Chapter 11

THE ROLE OF RISK ASSESSMENT IN PUBLIC HEALTH POLICY DECISIONS

Risk assessment seems to be gaining wider grounds in making public health policy decisions on the control of risks associated with human exposures to chemicals. This situation may be attributed to the fact that, the very process of performing a risk assessment can lead to a better understanding and appreciation of the nature of the risks inherent in a study, and further helps develop steps that can be taken to reduce these risks. Overall, the application of risk assessment to chemical exposure problems helps identify critical receptor exposure routes, and other extraneous factors contributing most to total risks. It also facilitates the determination of cost-effective risk reduction policies. Ultimately, based on the results of a risk assessment, a more effectual decision can be made in relation to the types of risk management actions necessary to address a given chemical exposure problem or a hazardous situation.

Indeed, the risk assessment process is intended to give the risk management team the best possible evaluation of all available scientific data – in order to arrive at justifiable and defensible decisions on a wide range of issues. For example, to ensure public safety in chemical exposure situations, receptors must not exceed some stipulated risk-based exposure levels or acceptable public health goals – typically established through a risk assessment process. In general, it is apparent that, some form of risk assessment is inevitable if public health and environmental management programs are to be conducted in a sensible and deliberate manner.

Inevitably, risk-based decision-making will generally result in the design of better environmental and public health risk management programs. This is because risk assessment can produce more efficient and consistent risk reduction policies. It can also be used as a screening device for the setting of policy priorities. This chapter enumerates the general scope for the application of risk assessment, as pertains to the management of potential chemical exposure problems; it also discusses specific practical example situations for the utilization of the risk assessment paradigm.

11.1. General Scope of Public Health Risk Assessment Practice

Risk assessment has several specific applications that could affect the type of decisions to be made in relation to environmental and public health risk management programs.

A number of practical examples of the potential application of risk assessment principles, concepts, and techniques – including the identification of key decision issues associated with specific problems – abound in the literature of risk analysis. Some of the broad applications often encountered in chemical exposure situations include uses:

- Analysis of human health impacts from chemical residues found in food products (such as contaminated fish and pesticide-treated produce), as well as a variety of consumer products – including cosmetics and pharmaceuticals.
- Addressing the health and safety issues associated with environmental chemicals – i.e., to determine 'safe' exposure limits for toxic chemicals used or found in the workplace and residences.
- Facilitation of decisions about the use of specific chemicals in manufacturing processes and industrial activities.
- Implementation of general risk management and risk prevention programs for public health and environmental management planning.
- Evaluation and management of potential risks due to toxic air emissions from industrial facilities and incinerators.
- Evaluation of potential risks associated with the migration of contaminant vapors into building structures.
- Facilitation of property transactions by assisting developers, lenders, and buyers in the 'safe' acquisition of both residential and commercial properties.
- Determination of potential risks associated with industrial, commercial, and residential properties – to facilitate land-use decisions and/or restrictions.

The application of the risk assessment process to chemical exposure problems will generally serve to document the fact that risks to human health and the environment have been evaluated and incorporated into a set of appropriate response actions. In fact, almost invariably, every process for developing effectual environmental and public health risk management programs should incorporate some concepts or principles of risk assessment. In particular, all decisions on corrective action plans for potential chemical exposure problems will include, implicitly or explicitly, some elements of risk assessment.

Appropriately applied, risk assessment techniques can indeed be used to estimate the risks posed by chemical hazards under various exposure scenarios, and to further estimate the degree of risk reduction achievable by implementing various scientific remedies. Overall, a risk assessment will generally provide the decision-maker with scientifically defensible procedures for determining whether or not a potential chemical exposure problem could represent a significant adverse health and environmental risk, and if it should therefore be considered a candidate for mitigative actions. In fact, several issues that – directly or indirectly – affect public health and environmental management programs may be addressed by using some form of risk assessment.

11.1.1. ILLUSTRATIVE EXAMPLES OF PUBLIC HEALTH RISK ASSESSMENT IN PRACTICE

In the applications of risk assessment, it is important to adequately characterize the exposure and physical settings for the problem situation, in order to allow for a proper application of appropriate risk assessment methods of approach. Unfortunately, there tends to be several unique complexities associated with real-life chemical exposure scenarios, and this can seriously overburden the overall process. Also, the populations potentially at risk from chemical exposure problems are usually heterogeneous – and this can greatly influence the anticipated impacts/consequences. Critical receptors should therefore be carefully identified with respect to numbers, location (areal and temporal), sensitivities, etc., so that risks are neither underestimated nor conservatively overestimated.

The determination of potential risks associated with chemical exposure problems invariably plays an important role in public health risk mitigation and/or risk management strategies – as demonstrated by the hypothetical example problems that follow below. It is noteworthy that, risk assessments may be formulated quite differently for differing situations or circumstances – such as one that is purely qualitative in nature, through a completely quantitative evaluation.

Evaluation of Human Health Risks Associated with Airborne Exposures to Asbestos

This section presents a discussion of the investigation and assessment of the human health risks associated with worker exposures to asbestos in the ventilation systems of a commercial/office building.

There are two sub-divisions of asbestos: the serpentine group containing only chrysotile (which consists of bundles of curly fibrils); and the amphibole group containing several minerals (which tend to be more straight and rigid). Asbestos is neither water-soluble nor volatile, so that the form of concern is microscopic fibers (usually reported as, or measured in the environment in units of fibers per m^3 or fibers per cc).

Processed asbestos has typically been fabricated into a wide variety of materials that have been used in consumer products (such as cigarette filters, wine filters, hair dryers, brake linings, vinyl floor tiles, and cement pipe), and also in a variety of construction materials (e.g., asbestos-cement pipe, flooring, friction products, roofing, sheeting, coating and papers, packaging and gaskets, thermal insulation, electric insulation, etc.). Notwithstanding the apparent useful commercial attributes, asbestos has emerged as one of the most complex, alarming, costly, and tragic environmental health problems (Brooks *et al.*, 1995). A case in point, asbestos materials are frequently removed and discarded during building renovations and demolitions. To ensure safe ambient conditions under such circumstances, it often becomes necessary to conduct an asbestos sampling and analysis – which results can be used to support a risk assessment.

Study Objective. The primary concern of the risk assessment for the ventilation systems in the case building is to determine the level of asbestos exposures that potential receptors (especially workers cleaning the ventilation systems) could experience, and whether such exposure constitutes potential significant risks.

Summary Results of Environmental Sampling and Analysis. Standard air samples are usually collected on a filter paper and fibers >5μm long are counted with a phase contrast microscope; alternative approaches include both scanning and transmission electron microscopy and X-ray diffraction. It is generally believed that fibers that are 5μm or longer are of potential concern (USEPA, 1990a,b).

Following an asbestos identification survey of the case structure, air samples collected from suspect areas in the building's ventilation systems were analyzed using phase contrast microscopy (PCM), and highly suspect ones further analyzed by using transmission electron microscopy (TEM). The TEM analytical results are important because they serve as a means/methods for distinguishing asbestos particles from other fibers or dust particles.

The PCM analysis produced concentration of asbestos fibers in the range of <0.002 to a maximum of 0.008 fibers/cm^3. From the TEM, chrysotile asbestos was determined to be at <0.004 structures per cm^3 (str/cm) in all the environmental air samples.

The Risk Estimation. For asbestos fibers to cause any disease in a potentially exposed population, they must gain access to the potential receptor's body. Since they do not pass through the intact skin, their main entry routes are by inhalation or ingestion of contaminated air or water (Brooks *et al.*, 1995) – with the inhalation pathway apparently being the most critical in typical exposure scenarios. That is, for asbestos exposures, inhalation is expected to be the only significant exposure pathway. Consequently, intake is based on estimates of the asbestos concentration in air, the rate of contact with the contaminated air, and the duration of exposure. Subsequently, the intake is integrated with the toxicity index to determine the potential risks associated with any exposures.

Individual excess cancer risk is a function of the airborne contaminant concentration, the probability of an exposure causing risk, and the exposure duration. By using the cancer risk equations presented earlier in Chapter 8, the cancer risk from asbestos exposures may be estimated in accordance with the following relationship:

$$\begin{aligned}\text{Cancer Risk} = &\ [\text{airborne fiber concentration (fibers/m}^3)] \\ &\times [\text{exposure constant (unitless)}] \\ &\times [\text{inhalation unit risk ((100 PCM fibers/m}^3)^{-1})]\end{aligned} \tag{11.1}$$

or,

$$\text{Risk Probability} = \text{Intake} \times \text{UR} = [C_a \times \text{INHf}] \times \text{UR} \tag{11.2}$$

The following exposure assumptions are used to facilitate the intake computation for this particular problem identified above:

- It is assumed that workers cleaning the ventilation system will complete this task within two weeks for a 5-day work-week. Hence, the maximum exposure duration is taken as, ED = 10 days – in comparison to a 70-year lifetime daily exposure.
- Assumed exposure time is 40 minutes per working hour, for an 8-hour work-day.
- Inhalation rate is 20 m^3/day (or 0.83 m^3/hr).

The exposure evaluation utilizes the information obtained from the airborne fiber samples collected and analyzed for during the prior air sampling activities; to be conservative, the maximum concentrations measured from the analytical protocols are used in the risk estimation. Thence, the fraction of an individual's lifetime for which exposure occurs – represented by the inhalation factor – is estimated to be:

$$INHf = (40/60) \times (8/24) \times (10/365) \times (1/70) = 8.7 \times 10^{-5}$$

Next, asbestos is considered carcinogenic with a unit risk of approximately 1.9×10^{-4} (100 PCM fibers/m^3)$^{-1}$ (see, e.g., DTSC/Cal EPA, 1994). Consequently, potential risk associated with the 'possible' but unlikely (represented by an evaluation based on the PCM analysis results) and the reasonable/likely (represented by an evaluation based on TEM analysis results) asbestos concentrations are determined, respectively, as follows:

- Risk represented by results of the PCM analyses is estimated by integrating the following information,
  - PCM-based airborne fiber concentration (maximum) $= 0.008$ fibers/cc $= 8 \times 10^3$ fibers/m^3
  - $INHf = 8.7 \times 10^{-5}$
  - $UR = 1.9 \times 10^{-4}$ (100 PCM fibers/m^3)$^{-1}$ $= 1.9 \times 10^{-6}$ per fibers/m^3

  Hence,

  Cancer Risk (based on PCM concentration) $= 1.32 \times 10^{-6}$

- Risk represented by results of the TEM analyses is estimated by integrating the following information,
  - TEM-based airborne asbestos concentration (maximum) $= 0.004$ structures/cc $= 4 \times 10^3$ str/m^3
  - $INHf = 8.7 \times 10^{-5}$
  - $UR = 1.9 \times 10^{-4}$ (100 PCM fibers/m^3)$^{-1}$ $= 1.9 \times 10^{-6}$ per fibers/m^3

  Hence,

  Cancer Risk (based on TEM concentration) $= 6.6 \times 10^{-7}$

A Risk Management Decision. All risk estimates indicated here are near the lower end of the generally acceptable risk range/spectrum (i.e., 10^{-4} to 10^{-6}). Thence, it may be concluded that asbestos in the case building should represent minimal potential risks of concern for workers entering the ventilation system to clean it up. Nonetheless, it is generally advisable to incorporate adequate worker protection through the use of appropriate respirators. In general, any asbestos abatement or removal program should indeed conform to strict health and safety requirements – with on-site enforcement of the specifications being carried out by a qualified health and safety officer or industrial hygienist.

A Human Health Risk Assessment Associated with PCB Release into the Environment

PCBs (polychlorinated biphenyls) are mixtures of synthetic organic chemicals. Different mixtures can take on forms ranging from oily liquids to waxy solids. Although their chemical properties vary widely, different mixtures can have many common components. Because of their non-inflammability, chemical stability, and insulating properties, commercial PCB mixtures had been used in many industrial applications, especially in capacitors, transformers, and other electrical equipment. These chemical properties, however, also contribute to the persistence of PCBs after they are released into the environment. In fact, because of evidence that PCBs persist in the environment and cause harmful effects, the manufacture of commercial mixtures was stopped in the late1970s – albeit existing PCBs continued in use.

Problem Scenario. Consider a release of PCBs onto the ground near a lake. Potential pathways of human exposure have been determined to include vapor inhalation, drinking water, fish ingestion, and skin contact with ambient water and contaminated soil.

The population of interest includes anglers who consume an average of two 105g portions of local fish each week; this translates into 30g of fish ingestion per day (i.e., [2 x 105g per week]/7days per week = [210/7] = 30g per day). They also spend most of their time in the area, on average, breathing 20m^3 of air and drinking 2L of water each day. Skin contact with ambient water and soil is negligible for this population. A 30-year human exposure duration is assumed, with a representative lifespan of 70years, and an average body weight of 70kg.

Environmental samples indicate long-term average concentrations of 0.01 μg/m^3 in ambient air, 5 μg/L in drinking water, and 110 μg/kg in the edible portion of local fish. Issues pertaining to dust in ambient air and sediment in drinking water are considered negligible.

PCBs persist in the body, providing a continuing source of internal exposure after external exposure stops. There may be greater-than-proportional effects from less-than-lifetime exposure, especially for persistent mixtures and for early-life exposures. PCBs are absorbed through ingestion, inhalation, and dermal exposure, after which they are transported similarly through the circulation. This provides a reasonable basis to expect similar internal effects from different routes of human exposure. Indeed, joint consideration of cancer studies and environmental processes leads to a conclusion that environmental PCB mixtures are highly likely to pose a risk of cancer to humans. Apart from the cancer effects, PCBs also have significant human health effects other than cancer – including neurotoxicity, reproductive and developmental toxicity, immune system suppression, liver damage, skin irritation, and endocrine disruption. Toxic effects have indeed been observed from acute and chronic exposures to PCB mixtures with varying chlorine content.

The Exposure Scenarios. Three different exposure pathways are assumed for this case problem – namely, vapor inhalation, water ingestion, and fish consumption. Because of partitioning, transformation, and bioaccumulation, different fractions of the original mixture are encountered through these pathways – and hence different potency values are appropriate. Vapor inhalation is associated with 'low risk' (because evaporating congeners tend to have low chlorine content and be inclined to metabolism and elimination), so the low end of the range (upper-bound slope of 0.4 per mg/kg-d) is used for vapor inhalation (USEPA, 1996). Similarly, ingestion of water-soluble congeners is associated with 'low risk' (because dissolved congeners tend to have low chlorine content and be inclined to metabolism and elimination) – so the low end (of 0.07 per mg/kg-d) is also used for drinking water (USEPA, 1996). (It is noteworthy that, if ambient air or drinking water had contained significant amounts of contaminated dust or sediment, the high-end potency values would be more appropriate, as adsorbed congeners tend to be of high chlorine content and persistence.) Finally, food chain exposure is more realistically associated with 'high risk' (because aquatic organisms and fish selectively accumulate congeners of high chlorine content and persistence that are resistant to metabolism and elimination) – and thus, the high end of the range (upper-bound slope of 2 per mg/kg-d) is used for fish ingestion (USEPA, 1996).

Risk Calculation. The lifetime average daily dose (LADD) is calculated as the product of concentration C, intake rate IR, and exposure duration ED divided by body weight BW and lifetime LT, as follows:

$$\text{Pathway Exposure, LADD} = [C \times IR \times ED]/[BW \times LT] \quad (11.3)$$

Thence,

Vapor Inhalation LADD

$$= [0.01\mu g/m^3 \times 20m^3/d \times 30yr]/[70kg \times 70yr] = 1.2 \times 10^{-6}\ mg/kg\text{-}d$$

Drinking Water LADD

$$= [5.0\mu g/L \times 2L/d \times 30\ yr]/[70kg \times 70yr] = 6.1 \times 10^{-5}\ mg/kg\text{-}d$$

Fish Ingestion LADD

$$= [110\mu g/kg \times 30g/d \times 30yr]/[70kg \times 70yr] = 2.0 \times 10^{-5}\ mg/kg\text{-}d$$

Subsequently, for each pathway, the lifetime average daily dose is multiplied by the appropriate slope factor to arrive at the estimated risk, as follows:

$$\text{Pathway Risk} = [\text{LADD}] \times [\text{Cancer Slope Factor}] \quad (11.4)$$

Thence,

$$\text{Vapor Inhalation Risk} = 1.2 \times 10^{-6}\ mg/kg\text{-}d \times 0.4\ \text{per}\ mg/kg\text{-}d = 4.8 \times 10^{-7}$$

$$\text{Drinking Water Risk} = 6.1 \times 10^{-5}\ mg/kg\text{-}d \times 0.07\ \text{per}\ mg/kg\text{-}d = 4.3 \times 10^{-6}$$

$$\text{Fish Ingestion Risk} = 2.0 \times 10^{-5}\ mg/kg\text{-}d \times 2\ \text{per}\ mg/kg\text{-}d = 4.0 \times 10^{-5}$$

Thus,

$$\text{Total LADD} = 8.2 \times 10^{-5}\ mg/kg\text{-}d$$

and

$$\text{Total Risk} = 4.5 \times 10^{-5}$$

A Risk Management Decision. The above evaluation leads to a conclusion that fish ingestion is the principal pathway contributing to risk, and that drinking water and vapor inhalation are of lesser consequence. Indeed, it would be advisable to examine variability in fish consumption rates and fish tissue concentrations to determine whether some individuals are at much higher risk. In any case, it also is important to recognize that, this specific site exposure adds to a background level of exposure from other sources.

11.2. The Public Health Risk Assessment Paradigm

In our attempts to shape public health risk management policy decisions, one must appreciate what Rachel Carson notes in her book, *Silent Spring*, that: "As the tide of chemicals born of the Industrial Age has arisen to engulf our environment, a drastic change has come about in the nature of the most serious public health problems" (Carson, 1962; 1994). Indeed, chemicals have become an integral part of modern ways of life – with the capacity to improve as well as endanger public health. The general population is typically exposed to chemicals in air, water, foods, cosmetics, household products, and a variety of therapeutic drugs. In everyday life, a person may experience a multitude of exposure to potentially toxic substances, singly and in combination, and both synthetic and natural. Levels of exposure tend to vary and may or may not pose a hazard – depending on the dose, route, and duration of exposure. The consequences of human exposure to chemicals have therefore become (or should become) a very important driving force in public health policy decisions. To effectively address this situation, the traditional approach to dealing with public health risk management issues may not suffice in this day and age. Contemporary risk assessment methods of approach may therefore be used to facilitate the design of more reliable public health risk management strategies/schemes. But it must also be recognized that, a given risk assessment provides only a snapshot in time (and indeed in space as well) of the estimated risk of a given toxic agent at a particular phase of our understanding of the issues and problems. As Moeller (1997) notes, unless care is exercised and all interacting factors are considered, risk assessments directed at single issues, followed by ill-conceived risk management strategies, can create problems worse than those the management strategies were designed to correct. The single-issue approach can also create public myopia by excluding the totality of alternatives and consequences needed for an informed public choice (Moeller, 1997). Indeed, to be truly instructive and constructive, therefore, risk assessments will usually be conducted on an iterative basis – being updated as new information and knowledge become available. Ultimately, it is quite important to examine the total system to which a given risk assessment is being applied.

It is expected that, there will be growing applications of the risk assessment paradigm to several specific chemical exposure problems, and this could affect the type of decisions made in relation to public health risk management programs. Such applications may cover a wide range of diverse problem situations – as exemplified by the illustrative application scenarios annotated below. This listing of public health study designs is by no means complete and exhaustive, since variations or even completely different and unique problems may be resolved by use of one form of risk assessment principle and methodology or another.

- *Investigation of blood lead (Pb) distribution amongst population groups.* This type of public health risk assessment study may be used to help determine the likely impacts of Pb exposures on various population groups.

    - *Study Rationale.* For young children, Pb can cause lower levels of intelligence, behavioral problems, and school failures. In fact, recent studies conducted by the Harvard School of Public Health in the United States have determined that, a woman's lead exposure during pregnancy can threaten the fetus' nervous system and other developing organs. Also, it has been noted that women of child-bearing age who were exposed to lead as children usually will have this lead accumulated in their bones, threatening the health of their babies many years later. The pre-natal exposure scenario is: if a little girl is exposed to lead, the lead is stored in her bones as she grows, and when she becomes a pregnant adult, the lead moves from her bones – exposing her fetus to lead. Furthermore, lead acquired pre-natally can contribute to the lead burden in young children, implying a potential concern for pregnant women. Further yet, recent studies (e.g., Tellez-Rojo *et al.*, 2002) designed to evaluate the impact of breast-feeding on the mobilization of lead from bone seem to confirm the hypothesis that lactation stimulates lead release from bone to blood. Lactation has indeed been recognized as a powerful stimulus for bone resorption; thus, Pb accumulated in bone from past exposures may be released into the bloodstream and excreted in breast milk, constituting an important source of lead exposure for the breast-fed infant (see, e.g., Silbergeld, 1991; Tellez-Rojo *et al.*, 2002). Also of significant interest, recent studies document the impact of low level lead exposure on blood pressure in adults (Schwartz, 1991). The significance of investigating lead exposure to a community can therefore not be underestimated, since it will ultimately threaten infant development as well as adult welfare.

- *Scientific Design.* A study may be designed to determine the presence of, and the degree of population group exposures and impacts in different regions. The study may document results with respect to gender differences, age categories and even the different socioeconomic classes of a community.

- *Significance of Study.* Considering the frequent occurrence of lead in several environmental settings, and in view of the dangers associated with lead exposures – especially to children – it is important to adequately document this kind of information, and then help develop strategies to deal with likely problems associated with the lead contamination and exposure situations. In fact, Pb is naturally occurring, but often is released into the environment from human-made sources; it has been mined, smelted, refined, and used for hundreds of years. For example, Pb has been used as an additive in paint and gasoline, and in leaded pipes, solder, crystal, and ceramics. Mining, smelting, and refining activities have resulted in substantial increases in Pb levels in the environment, especially near mining and smelting sites, near some types of industrial and municipal facilities, and adjacent to highways.

  Pb particles in the environment can attach to dust and be carried long distances in the air. Such Pb-containing dust can be removed from the air by rain and deposited on surface soil, where it may remain for many years. In addition, heavy rains may cause Pb in surface soil to migrate into ground water and eventually into water systems. Given its widespread distribution, everyone is exposed to 'background' levels of Pb. In fact, there are many possible ways to be exposed to Pb, including ingestion of Pb-contaminated water, soil, paint chips, and dust; inhalation of Pb-containing particles of soil or dust in air; and ingestion of foods that contain Pb from soil or water. Pb poisoning is a particularly insidious public health threat because there may be no unique signs or symptoms. Early symptoms of Pb exposure may include persistent fatigue, irritability, loss of appetite, stomach discomfort, reduced attention span, insomnia, and constipation. Failure to treat Pb poisoning in the early stages can cause long-term or permanent health damage, but because of the general nature of symptoms at this stage, Pb poisoning is often not suspected.

In adults, Pb poisoning can cause irritability, poor muscle coordination, and nerve damage to the sense organs and nerves controlling the body. It may cause increased blood pressure, hearing and vision impairment, and reproductive problems (such as a decreased sperm count). It also can retard fetal development even at relatively low levels of Pb. In children, Pb poisoning can cause brain damage, mental retardation, behavioral problems, anemia, liver and kidney damage, hearing loss, hyperactivity, developmental delays, other physical and mental problems, and in extreme cases, death. Although the effects of Pb exposure are a potential concern for all humans, young children (0 to 7 years old) are the most at risk. This increased vulnerability results from a combination of the following factors:

- Children typically have higher intake rates per unit body weight for environmental media such as soil, dust, food, water, air, and paint, than adults since they are more likely to play in dirt and to place their hands and other objects in their mouths;
- Children tend to absorb a higher fraction of ingested Pb from the gastrointestinal tract than adults;
- Children tend to be more susceptible to the adverse neurological and developmental effects of Pb than adults; and
- Nutritional deficiencies of iron or calcium, which are prevalent in children, may facilitate Pb absorption and exacerbate the toxic effects of Pb.

The current/typical blood Pb level of concern in children is 10 micrograms (μg) of Pb per deciliter (dL) of blood (i.e., 10μg/dL). However, since adverse effects may occur at lower levels than previously thought, various agencies are considering whether this level should be lowered further.

- *Assessment of risks from chemical contaminants in nursing mothers' breast milk.* This type of public health risk assessment study may be designed to help determine the potential risks associated with the breast-feeding of infants.

    - *Study Rationale.* It apparent that human breast milk is a primary source of infant nutrition – especially in most developing countries. But the investigation of the levels of chemical contaminants in human milk in some locales elucidate the potential risks of such contaminants to the health of breast-fed infants – and who are indeed more susceptible to chemical exposure effects. In view of the fact that welfare establishments have been encouraging mothers to breast-feed more often, the question needs to be raised as to whether this is always 'safe' for all the children – considering the fact that some nursing mothers may have high accumulation of dangerous environmental chemicals in their breast milk? For example, pre-natal exposures to PCBs in foods, etc. can be passed on to newborn infants.

- *Scientific Design.* A study may be so-designed to identify and quantify the presence and levels of select chemicals (e.g., Pb, PCBs, dioxins, and organochlorine pesticides such as DDT, dieldrin, lindane, aldrin, hexachlorobenzene, chlordane, etc.) in mothers' milk for nursing mothers in different locales, and from different socioeconomic classes of a community. Subsequently, the toxicological implications to the health status of both the nursing mother and the breast-fed infants can be determined.

- *Significance of Study.* The toxicological implications derived from this study can become a very important guide for health care providers – especially at post-natal health care facilities.

- *Analysis of human health impacts from chemical residues in food and consumer products.* This type of public health risk assessment study may be designed to help determine the potential risks associated with population exposures to chemical residues in food (including contaminated fish and pesticide-treated produce) and a variety of consumer products.

  - *Study Rationale.* It is almost indisputable that all peoples around the world consume a whole variety of plant and animal products, some of which have – directly or indirectly – been exposed to chemical substances at one time or another. Also, a variety of consumer products abound on the world markets today – some having questionable origins, and several containing potentially toxic chemicals.

  - *Scientific Design.* A study may be so-designed that consists of an investigation into the occurrence, and the measurement of the levels of selected chemical contaminants (including organochlorine pesticides residues and various inorganic chemicals) that may be present in typical staple food products of the average person in the case-study area – especially for fish, meat, and chicken eggs. In implementing this program, food samples can be collected and analyzed for selected chemical contaminants warranting investigation for the particular setting/location. Also, information can be collected on food consumption patterns of the various communities to facilitate realistic risk assessments. The relevant studies may also consist of an investigation into the types of toxic chemicals found in selected consumer products (such as hair products, skin care products, processed and canned food items, etc.) commonly found on the market for a case-study area, and that have widespread usage among various sectors of society. Based on an examination of the consumer use patterns and exposures, risks to human health from the widely used consumer products may be determined. As part of this study, a comparative look can be made for the urban populace *vs.* the rural dweller.

  - *Significance of Study.* Results of the investigation can help develop an effectual public health education and awareness program about the potential harms from toxic chemicals – such as PCBs and DDT – potentially present in common food and consumer products finding widespread use in a region. It can also help national or regional governments in establishing long-term national food contamination monitoring program – as part of the comparable United Nations/WHO programs.

- *Investigating the health impacts of mining activities on a community.* This type of public health risk assessment study may be used to help determine the potential impacts associated with mining activities.

  - *Study Rationale.* As part of the recent economic rejuvenation programs in a number of nations, mining activities seem to have become one of the most popular ventures attracting a wide spectrum of investors. But even long before the recent additions to the mining sector, in some regions (especially in the newly emerging economies), environmental degradation from mining activities has always been a critical but neglected issue.

  - *Scientific Design.* A comprehensive tiered study may be so-designed that consists of both general and specific investigations of the health implications of the various mining sectors in the case region. This study may also include a look at the distribution of likely health problems associated with the different mining sectors and communities. For the mining communities selected for more detailed investigations, attention could be focused on issues such as water quality problems, levels of various chemicals in the blood of the target populations, etc. that are associated with particular mining activities. For example, mercury will be of particular interest in the gold-mining areas (since it is often used to extract gold), especially when fishing streams can be found within the watershed. Also, the study may be so-designed to cover all seasons, in order to ensure accurate measurements and that will ensure effective policy decisions. The complete seasonal investigation is deemed necessary, in part because recent studies by some Canadian scientists in the Brazilian Amazon found a link between the seasons and methyl mercury (a highly toxic form of mercury created when the metal is released into streams and modified by bacteria) levels found in a village population in that region; in that case, it was proven that the contamination levels in the Amazon were highest during the rainy season. Whereas this seasonal variation in contaminant levels may not be universally true, it will seem prudent to extend such types of investigation to cover all the seasons – at least to give representative database for statistical analysis purposes.

    For practicality, this type of somewhat extensive project can be carried out in phases – albeit each phase can be designed to yield project outputs/results that can individually be used to make important public health policies and to guide risk management programs. For example, a 'Phase 1' may consist of a survey to identify the prominent types of toxic chemicals found to originate from mining activities; the collection of chemical and exposure data, based on the nature of mining activities; and a statistical compilation of common health problems in the target communities. The information from this initial phase can be analyzed (both qualitatively and quantitatively) in order to determine the potential risks to the exposed populations. A 'Phase 2' may aim at collecting specific material samples that can undergo appropriate laboratory analyses (to facilitate a more accurate quantification of the likely risks to populations exposed to mining-related environmental chemicals under a variety of conditions). The 'Phase 2' sampling program may involve taking blood and other biomarker samples from representative residents of the target community, to be analyzed for the suspect chemicals of concern, and also the sampling and analysis of potable water supplies and selected dietary/farm produce of the target communities.

- *Significance of Study.* Results from each of the project phases can be used to design appropriate mitigative and public health risk management programs in relation to the impacts of mining activities on various sectors of the populations in the study locale. The results of the study can also be used to help develop effectual corrective measures for current and future mining practices in a locale or region. Ultimately, such a project can be expected to help improve risk mitigation and public health risk management programs associated with mining activities in a region.

- *Health implications of pesticide use in agricultural communities.* This type of public health risk assessment study may be used to facilitate public policy decisions on pesticide applications.

  - *Study Rationale.* The use of a wide range of chemical pesticides seems to be an important aspect of agricultural practice worldwide. But then, such increased use of pesticides is of grave concern due to their potential effects on human health. In fact, the situation is particularly worrisome in the newly emerging economies, where lesser protective measures are generally taken and also where reliable data on the population exposures to pesticides (and indeed several other environmental and 'social' chemicals) is lacking. As has been affirmed by the World Health Organization (WHO) and the United Nations Environment Programme (UNEP), pesticides currently in use involve a wide variety of chemicals, with great differences in their mode of action, uptake by the body, metabolism, elimination from the body, and toxicity to humans. Also, it is an undisputed fact that, the health effects will depend on the health status of the individual exposed. Thus, malnutrition and dehydration – situations fairly prevalent in developing economies in particular – are likely to increase sensitivity to pesticides. In addition, several environmental factors – such as temperature and humidity – will tend to affect the absorption of pesticides by exposed individuals.

  - *Scientific Design.* A typical research study may be designed that consists of both general and specific investigations of the health implications of pesticide use in the selected agricultural (or other pesticide applicator) communities. In particular, the levels of pesticides in farmers can be investigated. The study may also cover such parameters as miscarriages and the prevalence of birth defects, in order to determine any possible association with pesticide usage in particular communities.

    As part of the overall program, information can be collected on the pesticide use/application patterns for major farming communities. Blood samples can be collected from farmers and analyzed for organochlorine pesticide residues, and indeed other related chemical contaminants warranting investigation for the particular setting/location. The study can also include an investigation of possible pesticide contamination of rural drinking water supplies located near farmlands.

Indeed, such type of project may be carried out in phases – albeit each phase can be designed to yield project outputs/results that can individually be used to make important public health policies and to guide risk management programs. For example, in a two-phase design, 'Phase 1' may consist of a survey to identify the prominent types of pesticides in general use; the collection of chemical and exposure data, based on the pesticide use patterns; and a statistical compilation of common health problems in the target communities. The information from this initial phase can be analyzed (both qualitatively and quantitatively) in order to determine the potential risks to the exposed populations. 'Phase 2' may then aim at collecting specific material samples that can undergo appropriate laboratory analyses (to facilitate a more accurate quantification of the likely risks to populations exposed to pesticides under a variety of conditions). The 'Phase 2' sampling program may, for example, involve taking blood and other biomarker samples from farmers, to be analyzed for organochlorine pesticide residues, and also the sampling and analysis of potable water supplies and selected dietary/farm produce of the target communities. Results from each of the project phases can then be used to design appropriate mitigative and public health risk management programs in relation to pesticide usage in the region.

- *Significance of Study.* Results from such a study can be used to help develop an effectual public education program about the potential harms from pesticide usage in region, by providing a basis for public education on pesticides use. Ultimately, such a project can be expected to help improve risk mitigation actions and public health risk management programs involving pesticide usage in a region, particularly for the 'pesticide applicator' areas.

- *Evaluation of selected urban occupational worker exposure risks.* So many innocent and unsuspecting workers in various countries are exposed to a variety of toxic substances on a daily basis – but this represents a preventable situation, achievable by using appropriate protective equipment and clothing. In fact, chronic worker exposure for select categories of workers who often work with dangerous chemicals without personal protective tools/equipment/clothes is becoming an even more serious problem in a number developing and newly industrializing countries – especially with the mushrooming of several small businesses and mini-industries.

  - *Study Rationale.* A study may be undertaken that consists of an investigation into the types of toxic chemicals widely used in consumer products (such as hair products, select food items, etc.); examination of the consumer use patterns and exposures (to include chronic worker exposure for select categories of workers who often work with dangerous chemicals without personal protective tools/equipment/clothes); and the assessment of human health risks from the use of various consumer products commonly found on the market in the region of concern, and that have widespread use among various sectors of society.

- *Scientific Design.* Typically, the study will focus on select 'high-risk' urban occupational groups – to include, e.g., hairdressers and beauticians (for various chemicals found in cosmetics, etc.), auto mechanics/automotive shop workers (for various solvents and metals), and fuel station attendants (especially for benzene and possible fuel additives) – all of whom are exposed to specific chemicals on an almost daily basis. The study may consist of an investigation into occupational hazards associated with the types of toxic chemicals widely used by these worker groups.

- *Significance of Study.* Results from this study can help develop an effectual public education program and worker protection campaign about the potential harms from toxic chemicals often encountered by various worker groups.

• *Morbidity effect of particulate matter (PM) exposures: an epidemiologic study of the human health effects from ambient particulate matter.* Epidemiologic studies that link population ambient PM exposures to adverse health effects can provide an indication of the measurable excesses in pulmonary function decrements, respiratory symptoms, hospital and emergency department admissions, and indeed mortality associated with ambient levels of $PM_{2.5}$, PM_{10}, and other indicators of PM exposures.

- *Study Rationale.* Epidemiology studies can be used to establish causal inferences about PM health effects. Subsequently, the causal inference methodology should play a key role in evaluating the effectiveness of proposed interventions (such as changes in regulatory standards for ambient PM). Ultimately, this would help clarify the predicted effect of reductions in ambient PM on public health.

- *Scientific Design.* Typically, epidemiologic studies are divided into *morbidity studies* and *mortality studies*. The morbidity studies would include a wide range of health endpoints – such as changes in pulmonary function test, reports of respiratory symptoms, self-medication in asthmatics, medical visits, low birth-weight infants, and hospitalization. (By the way, mortality studies from many causes tend to provide the most unambiguous evidence of a clearly adverse endpoint.)

  A typical study design may consist of the so-called 'cross-sectional' studies – that evaluates subjects at a 'point' in time, where measurements of health status, pollution exposure, and individual covariates are observed simultaneously. In general, studies with individual-level outcome data, covariates, and PM exposure indices should be preferred – albeit individual-level exposure data are the most commonly missing component.

  In this type of study, the hypothesis being tested will consist of the null hypothesis, H_0: exposure to ambient PM at current levels cannot cause adverse health effects in susceptible sub-populations or individuals *vs.* the alternate hypothesis, H_A: exposure to ambient PM or some component at current levels is associated with adverse health effects in some susceptible sub-populations or individuals.

- *Significance of Study.* Past epidemiologic studies strongly implicate respirable particles in increased morbidity and mortality in the general population. Specific epidemiologic studies can provide information on issues such as the following:
  - short-term PM exposure effects on lung function and respiratory symptoms in asthmatics and non-asthmatics;
  - long-term PM exposure effects on lung function and respiratory symptoms;
  - relationships of short-term PM exposure to the incidence of respiratory and other medical visits, as well as hospitalization (i.e., hospital admissions over limited to extended duration); and
  - effects of ambient PM exposure on acute cardiovascular morbidity

For most of the types of applications identified above, studies using various epidemiological designs would be employed; the various epidemiological studies may include both observational and experimental study designs – and that may consist of ordinary descriptive study designs, case control studies, prospective studies, and indeed various types of experimental studies. Overall, these types of public health risk assessment studies will seek to increase understanding and preventative strategies to be adopted by public health policy makers and also community healthcare providers in chemical exposure problem situations. Also, the specific projects or investigations could plan to involve students from the appropriate institutions dedicated to teaching health-related sciences, and thus help bring early awareness to the would-be healthcare providers at an earlier stage of their training. Ultimately, such projects are expected to help improve risk mitigation and public health risk management programs associated with various chemical exposure problems.

Finally, it must be recognized that a clear understanding and effective communication about the association between environmental hazards and disease incidence are indeed essential requirements of an effective environmental and public health risk management policy. Results from the types of projects exemplified here will help develop preventative strategies that can be adopted by public health policy makers as well as community healthcare providers.

11.3. Suggested Further Reading

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