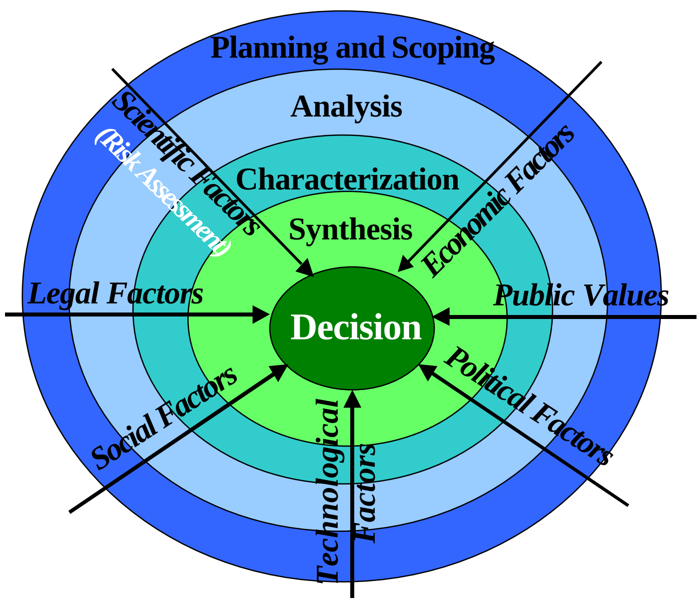
PRACTICAL USE OF RISK ASSESSMENT RESULTS

Lee R. Shull PhD
MWH Global
777 Campus Commons, Suite 175
Sacramento, CA 95825
Phone: (916) 921-3524, Email: Lee.R.Shull@mwhglobal.com

Coauthor:
Kenneth L. Kiefer, MWH Global

Background

Since the mid-1980's, risk science has rapidly evolved to the point that the risk assessment process is increasingly applicable to a wide range of situations and issues. In 2000, the USEPA succinctly defined in it's Risk Characterization Handbook (USEPA, 2000) the role of risk assessment in the risk-based decision making (RBDM) paradigm. The RBDM paradigm is foundational to modern public health and environmental protection programs in both the public and private sectors. As a key component of the RBDM paradigm, risk assessment encompasses relevant scientific factors that should be considered and addressed in making best possible decisions, regardless whether such decisions are associated with environmental corrective actions, product registration and stewardship, drinking water standards, or regulating discharges (*e.g.,* air emissions from a stationery facility). These scientific factors include relevant aspects of such disciplines as toxicology, ecology, chemistry, statistics, computer science, as well as risk science.



By inference, best possible decision making is a function of best possible risk assessment. As shown in the diagram, risk assessment elements of the RBDM process should be considered at the earliest stages (*i.e.,* planning and scoping) of a project lifecycle, and should be appropriately integrated with other applicable factors (*e.g.,* technological factors, social factors, economic factors). Therefore, maximizing the benefits of risk assessment results within the RBDM framework is dependent on several key factors: 1) define the role of risk-based decision making during initial planning (*i.e.,* begin with the end in mind), 2) incorporate "best" science (*e.g.,* tools, methods, data) and seek to derive "best" estimates of risk, and 3) don't hesitate to venture outside the box and be proactive, especially if scientific support is available.

Risk assessments can be subdivided into *forward* or *reverse* assessments. Whereas the fundamental question in a forward risk assessment is "what is the risk to human health and/or the environment posed by measured concentrations of chemical, radiological or biological agent(s) in environmental media (soil, water, air, food)?", the question in a reverse risk assessment is "what is an acceptable concentration of a chemical, radiological or biological agent(s) in an environmental medium?" Quantitative risk assessments, either forward or reverse, can be human health and/or ecological, screening and/or refined, prospective and/or retrospective, deterministic and/or probabilistic (one- or two-dimensional), default, prescriptive, customized or focused. Whereas forward risk assessments are more commonly employed to address specific situations (*e.g.,* contaminated sites, air pollution), reverse risk assessments are more commonly used to set regulatory standards (*e.g.,* water quality standards, Preliminary Remediation Goals [PRGs]) as well as derive site-specific decision criteria (*e.g.,* risk-based cleanup levels [RBCLs], soil screening levels [SSLs]).

Practical use of risk assessment results and the role of risk assessment in the RBDM process are demonstrated in the following property redevelopment project.

Methods

The example site is a 180-acre former commercial orchard, which operated as such for about 50 years. Conversion of the property to a rural residential land use was the redevelopment plan. The objective of the property developer was clearly stated: "determine what, if any, remedial action is needed to make the property safe for residential occupancy for the least cost, and obtain agreement from the regulatory agency." Site characterization was performed in accordance with a planned risk-based strategy, which comprised a logical, phased sampling plan. Chemicals of potential concern (COPCs) included lead, arsenic and organochlorine pesticides (*e.g.,* DDT, endrin). Background samples were collected to establish naturally-occurring levels of lead and arsenic in non-orchard areas.

A tiered risk assessment approach (screening [tier 1 in accordance with California's Preliminary Endangerment Assessment], site-specific deterministic [tier 2] and site-specific probabilistic [tier 3] in accordance with USEPA guidance) was designed and carried out in association with the involved regulatory agency. Probabilistic risk analyses were performed using Crystal Ball® (Decisioneering, 1999). Public interaction was established early in the project lifecycle and continued throughout the environmental investigation, risk assessment and corrective action stages. Geographic Information System (GIS) (ArcView®) was used to manage data, to perform spatial and geostatistical analyses, and for visualization during stakeholder meetings.

Standard risk assessment procedures were employed in association with project objectives and property end-use objectives. An end-use conceptual site model (CSM) was developed that addressed both residential receptors (age-adjusted residential adult and residential child) and workers associated with the presumed remedial alternative, which was placement of impacted soil into planned roadways in the development. Exposure pathways evaluated included direct contact with soil, incidental ingestion of soil, fugitive dust inhalation, and ingestion of homegrown produce.

Because background sampling results indicated highly variable and upwards of 20 mg/kg naturally-occurring arsenic concentrations, the bioavailability of ingested arsenic in site soil was measured to support the risk assessment. The geochemical form of arsenic in Sierra Nevada soil is known to be primarily arsenopyrite, which has low bioavailability. An EPA-recommended *in vitro* bioavailabilty method (USEPA, 1999) was used to establish arsenic bioavailability in soil, which reflected the combination of both naturally occurring and arsenical pesticide arsenic bioavailability.

Results and Discussion

Sampling results. A total of 88 soil samples were collected. Results indicated three separate areas for evaluation in the risk assessment; the orchard area where pesticides had been applied historically (~90 acres), a pesticide equipment filling and handling area (~1 acre), and the non-orchard native forestland area (~90 acres). All COPCs were distributed in the upper 1-2 ft of soil.

Risk assessment results. Using the maximum concentrations of COPCs as exposure point concentrations (EPCs) and assuming 100% bioavailability of all COPCs, the screening (tier 1) risk assessment indicated unacceptable non-cancer and cancer health risks to all receptors evaluated (residential child, age-adjusted residential adult, worker).

The site-specific deterministic (tier 2) risk assessment was performed using the calculated 95% UCL of the arithmetic mean for the orchard area and the filling/handling area separately. The measured soil arsenic bioavailability ranged from 32% to 56%. As a conservative measure, the highest value (56%) was applied in tier 2 and 3 risk assessments. The tier 2 results indicated unacceptable cancer and non-cancer risks to both child and age-adjusted residents, but not to workers, in both the orchard and the filling/handling areas. The direct ingestion and food-chain exposure pathways predominated. The remaining unacceptable risks were attributed entirely to arsenic.

A probabilistic (tier 3) risk assessment was performed using a combination of probability density functions (PDFs) for some exposure parameters and point values for other exposure parameters. The results indicated acceptable cancer and non-cancer risks at the 95th percentile in the orchard area, but not in the filling/handling area. The highest risks were posed to the age-adjusted adult.

Toxicology of arsenic. In light of the current debate over the applicability of the USEPA's arsenic cancer slope factor (CSF), we negotiated a site-specific risk-based decision-making approach for arsenic with the regulatory agency. Under this approach, it was agreed that the non-cancer endpoint, not the cancer endpoint, would be applied as the primary decision endpoint. However, it was agreed that post-remediation concentrations of arsenic should not pose a theoretical upperbound cancer risk greater than 1×10^{-4}.

Risk-based cleanup levels (RBCL) for arsenic. Probabilistic RBCLs (50th, 90th, 95th, 99th) were derived assuming the same exposure pathways as were applied in the baseline risk assessment. Non-cancer RBCLs were 13 mg/kg (99th percentile), 36 mg/kg (95th percentile), 61 mg/kg (90th percentile) and 230 mg/kg (50th percentile). By comparison, the deterministic (tier 2) RBCL was determined to be 22 mg/kg. Although an RBCL of 61 mg/kg (90th percentile) was proposed to the regulatory agency, 39 mg/kg (95th percentile) was stipulated by the agency on the basis that the 95th percentile is considered USEPA's "default" percentile for risk management purposes. To confirm the health protectiveness of 36 mg/kg, the 95th percentile probabilistic risk estimates from a forward calculation were confirmed to be an HI of 1.0 and an theoretical upperbound cancer risk of 2×10^{-5}.

Remedial action. In planning the soil remediation program, the location and area of soil exceeding the selected RBCL (36 mg/kg) was derived using a geostatistical program in GIS, which interpolated the location and area exceeding 36 mg/kg using the entire data set from the filling/handling area. This approach was negotiated and accepted by the regulatory agency.

Current status. A remedial action workplan was prepared, which considered several remedial options. The selected alternative was placement of soil exceeding the RBCL in a section of pre-planned roadway. This option was found to best meet all considerations of effectiveness, implementability, cost, and overall protectiveness. Remedial action at this site is currently underway.

Conclusions. The case study described in this paper exemplifies the practical use of risk assessment results. It also illustrates the key factors stated earlier in this paper:

- Define the role of risk-based decision making (RBDM) during initial planning (*i.e.,* begin with the end in mind). Stakeholders including the regulatory agency as well as the public were involved early and often in this project. An RBDM approach was established at the outset.
- Incorporate "best" science (*e.g.,* tools, methods, data) and seek to derive "best" estimates of risk. The strategic integration of essential tools, namely a tiered risk assessment approach, geostatistics in a GIS platform, and essential site-specific studies (bioavailability), were critical to the RBDM approach employed.
- Don't hesitate to venture outside the box and be proactive, especially if scientific support is available. Proactive negotiation of probabilistic risk assessment and the non-cancer decision making basis for arsenic are examples.

References

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