

## APPENDIX III

### Human Health and Environmental Risk Characterization and Health Concerns at the Dow Site

Method 3 Human Health Risk Assessment under the Massachusetts Contingency Plan (MCP) must be conducted according to specific rules and procedures, and must follow guidance presented in *Guidance for Disposal Site Risk Characterization* (Massachusetts DEP, July 1995, and supplemental guidance). Risk Assessment is possibly the most misunderstood aspect of hazardous waste site management - and one challenge faced by consultants to community groups is helping them to understand the role of Risk Assessment in the MCP process. Maybe more importantly, the consultant must also help community groups to understand what Risk Assessment does not do.

#### Human Health Risk Assessment

Risk Assessment consists of four components: 1) Hazard Identification; 2) Dose-Response Assessment; 3) Exposure Assessment; and 4) Risk Characterization.

In the Hazard Identification step, the risk assessor identifies Contaminants of Concern (COCs) that will be used throughout the Risk Assessment based upon review of analytical data from soils, groundwater, surface water, sediment, and other media, such as waste. The COCs are substances that, based on rules set forth in the *Guidance*, are most likely associated with activities that took place at the site, and are not the result of natural background, laboratory contamination, or laboratory error.

For each COC determined to be related to site activities, the risk assessor selects appropriate risk parameters to evaluate carcinogenic and noncarcinogenic effects. These values, called the Dose-Response values, are used to estimate the likelihood of health effects from COCs found on the site. The Dose-Response values are taken from several databases, EPA's *Integrated Risk Information System (IRIS)* and the *Health Effects Summary Tables (HEAST)*. These are the standard references for dose-response information used in risk assessment under the MCP and under similar U.S. Environmental Protection Agency (EPA) guidance. If a dose-response

value is not available from these databases, there are other sources, including values published by the Massachusetts Department of Environmental Protection (DEP), EPA, and other agencies.

For noncarcinogenic effects, the risk estimate for oral and dermal exposure is the Reference Dose (RfD), and is an estimate of the threshold dose below which no adverse response is expected. The RfD's are normally derived from animal studies to which several safety factors are applied to ensure that the values used for humans are conservative. Both chronic and subchronic RfDs are available. The chronic RfD is used for long-term exposures, usually for 7 years or more. The subchronic RfD is used to evaluate exposures that occur over less than 7 years.

For carcinogenic effects, the risk estimate used is the Slope Factor (SF), also called the Carcinogenic Potency Factor (CPF). The SF is also derived from animal studies, and from a mathematical model that represents the slope of the upper 95 percent confidence interval of the dose-response curve derived from a linearized model that extrapolates low dose estimates of carcinogenic risk from higher dose experimental exposures that caused cancer in laboratory animals.

In the Exposure Assessment, the risk assessor identifies potential receptors, exposure routes, exposure pathways, and exposure point concentrations of chemicals specific for the site.

In the Exposure Assessment, the following are determined:

Routes of Exposure                      How exposure can occur, in this case through ingestion and/or dermal contact and absorption.

Pathways                                      The environmental media and mechanisms through which exposure can occur.

Exposure Scenarios                      The circumstances under which exposure can reasonably occur given conditions at the site.

Exposure Assumptions

The characteristics of the people who are exposed, and the conditions under which they are exposed.

The exposure scenarios used in risk assessments must make assumptions on how the site will be used in the future as well as on how it is currently used. The first step in the Exposure Assessment is identifying groups of people called receptors who may potentially be exposed to COCs given the current and foreseeable uses of the site.

Exposure Point Concentrations (EPC) and Average Daily Doses (ADD) are then calculated for each chemical and each exposure pathway. Lifetime Average Daily Doses (LADD) are calculated for those COCs classified as carcinogens.

The EPC is the estimated concentration of a COC that the receptor contacts under the site-specific exposure scenarios. Pursuant to the MCP Risk Assessment Guidance, the EPC is normally the arithmetic mean (or simple average) of all the data for each chemical at a given exposure point. It is used to calculate the Average Daily Dose (ADD) or Lifetime Average Daily Dose (LADD), which are the estimated daily exposures to the COC that are evaluated for the probability that they will result in toxic and cancer effects, respectively.

Following estimation of the EPC, the ADD, and the LADD for carcinogens, are calculated using the following general relationship:

$$\text{(L)ADD} = \frac{\text{EPC} \times \text{Intake} \times \text{Relative Absorption Factor} \times \text{Frequency} \times \text{Duration}}{\text{Body Weight} \times \text{Averaging Time}}$$

where:

- (L)ADD the (Lifetime) Average Daily Dose (mg/kg/day)
- EPC the Exposure Point Concentration, which is the arithmetic mean of the data for each COC
- Intake the amount of and/or rate at which a receptor comes into contact with the environmental media that contain the COCs
- Relative a value derived from experimental data that
- Absorption Factor Estimates the amount of the COC that is absorbed by the human body after contact with the environmental media at the site that contain the substances

Frequency	The number of times that the receptor comes into contact with the media containing the COCs
Duration	The time span over which exposure occurs
Body Weight	The receptor's weight;
Averaging Time	The time over which the exposure is averaged. For carcinogenic effects, lifetime (75 years) is used and an LADD is determined; for noncarcinogenic effects, the time period covered by the duration of exposure is used.

The risk characterization step of a Risk Assessment involves comparing the average daily doses of chemicals calculated under the exposure scenarios to the dose corresponding to the appropriate risk estimate, either the RfD (for noncarcinogenic effects) or the SF (for carcinogens). These risk estimates are then compared to the MCP risk limits, a total site Hazard Index (HI) of less than 1.0 for noncarcinogenic effects and a total site Excess Lifetime Cancer Risk (ELCR) of less than 1.0E-5 (one in one hundred thousand) for carcinogenic effects.

The risk of noncarcinogenic effects is estimated by dividing the ADD by the RfD. This yields a HI for each COC:

$$HI = ADD/RfD$$

The sum of the HIs for each COC is the site HI.

Cancer risk is estimated by multiplying the LADD by the SF:

$$ELCR = LADD \times SF$$

The sum of the carcinogenic risks for each COC is the total site ELCR.

## How Risk Assessment is Used

Risk Assessment is a tool used in management of hazardous waste sites. Its primary purpose is to allow decision-makers to evaluate the risks associated with contamination present at the site without any remedial action. The Risk Assessment allows responsible parties and regulators to

evaluate the site conditions and how they would affect people and the environment by evaluating possible exposures to contaminants in site soils, groundwater, surface water, sediment, and other environmental media by hypothetical people who could live or work on or near the site. Risk Assessment evaluates these exposures by comparing them to exposure levels that would not be expected to cause harm. If the hypothetical 'receptor' is exposed to contaminants at a level lower than the exposure that should not cause harm, the outcome of the Risk Assessment is a condition of 'no significant risk'. If the exposure is higher, there is 'significant risk' as defined by the MCP.

Significant risk does not mean that people who live near a site are at risk of immediate or certain adverse health effects. Significant risk does imply that if the site is not cleaned up there is a chance that some people will be affected, particularly after being exposed to the contaminants in the environment for several years. Because Risk Assessments evaluate exposures under 'reasonable worst case' conditions, the probability that any one individual will be affected by living near or at a hazardous waste site is low. Worst case assumptions consider that some people will have extensive and repeated contact with contaminated environmental media; MCP guidelines recommend 'reasonable' worst case assumptions, which are not absolute worst case, but reflect activities that a 'reasonable' person could be expected to engage in at the site. For example, a worst case scenario considers that a person who lives at a contaminated site will be in contact with soils in his/her yard five days per week during the spring, summer, and early fall. This type of activity could be expected from someone who is a dedicated gardener or landscaper. A more likely scenario is that a person who lives at a contaminated site will be in contact with soils in his/her yard only one or two days per week. Worst case is used in Risk Assessment because regulators want to ensure that cleanup decisions protect people who engage in activities that are reasonable, although not necessarily typical or 'average'.

The outcome of the Risk Assessment is used to determine if remediation is necessary to ensure no significant risk at the site, both in the present and the future. However, Risk Assessment can evaluate only those contaminants present in site media at the time that the investigation is conducted. Risk Assessments evaluate the existing site conditions, and assume that these existing conditions are the basis for site conditions over the next 20 to 30 years. The basis for the baseline existing conditions in Risk Assessment is the monitoring results developed in the site investigation. These results are used to establish the "Exposure Point Concentrations" to which people who live or work at or near the site are exposed. Risk Assessment can also use

modeling to evaluate how site conditions and exposure point concentrations may change in the future. For example, contaminants in groundwater can be expected to migrate, and therefore to spread to new areas of the site. Monitoring data can provide information about migration trends, but modeling is needed to predict the extent of a groundwater plume in the future. Modeling is also useful in predicting the impact of groundwater or soil contamination on indoor air quality, as well as bioaccumulation potential in fish or other organisms. Modeling to predict behavior of contaminants at a site requires information about contaminant concentrations in the environment, as well as detailed information about environmental conditions that will affect fate and transport of the contaminant.

Risk Assessment cannot evaluate conditions that cannot be demonstrated at a site either through monitoring or predictive modeling. Therefore, Risk Assessment can evaluate past conditions if monitoring data are available, but if there are no historic monitoring data, Risk Assessment cannot estimate exposures that could have occurred in the past. This limitation is particularly true if suspected past exposures involved chemicals present in environmental media different from the media that are contaminated at the present time.

### **Risk Assessment Concerns at the Dow Site**

The primary media of concern at the Dow site – based on extensive environmental monitoring – are soils, surface water, and sediment. Although some groundwater contamination was detected, there is limited opportunity for exposure to groundwater at the site. However, residents living near the site expressed concerns about past exposure to contaminants in air. This is a rational concern given the reported past waste disposal practices at the Dow site – particularly incineration of wastes in the burn area. There were also concerns about chemical vapors and particulates discharged through the laboratory hoods while the facility was operating. Because monitoring was not done when these activities were taking place, it was not possible for the Risk Assessment to evaluate their impact on human health or the environment.

Some of the local residents expected that the Risk Assessment would evaluate the impact of these past exposures. This concern was heightened because one former resident of the area adjacent to the Dow site was diagnosed with cancer and was convinced that exposure to site-related contaminants during her childhood was the cause of her illness. The Neighbors'

consultants faced the challenge of explaining the role – and the limits - of Risk Assessment and how it would be used at this site.

## **Developing New Standards for Organotins**

The MCP provides options for evaluating risk to human health. Risk Characterizations conducted as part of hazardous waste site investigations can use one of three methods, the most common of which is Method 1, which makes use of standards established by the DEP for maximum concentrations of contaminants that can be present in soil and groundwater in order to ensure protection of human health. These ‘Method 1 Standards’ are reasonably conservative. The DEP set the Method 1 levels using a reasonable and rational approach that follows acceptable risk assessment practice. There are three levels of Method 1 soil standards that account for use of the property. The most stringent standards are called S-1, and represent concentrations of contaminants in soils that would not result in unacceptable health risks if they were present on residential property. These standards are indicative of what DEP refers to as a ‘level of no significant risk’ for the most sensitive uses of soil, which include children playing in it, eating it, and eating vegetables grown in it.

## **Method 1 Standards and the MCP**

Use of the Method 1 S-1 standards to determine if there is significant risk at a disposal site is not without some controversy and disagreement among various stakeholders in almost every disposal site situation. The most common arguments arise over what is ‘conservative enough’. Very often, people who live near disposal sites, and who are most affected - actually or perceptually - by contaminated soil, argue that any amount of contaminant in soil is too high. The argument for ‘zero’ as an effective measure of no significant risk is common, and explaining the meaning of significant risk is a challenge for a technical advisor to community stakeholders. Of course, Potentially Responsible Parties (PRPs) have been known to argue that the S-1 standards are too low, that they are not realistic, and that they do not adequately reflect site-specific background levels of some contaminants, particularly metals and fuel-related contaminants.

The MCP has similar Method 1 standards for groundwater, with the most stringent GW-1 Standards applying to sites where groundwater is used for human consumption or in an area

where it could be used for human consumption in the future. Other Method 1 groundwater standards protect against migration of contaminant vapors into buildings and also protect wildlife in surface water that serves as a receiving body for groundwater. The MCP rules for groundwater are more complex than those for soils, and groundwater at a site often has to meet more than one of the standards, depending on the use of groundwater, its depth below the surface, and the physical properties of the contaminants.

The MCP allows the PRP to perform a risk assessment at a number of stages in an investigation at a disposal site, but most risk assessments are done after initial remedial actions are completed. Under the 'rules' that govern MCP investigations, no further remedial work is required if the site meets the definition of no significant risk at any stage in the assessment and cleanup process. Therefore, the goal of many PRP-initiated initial cleanup actions is to 'meet the Method 1 Standards'. If the site soils meets the S-1 standards, and the site groundwater meets the applicable standards, the site is considered to be 'clean' under the MCP and no legal restrictions are placed on any current or future activities on the property. If the site does not meet the S-1 standards, the PRP has a few options. He/she can show that the site meets less stringent Method 1 soil standards (S-2 or S-3), but this finding would require an Activity and Use Limitation (AUL), which is a deed restriction that constrains some activities on the property in order to protect public health. The PRP can also use Method 3, which involves a more complex evaluation of exposure and risk, and take into account site-specific information about the types of activities present or likely in the future. Another option is to continue remediation until the appropriate Method 1 standards are achieved in soil and groundwater.

## **Method 1 Standards at Dow**

The Dow site ran into difficulty when, as part of the initial investigations of site soil, a number of contaminants were discovered for which there were no Method 1 standards. The MCP includes Method 1 standards for over 100 metals and organic compounds. These substances were selected because they are the most common contaminants at hazardous waste sites, but there are sites where contaminants that are not included in the Method 1 list are found. The Dow site is one of these sites. This circumstance was not unexpected because this site was a research facility where chemicals were synthesized and tested. Some of Dow's research in Wayland included producing and testing small amounts of organotin compounds. These were considered 'hot' new compounds in the 1970's, and Dow experimented with them in search of new chemicals that could prevent marine organisms such as barnacles and other marine crustaceans from attaching to boats and ships. These organisms damage paint, resulting in economic loss to owners of watercraft. The organotin compounds are toxic to barnacles, and by mixing these compounds with marine paints, the paints kill the organisms before they can cause damage to boats.

## **Organotin Properties and Toxicity**

Organotins are relatively simple compounds, with one or more methyl, ethyl, and other short-chain carbon groups attached to a tin molecule. The resulting compound interferes with cell function at the molecular level. Although there is no direct evidence of toxicity in humans, laboratory studies using mice and rats have demonstrated that organotin compounds can affect the immune system. Tributyl tin appears to be the most toxic organotin compound; it has been shown to be more toxic than dibutyl tin in laboratory studies. Researchers suspect that the organotin compounds affect the life span of cells. Each cell in an organism's body is programmed to die after a specific number of cell divisions, and cells exposed to organotins appear to die early. Some research indicates that this effect may be the result of an affect on the basic energy-producing reactions that occur in the cell.

In the years since the 1970s, organotins became implicated in toxicity to nontarget marine organisms. The overall ecological effects of use of these materials in paints is not

fully known, and their potential health effects on humans are also not well understood. Organotins in paints have been suggested as a reason for death of coral, the marine animal whose spiny exoskeleton forms coral reefs. Some scientists suspect that organotins leach from marine paints in shallow, warm water, and kill the living reefs. Research on the ecological impact of these compounds is continuing.

That organotins are toxic to marine animals other than the so-called 'target organisms' is not surprising given the current state of knowledge in toxicology. A lot has been learned about adverse responses on the cellular and molecular level in the twenty plus years since organotins were first marketed as miracle additives to marine paints. An underlying principle accepted by most toxicologists is that effects on cells and on sub-parts of cells are often noted across species, particularly when those effects are related to basic cellular function. For example, a chemical that affects the way a cell uses oxygen can be expected to have that effect on all cells that use oxygen - therefore on all animal cells. When chemical effects are evaluated on the cellular level, rather than on the organism level as they were in the not too distant past, it is easier to see similarities rather than differences in the way the organisms that are made up of those cells respond.

The effects of organotins on people, however, are still unknown, or more correctly, uncertain. Uncertainty is a technical term used by risk assessors to describe the statistical likelihood that the calculated results or outcome are reflective of the true or real risk. Uncertainty is always part of risk assessment, and part of risk management. Uncertainty is introduced into risk assessment because of scientific judgments and assumptions that are necessary to evaluate the inherent toxicity, potential for exposure, and potential for harm associated with chemical contaminants. One of the most difficult tasks in the public participation part of a hazardous waste site investigation is dealing with this uncertainty. Current society likes definite answers, and very little in risk assessment is definite. Risk assessment practice incorporates safety factors and conservative assumptions to account for uncertainty, and to increase the likelihood that if errors are made as a result of uncertainty, those errors reflect increased risk, rather than decreased risk from a given situation.

## Uncertainty

One area of uncertainty that is difficult to account for by conservative assumptions is uncertainty in whether a specific chemical causes an effect (i.e., uncertainty about inherent toxicity). Most people are aware at least anecdotally of substances that were previously thought of as safe, and turn out to be potentially harmful, and, conversely, of substances thought to be harmful that are found to be essentially safe.

All people have to do to be caught in this conundrum is to read the popular press. Is red wine good for you? Is it harmful? What is 'moderate consumption'? What about saccharin and cyclamates? Do they cause cancer? Didn't thalidomide cause terrible birth defects back in the sixties? Why is it coming back as an anti-cancer drug? Can it be 'safe'? With all the confusion about drugs and food and food additives, it is not surprising that people are confused about chemicals, especially about chemicals with exotic-sounding names, and particularly about chemicals that have known detrimental effects on other organisms, even if those organisms are marine invertebrates that cling to the bottoms of boats. There are many reasons for this - not least among them a basic fear of concern about objects that are not natural, somewhat mysterious, and totally out of the average person's control.

The organotins in the soils at the Dow site created and reinforced concerns that result from uncertainty. DEP did not set Method 1 standards for these compounds because very little is known about their effects on people, and because they are not common environmental contaminants. Combined with the limited flow of information on what was happening at the site and the knowledge of the vials, this uncertainty associated with what were perceived to be exotic toxic compounds produced at a secret research and development laboratory resulted in enhanced community concern.

## Developing New Standards

DEP's MCP guidance does provide for situations such as this, with uncommon contaminants. In this circumstance, the PRP has two options, 1) conduct the entire risk assessment using Method 3, or 2) use an alternative approach to Method 1, in which the risk assessor develops surrogate Method 1 standards, using the same procedure that

DEP used in the guidance, and apply these standards to the concentrations in soils or groundwater as if they were Method 1 standards. This approach is called Method 2. Both the Method 2 and Method 3 approaches require that appropriate information can be found in the literature to describe and quantify toxic effects of the contaminant on living organisms.

Dow's risk assessment consultant, Gradient, elected to use Method 2 at this stage of the investigation to show that a level of no significant risk was achieved after the initial cleanup and removal of the soil piles. In order to do this, Gradient had to develop Method 2 standards for several organotin compounds, in addition to several organomercury compounds that were also found in the soils. These compounds were not found in site groundwater. The source of the organo-metallic compounds was most likely disposal of waste chemicals from research projects that took place at the facility in the 1960s and 1970s. It is likely that these same substances were present in the vials; it is also likely that they contaminated soils when several vials broke, possibly while they were being buried. Because the vials have not been tested, how the organotins and organomercurials got into the soils will never be known.

Gradient used an acceptable procedure to develop Method 2 standards, but inherent uncertainties in the basic scientific data needed to calculate the standards resulted in additional uncertainties - and concerns - in the recommended standards.

In order to establish a Method 2 standard, an RfD is needed. The RfD is a dose rate - which means it is a mass (weight) of chemical that a person can take into his/her body on a per kilogram body mass basis per day. The RfD is expressed in units of mg/kg/day. The RfD represents the dose rate that will not result in adverse health effects; therefore, the smaller the dose rate, the more toxic the substance. For example, if a substance has an RfD 1 mg/kg/day, a 154-pound (70 kg) person can take in by ingestion or other means 70 milligrams (mg) (about 25 ounces or 0.15 pound) per day over a long term exposure period without adverse effects. However, if the RfD 0.1 mg/kg/day, the acceptable dose would be 7 mg, or less than 0.3 ounce per day. (An analogy to the RfD is the recommended daily dose set by the U.S. Food and Drug Administration for vitamins and nutrients in the diet. In this case, however, the recommended levels are not based on toxicity, but on beneficial effects). The EPA and other federal and international

agencies calculate RfDs using data from toxicological studies to determine the dose rate that will not result in toxic effects. Some of these data are from human health effects studies, but most are from animal research. For most of the organotins and organomercury compounds found at the Dow site, however, there were no RfDs. Gradient calculated RfDs from the toxicity studies that were reported in the scientific literature. Gradient followed standard procedures to do this, but made assumptions that were not applied consistently for all the compounds. The procedure for calculating an RfD requires a No Observable Effect Level (NOEL) from the literature, and enough information to determine the uncertainties in the study that produced the NOEL. The NOEL is a measure of threshold, which is the dose rate that will not cause adverse effects in the test species. Several uncertainty factors, including the number of species used, the variability in the results, the time frame over which the test animals were exposed to the chemical, and the method used to administer the chemical, are evaluated in developing the RfD, which is the NOEL divided by the product of the uncertainty factors.

The uncertainty factors that Gradient used to develop the RfDs were applied in a somewhat arbitrary and inconsistent manner. An example was Gradient's use of a factor of 3 (a relatively low value) for uncertainty associated with an incomplete database available for each contaminant, even though, tables provided in the Gradient report showed relatively wide variability in the quality, age, and types of studies performed. The TAG review expressed concern that the same value was used for all of the compounds, despite the demonstrated wide variability in data quality for many of the compounds. The TAG review recommended that different values be used to account for differing data quality.

Another example of inconsistent use of uncertainty factors in developing the RfDs was the treatment of subchronic studies, which are studies conducted in animals for less than six months. Subchronic studies are of concern because they may not be long enough to show several types of toxic effects that are linked to long-term exposure in humans. (Cancer was not considered in these studies because there is no evidence that organotins and organomercury compounds cause cancer). The accepted practice is to assign an uncertainty factor of 10 whenever subchronic data are used to develop an RfD for chronic exposure. Gradient did not do this for several compounds: trimethyltin,

dimethyltin, monomethyl tin, tricyclohexyltin, and dicyclohexyl tin, even though only subchronic studies were available.

For example, for dimethyl tin, three studies were referenced; two were single exposures and the third was a four-week developmental study in the neonatal rat. The NOEL from the developmental study was used to develop the RfD, and only three uncertainty factors were used, 10 for extrapolating from animals to humans, 10 to reflect variability among humans, and 10 for database uncertainties. The fact that this was a subchronic study was not accounted for. If this fourth factor were used, the resulting reference dose, and therefore the resulting standard, would be one order of magnitude, or ten times, lower than that derived by Gradient.

Gradient responded to the comments, and revised some of the standards based on TAG and DEP input. The resulting Method 2 standards were used to evaluate cleanup in the first phase.

The soils remaining after excavation met the definition of no significant risk based on the Method 1 and Method 2 standards. However, it was necessary to evaluate the final, complete site assessment using Method 3. DEP and the Neighbors' consultants agreed that the final Risk Assessment was adequate to evaluate risk at the site.