *SEARCH****.*

To our knowledge, SEARCH is the only internet database that identifies U.S. state agency risk assessment divisions and contact information (division address, phone number, and a link to the agency website) by State. Although other databases exist that list general state agency information (e.g., address and website), SEARCH is the first to provide information specific to agency risk assessment divisions. Because state agency risk assessment capabilities vary widely, contact information for state agency risk assessors is not always easily obtained or available on state agency websites, particularly if a state agency delegates that responsibility to another agency (e.g., state health department). Most agency websites offer a staff contact list, but no information on the staff members’ department or position, making it difficult and time-consuming to identify the proper contact. SEARCH will ensure that state risk assessors can access this information quickly by providing a direct contact to the division or department responsible for risk assessments within each state, thereby facilitating communications among state risk assessors and encouraging states to share risk information.

SEARCH is freely available at [www.allianceforrisk.org/SEARCH/index.html](http://www.allianceforrisk.org/SEARCH/index.html). Upon entering the SEARCH homepage, users are presented with an interactive U.S. map. Once a user clicks on the desired state, SEARCH directs the user to a new page containing the name of the agency division or other agency department responsible for human health risk assessments, address, and phone number.

**Figure 2. Screen Capture of the State Environment Agency Risk Collaboration for Harmonization database.** 

In addition, SEARCH will enable state risk assessors to track the latest developments in the risk assessment field. The home page will contain links to the most up-to-date risk-related information interfacing with the Risk Information Exchange (RiskIE), the Alliance for Risk Assessment’s database of in progress chemical risk assessment work, training modules, white papers and other risk-related documents.(33) In essence, SEARCH is a platform for collaboration to encourage more efficient and effective risk management, especially for states confronted with dwindling technical, financial, and human resources.

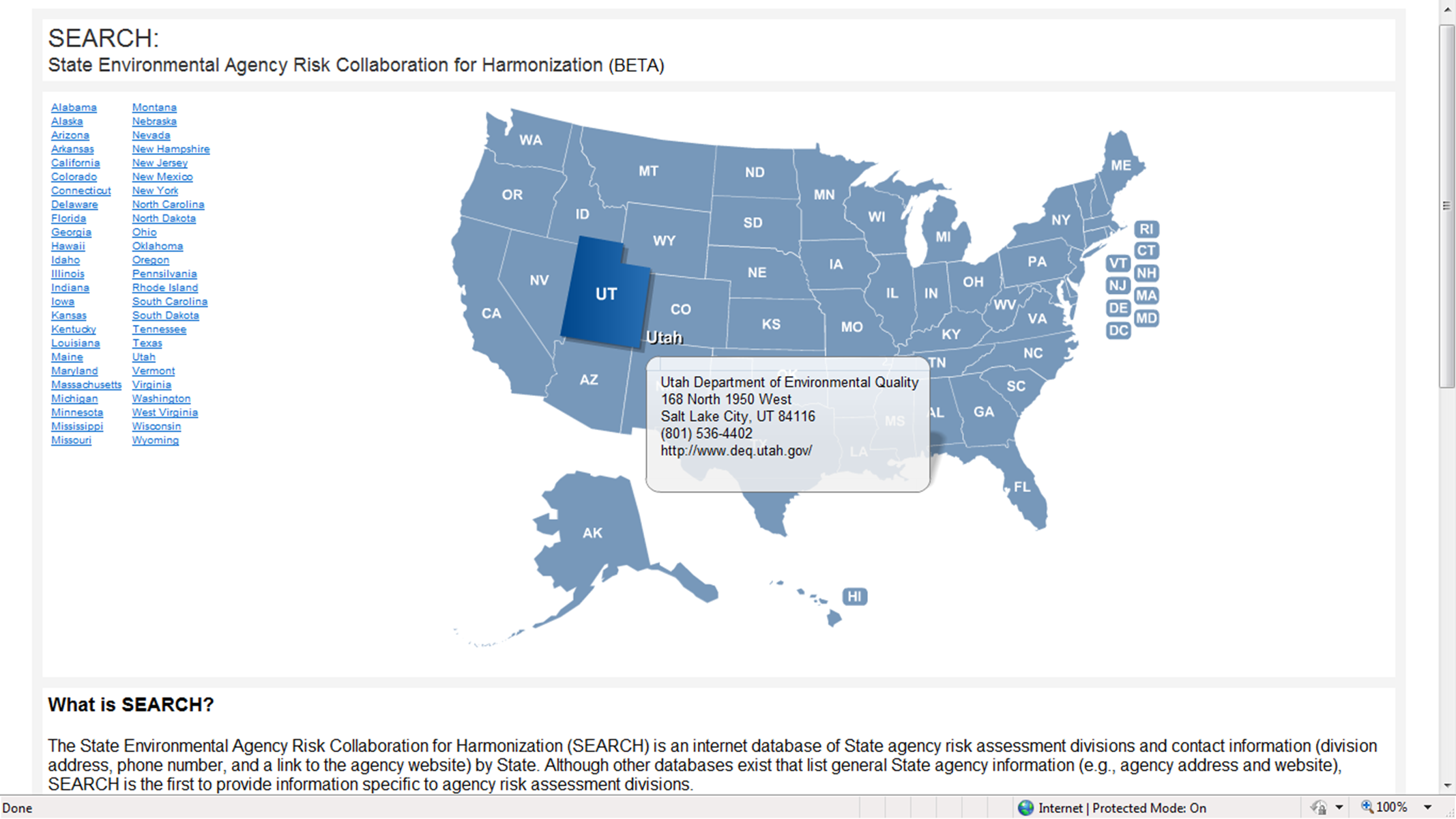
Finally, in an effort to maintain continuous communications with states regarding content, SEARCH will include a “State Feedback” item on the home page. The “State Feedback” will allow states to provide further suggestions for improvement of SEARCH. This key feature will ensure that SEARCH effectively promotes harmonization and collaboration enabling states to not only participate but even to lead.

* 1. ***Strengths and Limitations*.**

Because SEARCH is an evolving tool intended for U.S. state agency use, its success will depend largely on state risk assessors’ involvement. The majority of states that responded were enthusiastic about the creation of SEARCH, stressing the need and value of this tool given their shrinking budgets. In their responses, several states even provided links to state-specific risk-related information they felt would be useful to other states. Despite the initial enthusiasm, we acknowledge that some state risk assessors may not use SEARCH. Nine states did not respond to our queries despite several attempts to contact them. In addition, two of the risk assessors contacted questioned the need for a state risk assessment contact or risk information database because the information they use regularly is available on IRIS or other federal sources. While it is good to hear their data needs are currently being met, we hope to engage these agencies in the event that future contaminants are without federal values. Currently, SEARCH includes contacts for state agencies, but does not include risk values. In the future, SEARCH is intended to interface with existing platforms, such as the International Toxicity Estimates for Risk (ITER), which houses peer-reviewed risk values from organizations around the world (www.tera.org/iter/).

1. **Conclusion**

U.S. States risk assessment agencies are faced with dwindling resources, but environmental and public health protection is as important as ever. The TCE example demonstrates that without federal standards, U.S. states must work independently to derive their own toxicity values or consult other risk value resources through informal contacts. The resulting wide range of TCE toxicity values across the United States creates questions about the scientific credibility and the quality of the public health protection provided. We believe harmonization and collaboration among U.S. states can result in a cohesive, credible approach that ensures public health protection. Groups such as the IPCS and the EU and its Directives more than a decade ago proved that a collaborative approach to risk assessment can work and the emphasis on harmonized approaches in toxicology and risk assessment continues. Drawing upon the EU’s experiences, TERA developed SEARCH for U.S. state and community-based risk assessors. SEARCH is intended to meet the needs of U.S. State risk assessors faced with limited resources to identify and implement new strategies to cope with the volume of chemicals entering commerce each year across the country, and continue to protect the public and the environment.

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