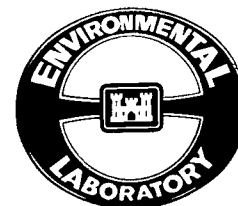




# *Environmental Effects of Dredging Technical Notes*



## **Risk Assessment: An Overview of the Process**

### **Purpose**

This technical note provides a nontechnical overview of the risk assessment process. A companion technical note regarding risk assessment terminology will be published in the near future.

### **Background**

In November 1989, Chief of Engineers LTG Henry J. Hatch convened the Environmental Advisory Board (EAB) to discuss the Dredging Program and its potential impact on wetland development and coastal erosion protection. The EAB is a blue-ribbon panel of outside experts which normally meets every 6 months to hear discussions and develop recommendations on any environmental topic of concern to the Chief of Engineers. At the November meeting, personnel from the US Army Engineer Waterways Experiment Station briefed the EAB on topics such as the Long-Term Management Strategy (LTMS), inshore versus offshore placement of dredged material, effects-based testing of dredged material, and research and development needs to support the Dredging Program. A central theme emerged in the EAB's response to these topics for the Chief of Engineers. The Corps must more fully use the risk assessment process, its concepts and procedures. LTG Hatch's response was positive: "Risk assessment should be much more fully utilized in dealing with both contaminated and uncontaminated dredged materials." LTG Hatch also called for additional research on risk assessment in response to the EAB recommendation. This technical note represents the initial effort by the Dredging Program in Headquarters, US Army Corps of Engineers to implement the EAB recommendations.

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## Historical Perspective

The foundation of contemporary risk assessments began some 40 years ago in the US Food and Drug Administration (FDA). The FDA is charged, in part, with ensuring food products in interstate commerce are "safe." To assess the risks posed by man-made chemicals the FDA adopted an approach using safety factors. That is, the "safe" level of a chemical was some fraction (usually 0.01) of the lowest concentration shown in laboratory studies to have an adverse effect. This approach was satisfactory for a while.

In 1958, Congress passed the Delany Amendment to the Food, Drug, and Cosmetic Act. Although well intentioned, this legislation prohibited the presence of *any* chemical in *any* product regulated by the FDA shown to cause cancer in *any* test under *any* circumstance. This total prohibition was based on the belief subscribed to by most scientists at the time that no safe level of exposure to a carcinogen could be established. The impact of the Delany Amendment was not fully felt until the mid-1960s when chemists began detecting more and more contaminants at lower and lower concentrations virtually everywhere they looked.

Advances in analytical chemistry, in particular high-resolution gas chromatography, lowered detection limits greatly, often by orders of magnitude. In addition, an increasing number of biological tests were indicating that many chemicals in common everyday use were causing cancer in laboratory animals.

The combined impact of these events created a significant scientific, legal, and economic dilemma. On one hand, the Delany Amendment mandated zero risk in FDA-related products. On the other, strict enforcement would literally shut down interstate commerce and have severe economic effects nationwide.

To solve this dilemma, the FDA adopted a *de minimis* policy. This basically said that chemicals at very low concentrations posed inconsequential human health risk. (*De minimis* is a shortened form of *de minimis non curat lex* — a legal doctrine which indicates that the law does not concern itself with trifles.) Although the FDA was criticized by many for taking this approach, the scientific community could provide no reasonable alternative.

At this same time the public and other Federal agencies were becoming more aware and concerned about pollutants in the workplace (for example, benzene and vinyl chloride), the environment (for example, mercury and DDT) and the home (for example, formaldehyde and radon). In 1981, the FDA asked the National Academy of Sciences (NAS) to review the science supporting the evaluation of human health risks posed by man-made chemicals. The NAS was also asked to

recommend to Federal departments and agencies a sound consistent approach for assessing those chemical risks. The result was a watershed document, the NAS "Red Book." In it the NAS proposed a general approach for assessing human health risks (National Research Council 1983). This paradigm has been the blueprint for virtually all risk assessments conducted since that time. The US Environmental Protection Agency (EPA) vigorously embraced the NAS risk assessment paradigm and has used it extensively to evaluate human health risks at hazardous and toxic waste (HTW) sites under its Superfund program.

## Overview of the Risk Assessment Process

There are four elements in the risk assessment process: hazard identification, dose-response assessment, exposure assessment and risk characterization. Each step is summarized below.

### Hazard Identification

This is the process of showing *causality*, that is, does a chemical cause cancer (a carcinogen) or induce some other adverse effect such as reproductive dysfunction or birth defects (a teratogen)? If this causality can be demonstrated, the chemical is referred to as a "hazard." In theory, hazard identification yields a quantal yes-or-no answer to the causality issue. In practice, the available evidence generally does not permit an unequivocal answer to the causality question. Consequently, when deciding whether a chemical is a hazard, the total weight of the evidence as well as the strength of the relationship are evaluated using guidance such as Hill's criteria (Hill 1965). Types of evidence considered in hazard identification include laboratory toxicity studies for both carcinogens and noncarcinogens, epidemiological studies, clinical case studies, and quantitative structure-activity relationships.

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### Dose-response Assessment

While hazard identification decides whether a chemical is toxic, the dose-response assessment determines the magnitude of the toxic response. This is almost always accomplished experimentally in the laboratory. Rats or mice or some other mammal acting as human surrogates are exposed to high concentrations of the chemical hazard and some effect (for example, incidence of tumors) is monitored over time. Results are typically expressed in dose-response curves, that is, the quantitative relationship between the administered chemical dose and observed biological response. To use these data in assessing environmental risks, results must be extrapolated from high dose to low environmentally realistic exposures and from surrogate test species to human beings. These extrapolations can be the source of considerable uncertainties.

In dose-response assessment, a clear distinction is made between carcinogenic and noncarcinogenic chemicals. For carcinogens, it is currently assumed that no "safe" concentration or threshold exists. All the data from the laboratory experiment are used to calculate the slope of the dose-response curve. The upper-bound 95 percent confidence limit of the slope (slope factor) reflects the chemical's cancer

potency. In contrast, a threshold concentration is assumed to exist for noncarcinogens. Below this threshold concentration no adverse effects can be expected to occur. Concentrations just above and below the threshold are called the lowest-observed-adverse-effect level (LOAEL) and the no-observed-adverse-effect level (NOAEL), respectively. The LOAEL and NOAEL are used to calculate the toxicity or reference dose (RfD).

## Exposure Assessment

In exposure assessment, the magnitude, frequency, and duration of chemical exposure relative to the target receptor(s) are determined. This process is model-intensive with both descriptive and quantitative models being used. Here, a distinction is made between pathways and routes. A pathway is where the chemical travels between the initial source of contamination and the ultimate biological receptor. A route is how the chemical enters the receptor (for example, ingestion, inhalation, or dermal adsorption). EPA currently uses a reasonable maximum exposure (RME) for most exposure calculations. The RME is defined as the upper 95 percent confidence limit of every exposure parameter. Exposure is generally assumed to occur over a full lifetime (70 years) or a working lifetime (30 years).

## Risk Characterization

Outputs from the dose-response assessment and exposure assessment are brought together to produce a numerical estimate of chemical risk. For noncarcinogens, this risk is expressed as a hazard quotient (HQ) or the ratio between RME and RfD. Chemical risks increase as the HQ approaches unity. For carcinogens, risks are expressed as the upper bound (95 percent confidence limit) estimate of number of humans developing cancer. The *de minimis* risk most often cited is  $10^{-6}$  or one in a million individuals. It is crucial to remember that the numerical estimate of risk is an upper-bound calculation and that the true risk lies somewhere between zero and this upper-bound estimate. EPA has provided recent guidance indicating that upper-bound lifetime cancer risks between  $10^{-4}$  and  $10^{-6}$  are acceptable at Superfund sites following remediation (EPA 1990). Finally, the uncertainties associated with the risk assessment process are addressed during the risk characterization stage.

## Risk Management

Once the chemical risk has been assessed, it must then be managed. This is the job of the risk manager. Management alternatives range from no action to extensive (and expensive) remediation. Chemical risks are almost always managed by controlling the potential for *exposure*. The intrinsic toxicity or dose-responsiveness of a chemical can rarely, if ever, be altered. In developing a management plan, the risk manager considers not only the results of the risk assessment, but factors such as applicable laws and regulations, engineering feasibility, potential benefits, costs, economic impacts, and the socio-political decision environment. Clearly,

this process is very similar to the one undertaken by District Engineers and their staffs in evaluating the potential environmental impacts of dredging operations.

The NAS strongly recommended that risk management be a discrete activity clearly separate from the risk assessment process. It was felt that the assessment of chemical risks should be carried out independently, free from potential biases such as political pressures or remediation costs. While this compartmentalization may increase the technical purity of the risk assessment, the risk assessor and risk manager must communicate at some point early in the process if the technical results are to be useful.

## **Risk Communication**

Risk communication is a dialogue, not a monologue. It occurs at two levels. The first is between the risk assessor and the risk manager. In practice, this usually occurs during risk characterization when the assessor communicates technical findings to the manager. The manager must be provided a clear and accurate picture of the results including an appreciation for the limits and uncertainties. If this does not occur, then the next level of risk communication, risk manager to the public, will be unsuccessful. At this step, the public includes not only the general public, but also all other interested parties such as resource agencies, other Federal agencies, special interest groups as well as the human population which may be at risk.

## **Risk Analysis**

Risk analysis is a broad, inclusive term encompassing the processes of risk assessment, risk management, and risk communication, as well as any field verification or monitoring activities. Field verification includes studies carried out to determine the accuracy of laboratory observations and predictions. Field monitoring (in the context of risk assessment) is undertaken to ensure that steps taken to manage the chemical risks have been successful. Risk analysis and its component parts are shown in Figure 1.

## **Uncertainties in the Risk Assessment Process**

Assessing risk will *always* involve uncertainty. If there were no uncertainties, there would be no risk and answers to questions would be known with precision and accuracy. The uncertainties associated with numerical estimates of chemical risk can be quite large. Some of the more important sources of uncertainty include the classification of chemicals as carcinogenic versus noncarcinogenic, extrapolating dose-response data from laboratory animals to humans and from high dose to low dose, selection of appropriate exposure models, and parameter inputs for those models. To cope with these potentially large uncertainties, conservative assumptions and safety factors are used throughout the risk assessment process. While this greatly diminishes the possibility of underestimating risks, it can also lead to very unrealistic, some would say, unusable answers. Uncertainty analysis, error propagation, safety factors, and the appropriate use of conservative

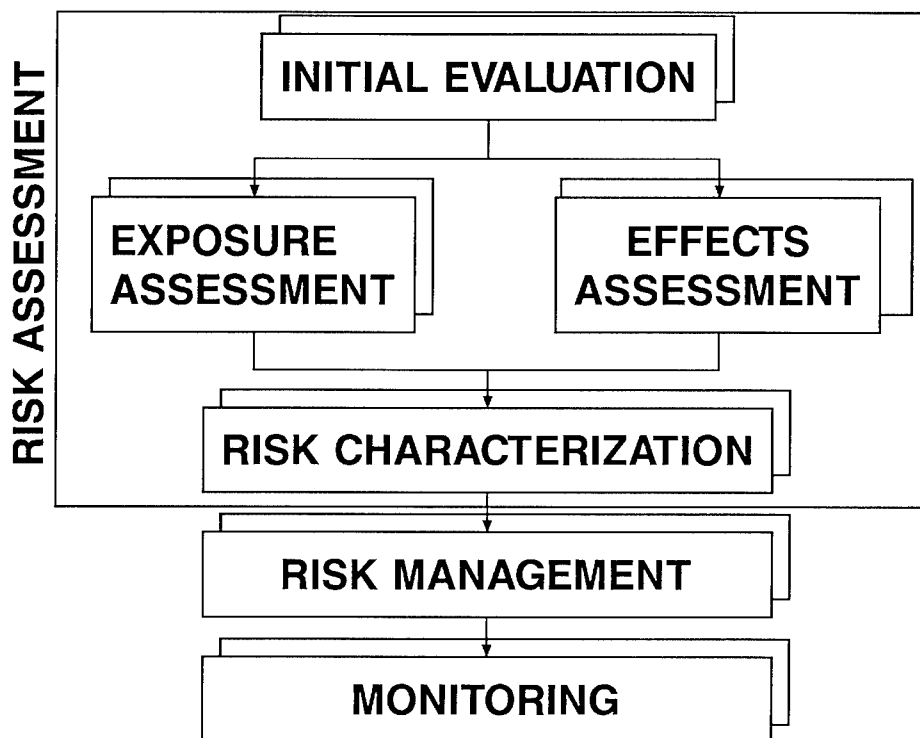


Figure 1. Risk Analysis

assumptions are now receiving greater attention by policy makers and the technical community.

## Nonhuman Target Receptors

Traditionally, risk assessments have focused almost exclusively on human beings as the target receptor for man-made chemicals. Methods and data bases have all been developed from the human health perspective. Only now are approaches being considered to assess chemical risks to nonhuman target species. Some methods will probably be modifications to technologies used now for human health risk assessments. However, new and innovative procedures will undoubtedly need to be developed. For example, what are the appropriate test species? In human health assessment, many mammalian species are used when there is only one receptor species of concern. In assessing risks to nonhuman species there may be many target receptor species. What suite of test animals is most appropriate? What type of extrapolation is required? Human health risk assessments are chemical specific. While this may be appropriate for nonhuman target species, an effects-based approach may be more desirable especially when exposure is to complex mixtures such as contaminated sediments. Another issue to resolve is endpoint selection. In human health risk assessment, the only endpoints have been carcinogenesis and teratogenesis. When nonhuman target receptors are of concern, the number of potential endpoints is virtually limitless. These and other issues will require considerable time and effort to resolve.

## Potential Application of the Risk Assessment Process to Corps Dredging Operations

Before discussing *how* risk assessment could be applied to Corps dredging operations, a more fundamental and legitimate question to ask is *why* should it be considered at all. The incentives for seeking risk-based solutions are found in the current decision-making environment for dredging operations:

- Regulatory decisions are always made in the absence of complete and certain data.
- Achievement of zero risk is impossible.
- Achievement of near-zero risk may be cost-prohibitive.
- Everyone will accept a certain amount of risk.

Using a risk-based approach in this decision-making environment has political, managerial, and technical advantages. Some of these are described below.

- Environmental risk assessment is the only approach currently available for quantifying chemical risks which has broad acceptance in the scientific and regulatory communities. It is not perfect and has its critics, but a logical, technically sound alternative for estimating chemical risks has yet to emerge. Risk assessments have been and will continue to be conducted by individuals and agencies within and outside the Federal government. Using an approach that is used and recognized by major portions of the scientific and regulatory communities (EPA, for example) will help ensure that Corps technical results and regulatory decisions are more readily accepted.
- The risk assessment process treats uncertainties explicitly. This eliminates the need for worst-case testing scenarios. When properly designed and conducted, risk assessments yield a continuous solution as opposed to a discrete yes-or-no answer. This solution is expressed in the form of *probability distributions*. While some managers (and scientists) will feel uncomfortable with this type of technical output, it offers considerable flexibility for the type of weighing and balancing that must be done in implementing Congressionally-mandated programs.
- Regulators are charged with making decisions, not finding scientific truths. The risk assessment process is commensurate with this charge because it deals with probabilities, not absolute truths.
- Risk assessments are, by their nature, highly conservative. Therefore, if projected chemical risks are found to be acceptable (for example, excess lifetime cancer risks of  $10^{-4}$  to  $10^{-6}$ ), the risk manager and the manager's constituency can be assured that the actual risk is quite low. This is because the highly conservative process yields upper-bound risk estimates.

- If projected risks are not acceptable (for example, excess lifetime cancer risks  $\geq 10^{-4}$ ), the risk assessment process offers a means of identifying where the problems are and how they can be corrected. Sensitivity analysis is the manager's tool for pinpointing these critical elements. Once the important forcing functions have been identified, supporting data and assumptions may be more closely scrutinized. If the data associated with these elements is poor or nonexistent, the risk manager has the option of collecting additional information. If the knowledge domain is sufficient, sensitivity analysis will help focus the risk management activities to the most critical elements.
- Large uncertainties can be partially ameliorated by conducting *comparative* or *incremental* risk assessments. In this approach, the quantitative *difference* associated with various scenarios is examined rather than the *absolute* risk of each. Many conservative assumptions and large uncertainties are common to each scenario and, thus, become moot. For example, one could calculate the incremental risk associated with relocating dredged material in a waterway versus taking no action. Conservative assumptions and large uncertainties common to both actions become irrelevant. It is the *difference* between the two which is important.
- Finally, using a risk-based approach has a distinct managerial advantage. Risk assessments identify what is important, what is unimportant, and what is unknown. This permits managers to allocate critical and usually limited resources to areas of greatest need. It provides an objective way for the manager to identify knowledge gaps and direct resources in such a manner that will facilitate the future conduct of his or her job.

## Applications to Navigation Dredging

The Corps' statutory authority for disposal or discharge of dredged material into the ocean or waters of the United States comes, respectively, from Section 103 of the Marine Protection, Research, and Sanctuaries Act of 1972 (PL 92-532) and Section 404(b)(1) of the Federal Water Pollution Control Act of 1972 (Public Law 92-500), as amended. Both laws specify that there shall be "no unacceptable adverse impacts" on the environment as a result of dredging operations. It is important to note that the law permits some "adverse impacts" as long as they are not "unacceptable." This statutory language strongly suggests a risk-based technical evaluation.

The Corps uses a tiered testing effects-based approach for assessing dredged material. Bioassays are conducted to determine the toxicity of project sediment to appropriate sensitive animals and to determine the bioaccumulation potential of sediment-associated contaminants. Results are compared to a reference sediment which represents the disposal environs in the absence of disposal activities. The procedure is technically sound, enjoys wide acceptance, and reflects a judicious marriage of state-of-the-art and the requirements for routine testing in a regulatory program. In most instances, however, this approach yields a qualitative yes-or-no answer. That is, dredged material is found to be either acceptable or



not acceptable for unrestricted disposal. Current procedures do not permit the manager to quantitate how "acceptable" or "unacceptable" the project sediment is. This is where a risk-based assessment procedure could more fully be used.

Historically, most sediments have been found to be "acceptable." Those considered marginal or "unacceptable," while representing a small volume of total material dredged, consume a disproportionately large share of limited resources. These costs, expressed as time, money, and productivity, are initially borne by the Corps and permit applicants. Ultimately, they are passed on to the consumer and taxpaying public. The lack of technically sound procedures for assessing the *probability* of adverse impacts associated with dredging operations is a major reason additional testing is always requested. To the manager or permit applicant the evaluation and testing probably seem to go on forever. If risk-based procedures were available to Corps Districts and Divisions, they would be able to balance potential environmental impacts with other factors (for example, costs) in a more technically defensible manner. These procedures would also provide the risk manager with a quantitative means of comparing the risks associated with different disposal options (for example, diked containment or upland confined disposal facility) including the no-action alternative. Corps Districts and Divisions carry out this weighing and balancing now, but the process is subject to criticisms of subjectiveness, bias, and inconsistency. Formal procedures for determining the degree of "unacceptable adverse impacts" of dredged material disposal would help mute these criticisms and signal a significant technical step forward. It would also likely increase the Corps' credibility among local agencies, the public, and the courts.

### **Applications to Environmental or Clean-up Dredging**

Sediments tend to act as sinks for environmental contaminants. In some lakes, rivers, harbors, and waterways, nonnavigational dredging may be considered as a means of cleaning up or remediating sites which are highly contaminated and pose substantial risk to human health and the environment. This environmental or clean-up dredging may be conducted under four separate authorities. The oldest, but least used is Section 115 of the Federal Water Pollution Control Act of 1972 (PL 92-500). This section authorized the EPA Administrator, acting through the Secretary of the Army, to remove and appropriately dispose of in-place toxic pollutants from harbors and navigable waterways. To date, only one Section 115 action has been carried out — dredging in 1974 of spilled polychlorinated biphenyls in the Duwamish River in Seattle, WA.

The second, more familiar authority under which environmental dredging can occur is the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) or Superfund. In 1980, Congress authorized \$1.6 billion for CERCLA for over five years to clean up hazardous materials at sites across the country. Many of these sites contain highly contaminated soils and sediment. One such site, New Bedford Harbor, MA, was the focus of a recent interagency study evaluating the environmental and engineering feasibility of dredging and dredged material disposal alternatives (Averett 1990).

The third authority is the Department of Defense's (DOD) Defense Environmental Restoration Program (DERP). DERP is analogous to the civilian Superfund program, but is specific to active and formerly used DOD installations. The two programs are so inextricably linked that when the CERCLA was reauthorized in 1986 (Superfund Amendments and Reauthorization Act (SARA) (PL 99-499)), DERP was included as Section 211 of this Act. Under DERP, the Secretary of Defense, in consultation with the Administrator of EPA, may carry out investigations and clean-up activities at DOD facilities in a manner consistent with the same procedural and substantive requirements used at civilian sites under the Superfund program. The Corps has been assigned the responsibility for Army sites involved in DERP activities. Human health risk assessments are conducted by contract and reviewed by the US Army Environmental Hygiene Agency prior to approval by the US Army Surgeon General. In both the Superfund Program and DERP, the US Army Engineer Division, Missouri River has the lead for remedial design and action.

The fourth and final authority for clean-up dredging is also the most recent. Under Section 312 of the Water Resources Development Act of 1990 the Corps was authorized to conduct environmental dredging in association with civil works navigation projects within certain spatial, financial, and sponsorship limitations. Field guidance for this authority is currently being prepared by Headquarters, US Army Corps of Engineers.

Under all four authorities, risk assessment can be used to establish effects-based clean-up goals for environmental dredging. It answers the question, "How clean is clean?" This is critical because clean-up to background, while desirable, is often not possible. For example, what constitutes "background" is often not clear. Risk assessment allows one to specify clean-up goals that are risk-based. Since outputs are expressed as probabilities, one can balance benefits achieved (that is, risk reduction) with other factors such as clean-up costs. This is a particularly attractive feature since costs associated with clean-up dredging typically run 1-2 *orders of magnitude* above navigation dredging (\$1-\$5/cu yd).

### **Applications to other Corps Operations**

Could the risk assessment paradigm be applied to Corps operations other than dredging; for example, the management of wetlands, lakes, reservoirs, and watersheds? There is no reason not to think so. The risk assessment process can be applied whenever there is uncertainty regarding a particular action or activity. The only obstacle would be the appropriate technical tools for assessing exposure and effects.

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