Commission for Environmental Cooperation of North America

Report of the North American Workshop on Risk Assessment and Children's Environmental Health

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19-21 February 2003

Prepared for the CEC by
Tanis Frame, Consultant

INTRODUCTION

Background

In North America, the impact of environmental hazards on children's health is receiving increasing attention among scientists, policy makers and the public alike. Recognizing the need for greater coordination and cooperation to protect children from environmental threats in North America, the CEC launched a special initiative to explore opportunities for involvement in this area in June 1999. The three countries—Canada, Mexico and the United States— committed to "working together as partners to develop a cooperative agenda to protect children from environmental threats with the overall objective of reduction human-made pressures on children's health."

CEC involvement in children's environmental health issues was initially informed by a trilateral symposium held in Toronto in May of 2000 where experts explored the health and policy issues. Risk assessment was identified as a powerful and useful tool but one that merits further discussion and refinement, particularly when it comes to addressing the particular vulnerabilities and exposure patterns of children**.** Through this and other public meetings the importance of addressing children's health in risk management activities has also been emphasized.

The CEC's initiative on children's health and the environment was confirmed in June of 2000 with Council Resolution 00-10. As directed by this Resolution, a Cooperative Agenda for Children's Health and the Environment in North America has been prepared as a blueprint for trilateral action.

A trilateral workshop was held in November of 2001 to discuss and develop elements of the draft Cooperative Agenda. Participants included officials from health and environment departments in the three countries, and representatives of the NAFTA Technical Working Group on Pesticides, as well as the CEC's Expert Advisory Board on Children's Health and the Environment. Workshop discussions confirmed interest among the three countries to share information and approaches to incorporating children's environmental health into risk assessment. Participants recommended that the CEC convene a North American workshop focused on risk assessment and children's health.

Further to the November 2001 trilateral workshop, the draft Cooperative Agenda was then reviewed at a joint meeting of the Expert Advisory Board and the Joint Public Advisory Committee (JPAC) in Mexico City in March of 2002, with involvement of the public and stakeholder groups. In response to the proposed actions outlined in the draft Cooperative Agenda, the Mexico City meeting heard public comments and concerns about risk assessment. This feedback included support for the workshop recommended in the Cooperative Agenda to enable broad public discussion of the scientific, economic, cultural, and ethical issues, including the need for transparency and the role of precaution.

The Cooperative Agenda for Children's Health and the Environment in North America was adopted by the CEC Council in June 2002 through Council Resolution 02-06. As part of this Cooperative Agenda (item 4.3), the three parties formally identified the need

for a workshop on risk assessment and children's environmental health. A common understanding of risk assessment terms and approaches among the three countries, between environment and health departments, among those dealing with toxic chemicals, including pesticides, and among the public and interested groups —is a prerequisite for effective collaboration and sharing of information and results to ensure that children's vulnerabilities are taken into consideration when assessing risks. Enhanced information exchange between the health and environment sectors can also foster mutually beneficial improvements in risk assessment approaches, particularly with respect to methods for incorporating children's health concerns and vulnerabilities into risk assessment. The roles played by precaution and transparency are important parts of the overall picture. A common understanding of risk assessment and its application in decision-making will also facilitate the sharing of work, expertise, information and ideas, while maintaining the capacity and flexibility of governments to take their own decisions based on the analyses and in light of national/local circumstances.

The Cooperative Agenda (item 4.4) also identified the need to increase the supply of people with training in children's environmental health risk assessment, in order to improve the capacity of governments to assess potential risks to children posed by chemicals, including pesticides. Mexico, in particular, has identified this as a priority need and has initiated a program of risk assessment training. Trilateral collaboration will support the inclusion of a children's environmental health focus within this ongoing training. The three parties have agreed to explore means to increase the number of people trained in children's environmental health risk assessment. A working session during the workshop in Oaxaca is to develop a profile of skills needed for children's health risk assessment, identify possible means by which more people can be trained, and propose actions to increase the number of trained people, for example staff exchanges, training programs at universities and the development of appropriate courses by universities and other training institutions.

Workshop objectives

This workshop was organized by the CEC in collaboration with the NAFTA Technical Working Group on Pesticides. The specific objectives identified for the workshop include:

1. To identify areas where the three countries can benefit from the sharing of work, expertise, information and ideas on risk assessment, with a particular focus on children's environmental health.
2. To share country-specific approaches in assessing environmental health risks to children.
3. To facilitate a common understanding of current risk assessment methodologies, principles, terms and concepts among practitioners, and identify emerging approaches, particularly with respect to children's health.
4. To coordinate the sharing of scientific information used within and among jurisdictions (i.e. health, environment, and research sectors) for regulatory risk assessment processes and identify information needs.

5. To identify current capacities with respect to risk assessment for children's environmental health within the three countries, assess future capacity building needs and suggest initial activities.
6. To discuss the context within which risk assessments are used to inform decision-making, including the role of precaution, the need for transparency, outreach, and risk communication.

Organization of this Report

The report is organized as a linear record of the workshop. A summary of each presentation is given. At the end of each session a summary of questions comments and interventions is provided. While each intervention made may not be presented in detail, every effort has been made to capture the input of participants over the course of the workshop. The results of the working sessions are presented in the form they were approved by the workshop participants. While further efforts will be made by the CEC to integrate the recommendations made by the working groups and the recommendations made by individuals throughout the course of the workshop, this report is a record of the outcomes from the workshop itself.

SETTING THE STAGE

Victor Shantora, the acting executive director of the North American Commission for Environmental Cooperation opened the workshop with a presentation on the history, structure, and role of the CEC and provided context to the issue at hand: Risk Assessment and Children's Environmental Health. Participants were welcomed and challenged to engage over the coming days to learn, share and develop a set of recommendations to move this important issue forward. John Buccini, was then introduced as the chair for the workshop. John gave a short presentation on the objectives of the workshop and on the basic concepts and elements of risk assessment as presented in the background document.

Assessing the Risk to Children's Health from Chemical Environmental Toxins

Irena Buka, MB, ChB, DCH, FRCPC, Associate Clinical Professor of Pediatrics
Chair, Expert Advisory Board on Children's Health and the Environment in North America

In order to assess the risk to children's health from chemical environmental toxins, it has been necessary to identify agents of concern and document the health effects to children of these environmental exposures. This has been a very difficult task because of many mitigating circumstances that prevent an easy "cause and effect" model. Children are exposed to many environmental agents simultaneously and in sequence that are very difficult to monitor. Health effects may not be diagnosed immediately upon exposure to a low dose of a particular agent. As scientific and epidemiological evidence grows, we are learning more about the unique vulnerabilities to children as they develop from conception through a process of cell growth and multiplication, development of organs and ongoing growth, development and maintenance of health of the body systems. By protecting the developing fetus and young child from the accumulation of chemical environmental toxins within their bodies we are creating a healthier environment for the

next generation of children to be conceived in. Preconceptual exposures are being recognized increasingly and need to be studied more extensively.

Physicians and scientists have become alerted to the health effects of environmental exposures on children by evidence from accidental ingestion of a large dose of the chemical toxins in question leading to acute toxicity. Lead toxicity is one of the best studied and understood environmental toxins to children. Other neurotoxins have been identified in a similar manner. The Minimata Bay disaster where children were born to mothers that had consumed fish contaminated by mercury released into the fishing waters from an industrial source and gave birth to babies who developed psychomotor retardation, seizures, blindness and deafness has led to further investigation of the neurotoxic effects of mercury on the developing fetus. There have been studies identifying the risks of polychlorinated biphenyls (PCBs) on the developing central nervous system of the fetus and the suggestions are that at fairly low levels neurotoxic effects can produce developmental delay and neurobehavioral disorders.

In assessing the risk of a potential substance, many health effects need to be taken into consideration, carcinogenicity, teratogenicity, genetic damage to cells, effects on the immunological and endocrinological system, effects on the respiratory system and particularly on the prolonged development of the central nervous system. Most chemical toxins will cause effects on several of these organ systems, depending on route and dose of exposure.

Timing of exposure, we believe, is often critical. Not only do we need to consider chronic low-dose cumulative lifetime exposures, but particular windows of opportunity, i.e. critical times of gestation when growth and development is occurring. We need to consider all sources of exposure to a particular agent in a child's lifetime. Assessing the risk of exposure to one agent via one source, e.g. arsenate in the sand in children's playgrounds without taking into consideration that children would also be exposed to arsenates in water and food would clearly be an omission. Scientific evidence has demonstrated synergistic effects between environmental exposures. For example, inhalation exposure of a child to environmental tobacco smoke when they are also exposed to moulds in the environment, potentiates the risk of developing asthma beyond a merely additive effect of the two agents. We need to take other factors into consideration when dealing with a chemical environmental exposure. For example, children who are anemic or who have other nutritional deficiencies demonstrate a higher absorption of lead, putting them at greater risk of lead toxicity versus the child with an adequate and healthy diet. A child's genetic predisposition to asthma may predispose them to symptoms of cough and wheeze when in contact with air pollutants.

The children we are protecting from the risk of chemical environmental toxins come from a broad range of environments throughout North America. The geographic climatic, economic and cultural environments that children are exposed to vary greatly between each of the three countries, Mexico, USA and Canada, but also vary greatly within each country and community. Children living in the same home as adults will be exposed also to different microenvironments. A child's vulnerability will depend on the

microenvironment that they find themselves in at that particular stage of life and development, e.g. the fetus in the uterine environment, the baby and young child closer to the floor. Children are vulnerable by way of their unique developmental physiology which changes rapidly during the development and growing phases. Thirdly, the normal neurobehavioral stages of children e.g. oral exploration, active play and immersion in soil, dust, etc., immature judgement with respect to contaminants. Children's life longevity needs to be taken into consideration when considering chronic low-dose accumulation of potential carcinogens, neurotoxins, etc. Knowledge of storage and excretion of toxins through a child's body mechanism is relevant when assessing total body accumulation with respect to carcinogens, neurotoxins and teratogens.

The task ahead of us is daunting. Over the next three days through our discussions as we make our plans and recommendations, we need to take all of these factors into consideration regarding the unique vulnerabilities of children and apply them to the strategies that we shall be developing. Risk assessments in children cannot be complete until we have studied "worse case scenarios" before taking decisions throughout the three day process. We need to remember that our methodology needs to demonstrate a precautionary approach.

Questions:

One participant noted in reaction to the presentation given by John Buccini that risk assessment can not be classified as an unbiased science and that there are imbedded values in the process that must be recognized and examined.
In response, John Buccini clarified that he did not use the term unbiased and repeated that there are always boundary conditions that define the process including mandate, legislation, experience etc.

One participant made two comments on Irena Buka's talk. First, they emphasized that environmental factors, while important are sometimes a very small percentage of the actual etiology of the disease and we must keep this in mind when setting priorities. Second, they commented that while multiple exposures are a reality and there is a lack of complete knowledge, we must not let that prevent us from taking action on individual substances we know are causing harm.
Irena Buka responded by commenting that understanding the balance and roles of environment and genetics in the etiology of disease is important and noted that often we are looking at the wrong generation. She suggested we need to look back in time and over generations to identify generational changes in the genetic make up of cells to develop cause and effect links.

WHERE ARE WE NOW

This session provided participants with the opportunity to learn about the current situation and current practices with respect to children's environmental health and risk assessment in North America.

The Use of Risk Assessment in COFEPRIS(*Comisión Federal para la Protección contra Riesgos Sanitarios)*

Dr. Leonor Cedilo Becerril, Executive Director, Federal Commission for the Protection against Health Risks
Victor Torres Manuel, Deputy Director, Federal Commission for the Protection against Health Risks

The Federal Commission for the Protection against Health Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios*—COFEPRIS) is an autonomous agency under the Mexican Secretariat of Health (*Secretaría de Salud*—SSA), comprised of the several health authorities as provided in the decree published in the Federal Official Gazette (*Diario Oficial de la Federación*—DOF) on 5 July 2001. The objectives of COFEPRIS include proposals and implementation the national policy on protection against health risks with regard to medicines and other health products, food and beverages, and other products intended for human consumption, and on the prevention and control of the harmful health effects of environmental and occupational factors; and the assessment of health risks within the scope of its jurisdiction.

The risk assessment and management carried out by CO is illustrated in the diagram entitled "Attention Model," seen on slide no. 9. Under this model, all health protection activities undertaken by COFEPRIS are supported and their effect assessed in a risk analysis. Current capacity to perform risk analyses within the organization is limited; therefore, the model has not been fully implemented for day-to-day activities such as the registration of pesticides, the determination of maximum limits for residues in food products, or import permits for toxic substances.

Studies are frequently undertaken based on citizen complaints or specific problems that often include exposure assessments and in some cases the assessment of effects and risk characterization.

Target populations in COFEPRIS programs and projects include children, women, workers, and indigenous groups.

Some of these groups have higher exposure or are more susceptible, such as in the case of children due to their physiological and behavioral characteristics.

There are maps with information on rough estimates of exposure to particles and lead generated in pottery and tobacco kilns, to water pollution and to metal contaminated sites, as well as the regional distribution of in-home drinking water faucets.

The mechanisms to strengthen COFEPRIS' current capacity in risk assessment are based on international, intersectoral and interinstitutional cooperation, particularly linkages with academia.

Questions:

One participant asked how someone can bring a complaint to COFEPRIS?

Leonor Cedillo explained that public complaints come through different routes including: directly to COFEPRIS by groups of neighbours, NGOs, or individuals who see a problem; and from other government agencies who refer the complaint.

Another participant commented that while hazard has been emphasized, this presentation highlighted the importance of examining assumptions about exposure and extrapolations.

Another participant asked if COFEPRIS is doing any follow up work on pesticides in water in areas of intensive use and if they are working with families regarding lead in glazed pottery.
Leonor indicated that they are have a project related to monitoring irrigation systems and that this is one of their priorities in the northern part of the country and that they are also looking at exposure routes and a national surveillance system to help diagnose problems, particularly epidemics of acute intoxication. With respect to lead in glazed pottery, she indicated they will address this in more detail in presentations later in the workshop and they have been working to coordinate efforts to implement a new standard that will not allow for lead oxide paints for pottery including examining alternatives.

One participant emphasized the importance of addressing the legislative gaps in Mexico that make it difficult to take action even once studies are completed and knowledge developed; the time line to action is too long.
Leonor indicated that she agreed that addressing legislative gaps is important. She also indicated that while taking action on lead in pottery has taken time, they have developed alternatives over that time that will help in implementation of the new standard.

Vic Shantora also noted that under the CEC Sound Management of Chemicals program they have launched a project to monitor certain pesticides in North America and that the World Bank is also sponsoring a project to look at the concentrations of persistent toxics in the blood of pregnant women.

Another participant made the comment that action is needed to manage and eliminate the risks of toxic chemicals; rather than further assessment we need action when we have enough knowledge to know health is being harmed by chemicals in use. They described a study conducted in their community where they found high level of pollutants in children and the evidence is presented in a video which was handed over to the CEC to show during the workshop and also to Mexican officials. They also commented on the importance of research being done in collaboration with the community and that results should be shared first with the community.
Leonor indicated they would view the video and also arrange to have it shown at the workshop.
[note: the CEC made arrangements for participants to view the video on Thursday and Friday.]

Canadian Approaches to Health Risk Assessment of Chemicals in the Environment: Industrial Chemicals And Pesticides

Anthony W. Myres, PhD, Safe Environments Program, Healthy Environments and Consumer Safety Branch; Health Canada, Health Canada
Christine Norman, MSc, Pest Management Regulatory Agency (PMRA), Health Canada

Safe and nutritious food, clean air and water are fundamental requirements for protecting the environment on which human life and health depends on. Of other factors determining health status, it is increasingly recognized that healthy childhood development (including the fetus) is a prime determinant of later adult health. The developing fetus, infant and young child may be more vulnerable to environmental hazards than at any other stage of the life cycle. It is a period of unparalleled growth rate when organs and tissues are developing and when detoxifying and excretory mechanisms are still maturing. Because of this, governments need to look closely at how well their statutes protect vulnerable groups, such as children, within the general population.

Environment Canada has overall administrative responsibility for the federal government's principal piece of environmental protection legislation, the Canadian Environmental Protection Act (CEPA). Health Canada has responsibility for the provisions of CEPA that deal with protection of human health from toxic substances. The federal government's legislation concerning pesticides is the Pest Control Products Act (PCPA). This governs the importation, manufacture, sale and use of pesticides and is the sole responsibility of the Minister of Health. The PCPA governs both environmental and health impact. The new federal Pest Control Products Act, which received Royal Assent in 2002, specifically requires that the Minister apply appropriate margins of safety to take into account different sensitivities to pest control products of major identifiable subgroups, including pregnant women, infants, and children. This requirement is consistent with current practices within Health Canada's Pest Management Regulatory Agency.

Both pieces of legislation encompass a dual approach to controlling chemicals. The first of these approaches is pro-active and preventative in that it seeks to identify and evaluate chemicals that might be harmful to health or the environment before they are allowed into commercial use i.e. pre-market assessment and registration. Detailed regulations prescribe the information requirements needed by the government for assessment of their potential to harm the environment and human health. In this case, the onus is on the manufacturer/importer to provide evidence which demonstrates to the satisfaction of the government that the chemical is efficacious and safe for its intended use.

The second approach is an attempt to control chemical substances already existing in the environment, i.e. those substances on the Domestic Substances List, which is an inventory of all substances in commerce in Canada. The risk assessment and management of these substances is addressed under the Existing Substances Program of CEPA. In the case of the PCPA the act mandates periodic re-evaluation of registered pesticides. Under CEPA, the federal government (HC and EC) must determine for substances already existing in the environment, whether they are CEPA "toxic" as defined by the Act. This is the trigger for initiating risk management of the substance.

Risk Management can take the form of controls on emissions or release of the chemical eg. secondary lead smelter emissions, dioxin and furan emissions from pulp and paper mills. In this case, the onus is on the government to identify the risk to health or the environment and to implement appropriate corrective action.

It is important to note that the definition of "toxic" in CEPA is strictly a legal rather than a scientific one. This definition corresponds to our understanding of the concept of "risk." It embodies the notion that harm to health (or the environment) is a function of both the inherent toxicity (i.e. toxicity in the scientific sense) and the quantity or concentration of the chemical to which humans (or the environment) are exposed (i.e. the degree of exposure). Encompassed by this definition is the potential for both immediate and long term effects.

For every pesticide regulatory decision, children's exposure via the oral, dermal and inhalation route are specifically considered. Tools and methodology to conduct exposure and risk assessment for children have been developed, in many cases cooperatively with the U.S. EPA. The comprehensive toxicology database which is required for each pesticide includes studies key for conducting health risk assessments for children including multigeneration reproductive toxicity studies, developmental toxicity studies and neurotoxicity studies. Registration or renewal of a pesticide is supported only if acceptable risk is demonstrated for all exposed subpopulations, including infants, children and pregnant females.

Illustrative examples under both CEPA (Priority Substance List 1 and 2) and PCPA demonstrate how toxicological studies are used to determine critical health affects and how these results are combined with exposure studies to estimate health risks. These studies illustrate how the unique exposure pathways and metabolic features of the fetus and young child are taken into account in risk assessment.

In order to establish accurate, defensible, health-based standards for chemicals in the environment, it is essential to determine the quantitative relationships between a given chemical and its effects. The term dose-response or exposure response is used to denote this quantitative relationship.

Clearly because of ethical considerations it is not possible to obtain such information from human populations and regulatory agencies use laboratory animals as the substitute for human beings and try to determine a level of exposure below which there are no apparent adverse effects. The No-Observed-Adverse-Effect- Level (NOAEL) is defined as a the highest dose, in an animal study which does not result in any observed effect. The NOAEL (sometimes the LOAEL) is used to derive the Tolerable or Acceptable Daily Intake (TDI/ADI) for non-carcinogenic substances. This is the daily human dose considered to be tolerable and below which no significant health risk is expected.

Uncertainty factors play a very important role in determining the TDI. They represent a measure of trust a toxicologist has in extrapolating animal test results to humans but also

include a number of other elements such as variability within humans, nature and severity of adverse effect, and the adequacy and quality of scientific studies.

Values of 10 are usually applied when animal studies are used. Another factor of 10 is applied to protect the most sensitive members of the population. Further safety factors may be used because of, for example, the severity of the effect, to compensate for lack of key studies used in the assessment, or to add extra protection for highly susceptible populations.

Different approaches are used to assess toxicity depending on whether or not the critical biological adverse effect is considered to have a threshold or not. For many types of toxic effects (non- cancer) it is generally considered that there is a dose or concentration below which adverse effects will not occur, i.e. threshold level. For other types of toxic effects it is assumed, but not proven, that there is some probability of harm at any level at any level of exposure i.e. there is no threshold. This assumption is considered appropriate for mutagenesis and genotoxic carcinogenesis

Questions:

One participant asked if considerations are made for off label uses when assessing existing substances and whether there is a standard full battery of tests required or whether triggers are used to limit test requirements.
Christine Norman indicated that assessments are done based on label prescribed rates with a focus on the maximum number, however for domestic products where they know there is less compliance so don't register products if require protective devises beyond gloves. Regarding triggers, she indicated there is a standard data set that is required that includes a full battery of acute and chronic studies required and then conditional requirements for additional studies. They feel there are enough studies in the core package to trigger the need for the additional studies.
Tony indicated that for new substances, the use is indicated in the application and under the new CEPA any significant new use requires notification.
Christine also emphasized the importance of risk communication to communicate label instructions.

One participant asked if they were using ethnical differences in their risk assessments- i.e. Inuit and urban.
Tony indicated those differences are taken into account in doing an exposure assessment using tools such as dietary studies.

One participant asked if the option of prohibition of a toxic substance is being used, questioning the use of prevention vs. controlling the application. They also asked if fungicides are included in pest management?
Tony indicated there is a list of prohibited substances that is enforced by Environment Canada. This list used when there is sufficient information to warrant the prohibition.
Christine indicated that substances like wood preservatives are treated as pesticides and undergo alternative strategies development and so on, but the risk management side was not focused on because of the workshop focus on risk assessment.

John Buccini noted to participants the recurring theme of public access to information and asked that presenters keep it in mind and address that question in their talks.

Children's Environmental Risk Assessment – U.S. Environmental Protection Agency
Gary Kimmel, PhD, Developmental Toxicologist, Office of Research and Development, U.S. EPA
Jennifer Seed, PhD, Branch Chief, Office of Pollution Prevention and Toxics, U.S. EPA
Elizabeth Doyle, Branch Chief, Office of Pesticide Programs, U.S. EPA
Presented by: Brenda Foos, Toxicologist, US EPA

This presentation provided participants with an overview through examples of children's risk assessment within the U.S. EPA and potential areas of collaboration. The presentation reiterated the risk assessment paradigm that has become a standard, and noted how the risk characterization becomes an important component of the overall risk management process.

An overview of several of the federal actions followed, in order to provide the legislative and programmatic perspective that gives direction to the use of risk assessment in the U.S. EPA. The focus was on those federal actions that specifically addressed the needs of children. The U.S. National Academy of Sciences report on *Pesticides in Infants and Children (1993)* served as a springboard for considerable legislative and programmatic activity over the next decade, all of which have a considerable focus on children's health and the environment.

This was followed by a discussion of components of hazard-dose response characterization, especially as they apply to windows of susceptibility during development and the differing sensitivity of children from adults. The parameters that the U.S. EPA uses to define a child are related to the time at which exposure occurs, not to when an effect is observed. Thus, childhood exposure is that which from germ cell development, to fertilization, through the prenatal period including but not limited to organogenesis, and continuing through the postnatal period until the time of sexual maturation. The resultant effects of such an exposure may be manifested at any point during the lifetime of the exposed individual (and potentially their offspring). As examples, aspects of the assessment of mercury and lead were presented, pointing out the potential differences and similarities of children's environmental exposures for the three countries, and an example of tools that can be used in determining these exposures was noted. Overall, hazard-dose response assessment is an area where the U.S. has had successful collaborations with other countries and there are many opportunities for further collaboration. Ideally, it should be possible to harmonize approaches among countries.

The presentation continued with elements of risk characterization and examples of how efforts in this area can support risk management actions and identify gaps in our knowledge, both of which will improve the environment for children. The risk characterization brings together the hazard-dose response and exposure in a way that is understandable and informative to a variety of audiences, including risk managers and the public. This is especially important when children are identified as part of the susceptible population. For example, the risk characterization should note that the assessment is tailored to the age group in question by selecting age-specific input parameters defining

behaviors or physiologic characteristics. Certain behaviors such as mouthing are significant sources of exposure to children, but are relatively unimportant to adults. The presentation went on to note that Canada and the US have worked very hard in the past few years to harmonize their risk assessment practices for pesticides and often make common decisions.

Finally, other potential collaborative areas were noted in the area of children's health and the environment. The U.S. EPA looks forward to the opportunity to interact with Canada and Mexico in building a better environment in which our children can grow and mature.

Policy Interpretation Network on Children's Health and Environment
Moniek Zuurbier, MSc, Public Health Services Gelderland Midden, The Netherlands

The PINCHE-project is a Policy Interpretation Network on Children's Health and Environment, which is funded by the European Union for three years. The PINCHE project is designed to provide decision makers, environmental health professionals, and other stakeholders with information relevant for policy development.

The Policy Interpretation Network on Children's Health and Environment aims at the creation of a widely supported basis for public health policy-making, related to the improvement of children's environment and health in Europe. To reach this, studies related to children's health and environment will be analysed and interpreted. The results will be used to make recommendations for policies on children's health and environment. The network is formed by stakeholders of research institutes, UN and related organisations, consumers organisations, industry, institutes on education, and environment and health NGO's).

Four themes have been selected: Air pollution, Environmental carcinogens, Noise, and Neurobehavioural and developmental toxicants. Four working groups will evaluate and analyse studies on Children's Health and Environment work, looking at studies in the fields of exposure assessment, epidemiology, toxicology and biology, and risk assessment. In addition the socio-economic impact on the health of children will be studied, compared to the health effects due to environmental factors.

The project is funded for three years, from 2003 till 2005. At that point, it will be decided whether follow-up activities are desirable. It is expected that the policy part of the Network has accomplished its aim by then, and participants can continue to network on scientific and policy activities within a global network on children's environment and health. Research gaps will be identified during the process of the working groups and reported upon.

Questions:
One participant asked if Moniek had any comments on legislation issues we're encountering in north America.

Moniek indicated that there is a significant difference between the Netherlands and the EU. Legislation in Europe varies among countries but feels there is a good regulation system for pesticides, much better than in North America.

Another participant asked if they are doing anything specifically for farm workers.
Moniek indicated their work will include children's exposure on farms but farm workers are not specifically in the scope of their work.

One participant asked if they have considered ethnic specificity.
Moniek indicated they are taking this into account in Europe and also in Africa where the differences are very large.

One participant asked whether there has been consideration of industry having to conduct the risk assessments following the "white paper" and discussions of where the burden of proof should lie.
Moneik indicated that industry now has high involvement in the regulatory scheme because they know they have to.

Another participant asked whether incidences of asthma in different countries have been attributed to specific causes?
Moniek indicated there have been many studies done. In particular she noted a study done in germany examining the differences in asthma occurrence in East and West Germany, indicating environmental causes.

Evaluating Potential Risks to Children's Health: Tiered Toxicity Testing & Risk Assessment of Industrial Chemicals
Prepared by: Richard A. Becker, PhD, DABT, Toxicologist & Senior Director, Public Health Team, American Chemistry Council
Presented by: George P. Daston, Ph.D, Research Fellow, Miami Valley Laboratories, Procter & Gamble

Child focused health initiatives are increasing across the world, and risk assessment methods to evaluate potential threats to children from chemical exposures are needed. We describe a tiered risk-based process for developing and evaluating hazard and exposure information for child focused safety assessments for commodity chemicals. This tiered toxicity testing and evaluation approach is structured upon a core battery of tests that cover major endpoints and target tissues. The process begins with a screening level risk assessment, drawing hazard information from the internationally harmonized core set of toxicity tests (OECD-SIDS & HPV Challenge) and exposure information from readily available sources. The base set of hazard studies identifies sites of toxicity, effect and no effect levels for all major organs from acute, repeat dose (subchronic) and in utero exposures and includes evaluations of reproductive effects and the potential of a substance to damage DNA. A defined set of biologically based toxicity criteria are used as part of the decision matrix. Comparisons are made between NOAELs and estimated exposures to derive margins of exposure and this information, considered in conjunction with the toxicity criteria (triggers), provides the basis for determining subsequent actions. Options include: low priority for further studies; refining the exposure assessment and/or

conducting additional toxicity tests. The biologically-based toxicity triggers guide decisions as to whether additional toxicity tests are warranted and indicate which specific types of studies are important to gain greater certainty concerning a substance's potential hazard to children. Applications of this approach, including EPA's Pilot Voluntary Children's Chemical Evaluation Program are discussed.

Questions:

One participant inquired about the benefits and difficulties of the tiered approach; benefits including increasing capacity to look at more chemicals, difficulties depend how tiered system is structured. If 1st tier is conservative enough it may be ok. See benefits of tiered approach for exposure but for toxicity one would miss endpoints particularly for pesticides.

George indicated that in using the tiered approach the tests selected would relate to the intended mechanism of action of that particular pesticide. Ideally we'd have comprehensive test for everything but it isn't pragmatic, this pilot test of the tiered approach is an experiment to improve the design.

The Scientific and Ethical Challenges of Risk Assessment – An NGO Perspective

Kathleen Cooper, Researcher, Canadian Environmental Law Association

The topic is addressed through the lens of well-known examples to enable quick entry into a list of lessons learned and challenges posed by existing and evolving risk assessment and risk management (RA-RM) approaches. The science behind the assessment continues to evolve. However, this ever-increasing complexity is still overmatched by the greater complexity of the problems being addressed, including accounting for the special exposure circumstances and vulnerabilities of children. Children are experiencing long-term, multiple, simultaneous, and intergenerational exposure to low levels of chemicals. The RA-RM policy framework enables such exposures to continue until a high degree of scientific proof of harm is provided or verified by agencies unequal to the task, scientifically, financially, or in some cases, politically. Some fatal flaws exist that may never be addressed. When "windows of vulnerability" are always open but the subject of scientific debate, tolerance limits will be too high if they are only based on agreement about acceptable risk during less vulnerable life stages. Ethical issues arise throughout. When action is only taken in the face of rigorous proof of harm, chemicals ostensibly have greater rights than the human population. Chemicals are generally assessed in isolation from each other and from existing, real-world circumstances of multiple exposures. Each is allotted an "acceptable" risk level, whereas the human population is not entitled to a similar right to avoid the cumulative risk of real-world exposure to many different chemicals in the environment. The greatest challenge is the scientific assessment and/or re-assessment of existing substances. Assessments of those long in use could continue to be undermined by the compromises made during risk management exercises that provide excessive accommodation for commercial interests over the interests of less quantifiable child health concerns.

Questions:
One participant indicated it would be useful to hear practical approaches to dealing with these issues as opposed to just listing the problems with current approaches, and specifically noted that while there are significant data gaps we are working to fill them.

Another participant, in response, reiterated Kathy's practical suggestion regarding the need to expand our biomonitoring study and link that with health outcome information particularly in young children. One model that has already been mentioned is the US national longitudinal cohort study that they would like to see replicated in Mexico and Canada.

Plenary Discussion Period
The plenary discussion period provided participants with the opportunity to ask questions and to share ideas. A panel composed of the session speakers was available for questions and participated in the topics for discussion including: strengths and weaknesses of current use of risk assessment, similarities and differences in country approaches, and opportunities for collaboration.

One participant asked for more information about the new Mexican standard that will ban the use of lead, and expressed concern that these communities do not know the risks and will find the lead illegally unless they are engaged in the process.
Leonor responded by agreeing the impacts are concerning and acknowledging how difficult it is to do something. She described the perception of risk issue, that they haven't yet developed a culture of precautions. To date efforts have included work with associations of artisans with some success. Over the next two days more details will be presented including the educational component of risk communication, and they are open to suggestions of how to improve.

Jose Carlos reminded the group of the success in finding substitutes for DDT; there was doubt but now it has been achieved. The CEC is making progress on substitutes for lead and invited participants to discuss alternatives with the CEC.

One participant expressed concern that presentations have been imbalanced, as we have only heard from government in Mexico, not from academics, the public, and NGOs. It is important to the assessment of strengths and weaknesses and that in general communication between the government and universities is a problem. Meetings such as these could provide the venue to include presentations from non-government experts.
Leonora responded by indicating that there are presentations scheduled later in the agenda from academics and NGOs, and also expressed an openness to academics who have means to do risk assessments to work with the government in Mexico to build this capability.

One participant noted that in Mexico if we don't introduce in the laws that require risk assessments be done then there won't be the demand for risk assessors, so universities

will not produce them. Thus if we want the to develop more capacity for risk assessment then we need to change laws.

This participant also noted the importance of socio economic considerations when making decisions with implications for high poverty areas. The example discussed was the competitive food markets under NAFTA.

One participant, in response to comments made throughout the day, noted that perhaps the scepticism of risk assessment is misplaced, that the criticisms seem to be about the actions taken following the risk assessment; a dissatisfaction with controls and risk management actions. He noted examples where the science was less disputed than the actions society was willing to take. Risk assessment is the only logical useable system in a regulatory environment that provides the burden of a consistent documented approach to take action. It is also the only viable way to give risk managers real information. We see that there were times we missed opportunity to take action but that was risk management not risk assessment. He then recommended action in the area of improving the communication of risk assessment in a less technical manner, to make it more understandable to facilitate action, to get stakeholders involved to communicate risks and uncertainties in a better way. He noted we must be careful of taking our dissatisfaction with lack of action and blame that on RA, because we will then miss the opportunity to improve risk assessment itself.

Another participant noted the delay of action enabled by debate in the risk assessment stage, while agreeing with the previous participant, did not think the risk assessment and risk management can be entirely separated.

One participant noted that some of the different opinions are based in different philosophies about separating risk assessment and risk management and these are issues of values. It is important to examine the values embedded in the risk assessment process and to examine the democratization of risk based decision making to define what risk is acceptable to whom. Currently it is an expert driven process but there are ways to engage others in deciding what is acceptable. Risk assessment and risk management cannot be torn apart and there are values imbedded throughout.

One participant asked whether in fact risk management should come before risk assessment. There is a call for alternatives assessment and determining the role of precaution and burden of proof. Why couldn't we make a major decision first, and then do the assessment.

This participant also asked for clarification of the deadline for DSL categorization and screening in Canada. Tony indicated that there is a 7-year deadline for categorization but none for assessment.

Another participant pointed out the difference between risk assessment for chemical and for contaminated sites, and stressed the need to also focus on contaminated sites.

One participant asked for clarification of what the criteria are in US and Canada for registration of a new product and if chronic effects are considered. They also asked why chronic effects are not on pesticides labels.
Christine Norman from Canada indicated that both acute and chronic effects are considered in the risk assessment and that details of the assessment process are available on the Health Canada website. Regarding labels she explained that only acute effects are now included there is an international harmonization process under way to add chronic hazard labels.
The USEPA also indicated they consider human health and ecological acute and chronic risks.

One participant commented that the CEC activities and meeting costs should be assumed by industry and not citizen taxes. In addition there should be North American bans on pesticides which cause harm to farm workers because the use of banned products in Mexico causes socio-economic and health problems because the products can not be exported. The three governments should finance organic production, and ban transgenic seeds and herbicides. There needs to be a venue to hear the voices of the affected populations like farm workers and artisan communities.

Another participant was very pleased to hear microbial risk assessments are being conducted and that this issue is of great import to Mexico, and recommend as a follow-up item that this methodology be shared.

NEW DEVELOPMENTS IN RISK ASSESSMENT: EMERGING SCIENCE, ISSUES, AND CHALLENGES

Exposure Assessment

Mark Miller, MD, MPH, Director, University of California San Francisco, Pediatric Environmental Health Specialty Unit

Several recent sources of interesting exposure data were presented and some lessons learned were also discussed. In California, recent funding has provided for a study to look at air pollution in places where kids are know to inhabit. Soon we will see data that will solve some exposure data issues and ease the need to extrapolate as much. The Centre for Disease Control has just released its 2nd National Exposure Report, which is based on a large program built on many technical innovations at the CEC including an ability to test urine for environmental chemicals. This report has added several chemicals and metabolic products. The report shows several positive trends but also highlights areas where childhood exposure is an issue and sometimes not as expected.

Exposure data is very important for RA to give us a guidepost to see if assumptions we're making are close to real life. Gathering exposure data through body burden data can also help identify susceptible sub populations. For example a recent study identified a wealthy subpopulation who had high mercury levels correlated with swordfish and tuna consumption. We need to be careful because this population would not have likely been surveyed as a suspected vulnerable population. Recent studies of PCBs in breast milk indicate high exposure to PCBs early in life, which is linked to delays in reading ability. Other countries have demonstrated that breast milk banks are very useful tools to see trends over time. If an emerging issue arises, these banks allow us to look back in time to determine exposure trends and provide the basis for an "early warning system".

Finally, how exposure data is communicated is very important. For example, while breast milk monitoring programs are very useful tools, some are concerned that the data would encourage mothers not to breast feed when in fact breast-feeding is still considered much better for the child. Also when communicating risks, it's important to identify what messages resonate with the public, the example of levels in fat resonating less with the public than levels in breast milk was used.

Questions:

One participant asked why in the CDC report PCDEs are not included?
Mark indicated that while he did not know, he speculated that perhaps at the time they weren't a known issue of concern.
Both suggested a recommendation from this group could be sent to the CDC that PCDEs be included in the next report.

One participant commented that while biomonitoring data is useful for priority setting for action, it must also be combined with the likelihood for an effect to occur.

Effects Assessment

Miriam Levitt, PhD, Vice President of Research, Policy and Programs, Canadian Institute of Child Health

The realization that children differ from adults in regard to matters of environmental health has presented many challenges for risk assessment. Risk assessment must take into account the rapidly changing and variable vulnerability of the fetus and child as he/she develops. Development does not proceed linearly, but occurs in spurts, is associated with windows of activity and susceptibility in specific organs such as brain, immune and endocrine systems, and may be influenced by individual or group genetic heterogeneity. The complexity is only now being realized and much more research is needed.

Fetal, infant and child life assessment must account for potential multiple exposures from parental and other exposures before, during and after pregnancy. If the infant is breastfed the chemical content of the milk becomes a further factor. Other factors include increased exposure due to higher food, fluid and air intakes per Kg body weight, and permeability of the blood-brain barrier until about age 6 months; and behavioral factors such as crawling and hand-to-mouth activities. Nutritional status, which influences toxic effects, also ranges greatly and often unpredictably. Environments of growth are equally varied – rural to urban, poverty to wealth, literate to illiterate, arctic to tropical, secure to insecure water supply, and so forth. And definitions and degrees of 'poverty' differ across the world.

Further adding to the complexity is the potential of multiple synergistic chemical exposures that children experience, or to which they are exposed through their parents' activities and occupations, which relatively little research has yet addressed. And finally there is the fact that adverse effects may take many years, even to later adulthood to appear.

This presentation focused on examining the new knowledge, approaches, tools and techniques of effects assessment and the impact on children's health.

Questions:

One participant commented that the presentation gave a very good message but questioned some misunderstanding about what RA can be- that is a process of integrating science and establishing a reasonable estimate of risk, it is not just number crunching. We need to broader our view of RA and what it is capable of.
Miriam agreed, emphasizing the need to take a multidisciplinary approach and the need to include different partners at the table beyond natural scientists; there is a need to include social scientists and the community.

Another participant concurred that it is indeed a misperception that RA is necessarily narrow and just "number crunching". In fact there are very different situations and types of RA, we often present very simple models to communicate the work but this may do the depth of RA a disservice.

Reducing Risks to Children Near Contaminated Sites in Mexico

Fernando Diaz-Barriga, PhD, Coordinador de Toxicologia Ambiental, Universidad Autonoma de San Luis Potosi
Prepared in collaboration with: Batres L, Calderón J, Carrizales L, Mejía J, Ortiz MD y Yáñez L

In San Luis Potosí, Mexico, 47 contaminated sites have been located, at all of which there is evidence of health risks to children living in the surrounding areas. Our group has established a risk assessment methodology that includes an exposure analysis and an analysis of biological damage biomarkers. This methodology has been applied with success at mining sites, pesticide contaminated sites, areas with naturally contaminated aquifers and industrial zones. In this work we submit the results of the application of this methodology and how we have used it to introduce corrective measures to reduce child exposure to pollutants. For example, urinary arsenic levels around an arsenic smelter have decreased by 72%, while fluorine-free water has been supplied to the populace near a fluorine-contaminated area. We are presently carrying on studies at mining sites, pottery-producing communities, dioxin-contaminated areas and DDT-contaminated indigenous communities. We will describe the new procedures being followed in these communities.

Questions:

Several participants offered congratulations to Fernando and his team for their accomplishments.

One participant commented that this has been a very successful institutional development model where one school of medicine having Mater's and PhD programs in environmental sciences has developed and been able to compete internationally. We should be focusing on increasing capacitates in Mexican academic institutions which are more stable than government.

One participant noted the importance of involving the affected communities in the research process and asked how involved the communities have been in this work. Fernando indicated that they had wanted to work with the parents of the children but efforts there failed. They changed their strategy and worked directly with the kids and this has been a huge success and the kids now educate the parents. This approach has worked in indigenous communities as well and they have prepared a teaching package for others to use.

WHERE DO WE WANT TO GO FROM HERE

Developments in Risk Assessment- Children's Health

Anthony Myres, PhD, Environment Contaminants Bureau, Health Canada

M.E. Meek, MSc *and Anthony W. Myres,* PhD*,* Environmental Contaminants Bureau, Healthy Environments and Consumer Safety Branch, Health Canada

Under the renewed Canadian Environmental Protection Act, 1999 (CEPA '99), there has been a shift of focus from assessment of limited numbers of substances for which considerable data are available to systematic prioritization and assessment of all Existing Substances. There are approximately 23000 substances on the Domestic Substances List, an inventory of chemicals and biological agents that were in commerce in Canada between January 1984 and December 1986. These must be "categorized" by September 2006 with subsequent screening and full assessment, where warranted, in an iterative approach to priority setting for risk management for all Existing Substances in Canada.

The purpose of "categorization" is to determine which substances on the DSL may have the "greatest potential for exposure" to the general population or are persistent or bioaccumulative and "inherently toxic" to human beings or to non-human organisms. In both of the streams of "categorization" for which Health Canada is responsible, namely "greatest potential for exposure": and "inherent toxicity" to humans, there is opportunity to identify at an early stage, potential exposures (in particular product uses) or effects (such as developmental/reproductive) of particular relevance to children. The relevance to children of these evolving approaches for categorization and screening of much larger numbers of Existing Substances will be described.

For full (Priority Substance) assessments under CEPA, in addition to assessing exposure for several age groups of infants, children and adolescents, there is provision for incorporation of data on variability in life stage specific kinetic or dynamic parameters. In lieu of the general default factor this allows for development of tolerable or acceptable intakes or estimates of carcinogenic potency, based on understanding of mode of action. In collaborative projects, the possibility of developing age group specific defaults for particular metabolic pathways is being investigated and data on kinetic parameters for children compiled. In addition, a framework for risk assessment for life stage analysis is being developed on the basis of consideration of specific case studies.

How Are We Going to Improve the Use of Risk Assessment in COFEPRIS

Dra. Leonora Rojas Bracho, Directora Ejecutiva, Comision Federal para la Proteccion Contra Riesgos Sanitarios

At the Federal Commission for the Protection against Health Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios*-COFEPRIS) under the Secretariat of Health (*Secretaría de Salud*-SSA), we have been developing various strategies to strengthen and broaden children's risk assessment to support the decision-making process. I will present both general and specific strategies. In the first group, are the structural changes involved in the agency's creation and the organization of processes within COFEPRIS for better

risk analysis and management, including the development of policies such as the inclusion of child populations in the management of environmental and occupational risks.

Some examples of projects and procedures from the group of specific strategies include projects such as one aimed at the elimination of lead in the production of glazed pottery, fired at low temperatures and used to store or cook food in pottery-producing communities. That project will include the assessment of levels of lead in blood and environment and the assessment of neurotoxicological effects. Base measures will be taken before intervention, and follow-up measures will be taken to assess such intervention. Other sectors and the CEC have cooperated in the project's development; the CEC's support involved the market study for a lead-free pottery market. Another project deals with the ecosystemic approach to malaria control in Mexico (Oaxaca), based not on DDT usage but rather on hygiene, the elimination of vector breeding grounds and the focalized distribution of medicines. Given the success of this approach, we are now working on demonstration projects in other regions of Mexico and Central America.

Lastly, are two examples of procedures carried out by COFEPRIS: the calculation of maximum residue levels and pesticide registration. These procedures require joint reviews, the participation of working groups and academic institutions, and the establishment of registration rule procedures.

Where Do We Go From Here - U.S. Environmental Protection Agency
Joanne Rodman, Acting Office Director, Office of Children's Health Promotion, U.S. EPA

Introduction: As we continue to develop and refine methodologies and supporting data for children's risk assessment, it is essential that we look forward strategically at our overall goal of improving our understanding of children's unique risks, as it is not adequate to consider children to be the same as adults.

Methodology Development: In the US we are looking forward to the application and advancement of children's risk assessment methodologies through the development of *Children's Risk Assessment Guidelines*, as well as the upcoming draft *Supplemental Guidance for Assessing Cancer Susceptibility Resulting from Early-Life Exposure to Carcinogens*. The draft supplemental guidance will discuss methods for use in assessing adult cancer risks resulting from early-life exposure to mutagenic environmental contaminants. However, we already realize that more robust information is needed in children's cancer assessment, particularly with respect to non-mutagenic carcinogens - for which currently no children's information is available.

Recognizing that additional research is needed to develop and refine methodologies and guidelines, as well as risk assessments, EPA has developed the *Strategy for Research on Environmental Risks to Children*, which addresses children's environmental health research on many issues. The National Children's Study, an extensive longitudinal

cohort study that has been proposed in the United States, is an excellent example of looking forward on children's environmental health research.

Additional Data: Many individual children's health risk assessments are limited - to varying degrees - by the unavailability of appropriate early life-stage data. We look to many areas of research and additional testing to provide the information necessary to fully assess the unique exposures, sensitivities, and risks of children. With respect to exposure assessment, the US is currently working to establish a consistent set of early life stages to include in children's risk assessments. We also recognize the need for additional testing and research for children's hazard assessment.

Cumulative Risk: Cumulative risk assessment is not specifically a children's risk assessment issue. However, it is critical that we develop the ability to assess children's cumulative exposures and responses in multi-chemical, multi-pathway cumulative risk assessments. It has been observed in non-cumulative assessments that children often have increased exposures and can have unique sensitivities. As such, we expect cumulative assessments will illustrate even more clearly how children's risks are different from those of adults.

Conclusions: As we are looking to where we want to go in the field of children's health risk assessment, it is important to focus on continuing to refine and improve the methods and information available for children's health risk assessment. It is essential that our countries collaborate on children's health risk assessment. There are great potential benefits for all of us, and for the international community, in sharing risk assessment methods, data, and related information. We must continue work together to sustain commitments to children's health protection, as this will assure progress toward our overall goal of improving our understanding of children's unique risks. Workshops such as this one establish the forum for such collaboration, and are thus improving our ability to progress the science and application of risk assessment.

Academic Vision of Risk Assessment: Present and Future

Dr. Irma Rosas, Coordinadora de PUMA, Universidad Nacional Autonoma de Mexico

Academia's risk assessment challenge, especially with regard to children, is to offer solid scientific evidence to be used in decision-making and to organize scientific and social information. Attainment of this goal requires interaction with other disciplines to structure an appropriate experimental or analytical design enabling a response to clear questions that are raised.

It is important to keep in mind that risk assessment must always be based on scientific facts, which requires an ongoing review of information and analytical techniques. Risk assessment also requires a flexible, constantly changing instrument, as science is continuously contributing important evidence. An interdisciplinary approach, which provides very interesting results, is needed as well.

There are currently three major research groups at *Universidad Nacional Autónoma de México* (UNAM) involved in risk assessment:

1. Researchers carrying on environmental research and identifying problems in the ecosystem, assessing a particular water, soil or biota pollutant.
2. The group assessing potential exposure based on the presence of the pollutant in the environment or food, and researchers measuring exposure through digestion, inhalation or contact.
3. This last-mentioned group is very small and is involved in risk characterization.

In this regard, we first must consider the creation of working groups and the development of environmental toxicology, which will enable the following::

1. Behavioral and destination models for environmental pollutants.
2. Exposure-, damage- and susceptibility-specific biomarkers.
3. In vitro and in vivo assays with compounds and mixtures, considering both soluble and insoluble materials.
4. Toxicokinetic and toxicodynamic aspects
5. The full risk assessment process.

The challenge faced by the scientific community in this area is not just human resources development and budgetary considerations, but rather to be heard by decision makers and to have them find such an instrument useful, based on risk management to restore, rehabilitate, regulate or ban. It is important that such decision makers approach risk management as part of environmental policy, and that the university authorities view it as a way to link science with society.

Current Research and Best Approaches for Childhood Risk Assessment

George P. Daston, Ph.D, Research Fellow, Miami Valley Laboratories, Procter & Gamble

The risk assessment paradigm, which combines hazard and exposure assessment, is appropriate for children's risk assessment, but unique aspects of development need to be considered in the process. Recent advances in risk assessment, such as the ILSI Risk Science Institute's framework, provide guidance on how to formulate childhood-specific assessments (Daston et al., 2003, Env. Health Perspect., in review) that explicitly takes into account the unique features of susceptible lifestages, including intrinsic factors that influence toxicity and exposure considerations that are characteristic of particular developmental stages. Research in toxicology and exposure assessment is being conducted in government and industry labs to provide a foundation for improved children's risk assessment. This research includes the evaluation of modified study protocols such as the U.S. National Toxicology Program's PestiKids design (Chapin et al., 1997, Fund Appl. Toxicol. 40: 138-57), and toxicogenomic studies to identify developmental effects that may be latent (e.g. the effect of prenatal estrogen exposure, Naciff et al., 2002, Toxicol Sci. 68: 184-99). Thorough consideration of exposure is of paramount importance in childhood risk assessment and chemical regulation. Exposure assessment is a central feature of the U.S. EPA's Voluntary Children's Chemical

Evaluation Program (VCCEP). The VCCEP program will provide an opportunity to evaluate and refine child-specific exposure assessment methods in a manner that has the full participation of industry and regulators, and will receive independent review. In the future, better exposure assessment may be coupled with additional laboratory approaches that augment our ability to characterize the hazards of environmental agents, including genomics-based biomarkers that bridge the gap between animal studies and human response.

Where Do We Go From Here – An NGO Perspective

Renee Louise Robin, J.D., California Director, Children's Environmental Health Network

The Children's Environmental Health Network presented an overview of environmental risks of concern to the NGO community, using California as an example. These issues are in the categories of (1) Methodology and data gaps, (2) Valuation and Precaution, (3) Consistency and (4) Independent Science. Recommendations include (a) making risk assessment protocols based on a child protective standard, (b) improving toxicity testing with more sensitive test protocols, (c) require a shifting of the burden, to institutionalize the precautionary principle, (d) licensing requirements for chemicals should include testing for multiple, synergistic and cumulative effects, (e) include the variable of "timing" of development along with dose and exposure, (f) add a pediatric review step where data based on adult tolerance, (g) recognize the disproportionate burden of environmental risks on under-represented groups and take protective steps to obtain equity, and ((h) improve implementation of existing laws. Overall we recommend that standards be based on the highest common denominator as the three countries work collaboratively and share their best skills.

Plenary Discussion Period

One participant commented on the high quality of presentations on both days.

One participant commended industry for voluntary action and noted the use of some voluntary programs, they also indicated that they felt there was much more data available and government needs to put more teeth to these activities to ensure the data is shared with the governments and the public. In addition new testing methodologies are being developed by industries such as drug companies where they have an interest in identifying side effects; the chemical manufacturers on the contrary, have interest in not finding out if there are toxic effects.

Another participant stressed the importance of developing training programs not just for scientists but also for local health providers and people in charge of managing risks. In Mexico, health is decentralized and many important decisions are made at the state level thus it is important to build capacity there so RAs will be translated into action.

One participant commented on the importance of having several types of exposure data including micro environmental monitoring, direct exposure measurements, and biomarkers in order to give you the information you need to address the risk.

One participant offered support for the tiered approach to RA as a way to set priorities. This participant also commented on the repeated calls for more data, indicating that we also still need to use what we have to take action.
In response, Joanne Rodman agreed that it takes years to get data but if we develop policies to require and promote research to get the data, then ten years from now we won't be talking about waiting to get data. We do need to take action, but we also need to start getting data for the future.

One participant stressed that new chemicals are a very small proportion of chemical manufacturing in the three countries so we should be focusing on existing substances.

One participant indicated that they are working on a project intended to create a list of substances of concern for kids in Canada. They noted that they are having difficulty gathering use and production emission data, which is key to identifying risks, and asked what mechanism Health Canada is using to gather the use info, is it confidential business information and, how can NGOs gain access to this information.
Tony in response indicated he was unsure about it being confidential but they could follow up after the workshop.

One participant noted the real absence of addressing Precaution or environmental justice and hotspots issues. They also noted that voluntary programs without a regulatory framework to back them up don't work. They also indicated that they would like to see pesticides in Canada linked to the NPRI because the public has a right to know about what is in their community.

Another participant noted that the new testing technologies should be used to do research by the companies that can afford to use them, and that animal studies should include mixtures so we can have some certainty about extrapolation to humans. This participant also suggested that with money from the Superfund, research could be launched to evaluate risks to children from contaminated sights and have similar programs in Canada and Mexico.

OPPORTUNTITIES FOR COLLABORATION WORKING SESSION

This working session was an important part of the workshop where participants built on the learning and sharing of information from the first two days, and worked in groups to identify concrete recommendations for a path forward. There were three concurrent break-out groups addressing the following areas for proposed North American cooperation:

1. Information Sharing
2. Capacity Building
3. Harmonization of Risk Assessment Terminology and Concepts

Background information on each of these three topics and guidance questions for the participants was provided (see Appendix 2).

Following the afternoon break out sessions the facilitator and reporters presented the recommendations developed by each group. The floor was then open to comments on the presentations to ensure they accurately reflected discussions that took place; these are also captured below. On the final day of the workshop the recommendations, as they are presented below, were reviewed by and agreed to by workshop participants.

Information Sharing

Facilitator: Paul Miller, Reporter: Sandra Schwartz

1. Investigate exchange mechanisms among risk assessors / interested communities on information gaps, experiences, etc.

a. trinational case study on the assessment of specific substances or group of substances
b. sharing of work among risk assessors in NA evaluating new and existing substances
c. need more biomonitoring
d. improve information exchange and training for large body of data already existing on pesticides among the RA community
e. promote government-based discussions/meetings on RA methods and policy implications
f. make projects available electronically - listserve for risk assessors to informally share information and pose technical questions - risk assessment summaries, reviews and the raw data could be made available within the RA community
g. collaboration with industry - industry needs to provide info in relation to risk - also needs to provide a remedy (obligation)
h. exchange lists of scientists working on specific chemicals - has been done between Canada and US - work sharing and exchange of personnel is useful
i. expand child health study in US to all 3 countries if we want valid NA information
j. need to evaluate the effectiveness of how we gather the data we use and how we conduct RA/RM- compare and contrast different situations (where we have good info and where we have lack of info)

2. Need to develop new, better, more targeted public outreach and community participation

a. curriculum materials / alternative modes of communication
b. children as advocates / educators
c. target affected communities such as farm workers' children in fields and "take home" exposure occupations, etc. / email-internet inadequate / need radio and TV
d. translation of materials into indigenous languages
e. information on alternatives
f. information exchange among NGOs, scientists, researchers, and government on community research, monitoring, prevention and alternatives
g. improve/expand upon labelling as information tool, but be aware of cultural differences in interpreting symbols (e.g. symbol of skull does not necessarily imply danger, but has positive meaning among some groups)
h. Taking Stock report as the model for comparative studies - with focus on how to get the info out to the communities who can use this info, such as targeted pamphlets to enhance public awareness on CEH issues
i. develop local promoters by using leaders from affected communities, farmworker groups, etc.; train personnel that have contact with people in communities; consider efforts already underway
j. Pesticide worker training - NAFTA technical working group on pesticides should receive recommendations from this workshop
k. Increase awareness among health professionals - increase number of PEHSUs - need to add CEH to family medicine curriculum
l. Finance solutions for sustainable agriculture
m. Trinational workshop among NGOs and scientists about community participatory research on children's health including implementation of pollution prevention and alternatives assessments of products and processes that create irreversible health effects and prevention of risk (not only focus on sound management of chemicals) - e.g. Breast milk contamination; hot spots remediation; pesticides substitution

Building Capacity

Facilitator: Chrisitna Cortinas, Reporter: Fernando Diaz-Barriga

1. **The development of a conceptual framework about risk assessment:** that allow a common understanding of its complexity and multiple dimensions, that makes clear that toxicology (in particular developmental toxicology) is an important component but requires the support of other disciplines.

2. **The formulation of a Science Policy**: to orient future efforts to develop the field in educative and research institutions, with the purpose of establishing short, medium and long term activities that lead to the formation of the specialized human resources required in the field and of the investigations that fill the gaps on the knowledge about the risks for children of environmental factors.

3. **The inclusion in the agenda of the Program on Children's Environmental Health of the consideration of other possible risk factors that could be relevant for Mexico**, such as the risks of microbial contamination of food or -in the case of Veracruz- the risks for children of nuclear energy production.

4. **The development and implementation of a basic training course to train risk assessors in this field**: that fill the needs of decision makers in the three countries, covers the themes considered relevant, involves the concept of "training the trainers" and the training of specialists in multiple disciplines and from different sectors, and could be developed with the support of well known academic institutions (ie. Harvard University, San Luis Potosí University/CINVESTAV), professional associations (ie. American Toxicology Society), governmental agencies (ie. the NAFTA Pesticides Technical Working Group, US EPA).

5. **The establishment of a visitors exchange programme**: through which specialists from different sectors from the three countries could stay for several weeks in one or the other taking part in ongoing children risk assessments.

6. **The development of a capacity building program oriented to the community**: that could benefit from the experience of Non Governmental Groups of the three countries on educating and promoting the participation of the communities in programs oriented to the protection of children's health.

7. **The strengthening of Mexican legislation to introduce requirements related to the development of risk assessments**: in order to promote the demand of experts and creation of institutional activities focused on the assessment of health and environmental risks, to support risk management decisions and risk communication.

8. **The development of a strategy to promote the application of risk assessment (in particular children's risk assessment) in industrial settings.**

Harmonization Of Risk Assessment Terminology and Concepts

Facilitator: Victor Shantora, Reporter: Irma Rosas

1. **Adopt a childhood risk assessment (CRA) model that identifies the process, with the components thereof and with the opinion of experts in the three countries.**

    a. Develop a glossary of CRA terms and concepts, clearly noting the difference between risk assessment and risk management.
    b. Identify the CRA triggers in each country: legal framework, citizen demand, site contamination, industry, and academia.
    c. Share these ideas with other CRA experts and professionals.

d. CRA undertaken in the United States and Canada may be used, provided that the necessary adjustments are assessed and incorporated in Mexico, given the differences in the local environment, bioavailability and population.
e. Assess the CRA models used in the United States (dosage-response, exposure, etc.) under different conditions (for example, in Canada and Mexico).
f. The potential importance of CRA in the context of health barriers to international trade has been mentioned.
g. Build an archive of CRA information, including databases (such as IRIS), tools for different stages in risk assessment, software programs (such as @risk). This archive could be a virtual library.
h. Release the PAHO document on exposure assessment.
i. Processes to harmonize the legal differences among the three countries should be taken into account.
j. Develop publications on this topic.

2. Información Sharing:

a. Creation of a mechanism to share information among expert CRA professionals. It could be a portal (e-room) or listserve for technical discussions and working documents (requiring membership with a user ID), facilitated by CEC.

3. Integovernmental Cooperation:

a. Include Mexico in the U.S.-Canadian experience in pesticide worksharing, in which industry submits information once to be assessed by the three countries in a joint, coordinated effort.
b. Mexican and Canadian participation in the U.S. Federal Advisory Committee is advisable.
c. The appropriateness of Mexican and U.S. participation in Canada's review of 23,000 substances on the market has been discussed.
d. It has been recommended to build Mexican and Canadian analytical capacities with intercalibrations, quality control, etc., for environmental and biological tracking. This may link with the study of the CEC Monitoring and Assessment Initiative and human resources development.
e. A case study workshop involving the three countries should be developed. We suggest that the first such workshops be on lead and pesticides, to respect Council Resolution 00-10.

4. Include the "Assessment of Alternatives" in the risk management process to assess the safer approach.

Plenary Discussion Period

It was also suggested that the CEC should compile the information sources that have been identified throughout the workshop into one place for easy reference. This could be part of an electronic reference center.

One participant commented that continued discussion is needed on risk assessment and possibly public participation and that discussion about risk management and risk communication are also required so perhaps two streams of recommendations should come out of this workshop.

Another participant made the clarification that while many of the recommendations are relevant to risk assessment in general, it should be clear that all the recommendations made are with respect to children's health risk assessment specifically.

With respect to building capacity, one participant emphasized the importance of building on existing processes and groups that have knowledge in the three countries.

One participant noted that when we refer to farm workers we need to remember that children's don't just live with these farm workers but also actually work in the fields.

One participant wanted to emphasise the request from NGOs to the CEC to facilitate ongoing exchange among NGOs, government, and academics to discuss experiences with community research and health and tools to strengthen community participation. Further discussion on alternatives is also needed including alternative behaviours, alternative process for evaluating risks and for evaluating alternatives.

Another participant noted the importance of how we determine acceptable risk, and to ensure we take into account the different susceptibilities of Mexican children vs. Canadian or US children.

One participant noted that the expected elevation of standards as a result of NAFTA has not occurred as expected. It is important that just as we have learned the need to distinguish children in risk assessment, we also need to distinguish between the children in the three countries, not only culturally but also metabolically.

One participant questioned why we shouldn't consider a paradigm shift towards having a large task force on alternatives assessment instead of just risk management, in doing so precaution needs higher role.

HOW RISK ASSESSMENT IS USED IN DECISION MAKING, TRANSPARENCY, AND RISK COMMUNICATION

This session will provide participants with the opportunity to examine the context within which risk assessments are used to inform decision-making, including the role of precaution, transparency, and risk communication. A short question period will follow each presentation, and a plenary discussion period will provide participants with the opportunity to ask questions and to share ideas.

Risk Assessment and the Precautionary Approach: How far should children's health be cradled?

David VanderZwaag, Mdiv, JD, LLM, PhD, Professor of Law, Dalhousie Law School

The role of the precautionary approach and risk assessment in protecting children's health is explored from three perspectives. First, the potentials of the precautionary approach to strongly cradle children's health are discussed. Core notions of precaution arising from the academic literature and often advocated by NGOs include: reversing the burden of proof to proponents of change; adopting a "reverse listing" approach to toxic substances and waste management; increasing transparency and public participation in decision making; and encouraging strict and absolute liability approaches whereby polluters will be pressured to prevent pollution. Second, the non-cradling legal and political realities are highlighted. The precautionary approach is being restricted in various ways including: general/weak versions of precaution adopted in diplomatic practice, such as the Rio Declaration on Environment and Development; lack of an effective global environmental governance framework; lack of global conventions in key areas such as heavy metals and land-based marine pollution; lack of comprehensive agreements / arrangements for addressing chemicals and biotechnology; aversions to precaution in international trade agreements, such as the Sanitary and Phytosanitary Measures Agreement, which may require import restrictions to be justified by risk assessment; and limited adoption of the precautionary approach at the regional level, for example, in the CEC's Sound Management of Chemicals project. Canada's mixed record of implementing the precautionary approach is also critiqued including limited embraces of the precautionary principle in the *Canadian Environmental Protection Act, 1999* and the new *Pest Control Products Act*. The presentation concludes by predicting future implementation of the precautionary approach will hardly be a "lullaby". Human value and socio-economic conflicts are not likely to abate and will continue to fuel divergent opinions over how precautionary regulators should be. Human rights arguments are likely to be increasingly raised to support strong versions of precaution, for example, the children's right to the highest attainable standard of health and indigenous rights, especially the right to environmental integrity. The legitimacy of traditional scientific risk assessment will also come under increased scrutiny with strong voices for giving alternatives assessment priority and for taking social science perspectives more seriously. Perhaps the biggest question of legitimacy will be: whose interests does risk assessment serve? Does risk assessment serve the interests of industry and free trade or does
risk assessment serve the interests of human health and environmental protection? Depending on how it is interpreted, the precautionary approach offers an answer.

Risk assessment implementation in Mexico, the path forward...
Alejandro Lorea Hernández, PhD, Environment, Safety and Hygiene Director, Asociacion Nacional de la Industria Quimica, A.C.

The Mexican chemicals industry has been using a risk assessment methodology for nearly 20 years. This has enabled us to assimilate its application and assess its potential as a decision-making tool.

However, at present it is necessary for this tool to be understood and used much more broadly, to attend to matters of national interest, such as the prevention of adverse effects of environmental agents on children's health. This does not mean that use of the methodology is reserved to the assessment stage of the possible effects of an agent once it is found in the environment. Rather, it should be applied as the first preventive measure in the assessment of chemicals, complemented with representative models of actual exposure conditions.

It is necessary to have a science-based focus as an essential factor in the drafting of laws and policies. We are certain that the exclusion or at least the systematic questioning of scientific evidence as a determining factor in the drafting of rules may lead to stagnation in business innovation and development. In this regard, we suggest a discussion and analysis of the "Precautionary Principle," enabling a common interpretation to guide the appropriate application thereof.

Likewise, in order to solidify the advantages and benefits of the risk assessment model, we propose a program that enables us to:

1. Establish/create the corresponding analysis model(s).
2. Determine the data and information needs.
3. Set priorities.

The tentatively proposed objective for the aforesaid program is to create a procedure allowing for the systematic establishment, review and updating of maximum allowable exposure limits.

NGO Perspective
Beatriz Barraza Roppe, Director of Health Promotion, Colaborativo SABER, Environmental Health Coalition

The important role of community in protecting children's health was discussed. The work of Collaborativo SABER and the Environmental Health Coalition was presented as a model for making use of the valuable attributes of communities to protect children's health. The program is a family centred, school based, and community supported program within the Latino community in San Diego California. The program focuses on recruiting, training, and retaining 'promotoras'. Promatoras are those who are best

indicated and nominated by the community; a person from who others will learn about behaviour change, for example, tobacco, nutrition, breast cancer, dental health. Work is also done in the area of curricula development, training, health education, and community advocacy for environmental justice. Individuals are also trained as community evaluators. Asset mapping is used to identify and work with the effective networks that already exist in the community.

At these types of workshops we should take the opportunity to look at other models and approaches. The community based approach and methodology discussed here is based in Latino culture and there are many lessons to be learned. The concept of community important traits was introduced and the reasons to involve community we emphasized: 1) they have the ability to efficiently and effectively communicate amongst themselves, 2) they have consensus building skills, and 3) they can organize and mobilize data or demographics collection. These traits make individuals from within affected communities the best placed researchers, partners and advocates those of us working for children's environmental health could wish for.

There is also a need to think about how we communicate with communities about risk and the vocabulary we use. Changing the words used will change what they hear and what communities can respond to. A complex presentation of science can create confusion and a lack of clarity this includes risk, hazard, danger, and "precaution". What we may want to communicate is the idea of caring first about children, families, and a sustainable future. Because community members naturally care about what happens next, the future- fore caring- they make ideal partners for children's health.

Commission for Environmental Cooperation Update on Precaution and Public Access to Information

Victor Shantora, Acting Executive Director, Commission for Environmental Cooperation

The following is a brief update on other relevant CEC initiatives that may be of interest to participants.

The Article 10(6) of the NAAEC mandates the Council of the CEC to cooperate with the NAFTA Free Trade Commission in order to achieve the environmental goals and objectives of NAFTA. A tri-partite group was created, called the 10(6) group, for which the CEC secretariat acts as a secretariat. The first product of the 10(6) group is a set of three papers on the use of precaution in the three countries and in international law, two of which have been cleared and published in Volume 10 of the Law and Policy Series. Follow-up steps include holding a workshop on the application of precaution in domestic regulations in the three countries. The workshop, tentatively entitles "Technical Regulator-to-Regulator Workshop: The Use of Precaution in Domestic Regulations in North America' is now tentatively scheduled for Fall 2003. Currently, the plans are to have a two-part workshop: one part will be an exchange among government officials working in this area, and the second part will be a public session. The CEC is working to ensure links are made between complementary events such as this workshop and the Fall workshop on precaution.

In addition, Volume 10 of the Law and Policy series also contains a new CEC report on access to government-held environmental information. This is a particularly important time with respect to information policy in North America. Mexico, Canada, and the United States are currently reviewing their ground rules on access to information. The Law and Policy series is available on the CEC website and can also be mailed to you on request.

Risk Assessment in the Canadian Context: Dioxins and Furans in Pulp and Paper Mill Effluent, A Case Study

Nicki Sims-Jones, RN, MScN, Office of Children's Environmental Health, Health Impacts Bureau, Health Canada

A Case Study On Moving From Risk Assessment To Risk Management - Dioxins And Furans. *Nicki Sims-Jones* RN, MScN, Health Canada; *Narmin Rahemtulla*, BSc, CPHI, Environment Canada

The case study will identify why dioxins and furans are important for children's health and describe how the Canadian Environmental Protection Act supports the reduction of these substances in the environment. Breastfeeding infants have the highest daily intakes of dioxins and furans and exposure early in life could have an impact on the developing nervous, immune and endocrine systems. Dioxins and furans were recognized as a hazard and assessed through the CEPA process in 1991. The findings of this risk assessment indicated they were highly persistent compounds with high potential for accumulating in the food chain and in humans. They were declared toxic under CEPA. Because they are persistent, bio-accumulative and result largely from human activity the goal of risk management was their virtual elimination. In 1991, major Canadian sources of dioxins and furans included pulp and papers mills, municipal incineration and pentachlorophenol. Pulp and paper mills were identified as a priority for risk management because of their significant emissions of dioxins and furans(many fisheries were closed due to contamination). A number of strategies were put into place which largely eliminated dioxins and furans from pulp and paper mill effluent allowing fisheries to be reopened. Other initiatives and international agreements will continue to reduce the amounts of these substances in the Canadian environment thereby reducing their potential to risk human health.

Risk Management and Risk Communication in COFEPRIS

Lic. Laura Jarque Alonso, Director of Risk Communication, Federal Commission for the Protection against Health Risks

This work presents a new methodological focus for risk communication, representing an anthropological view of risk analysis, assessment and management considering social, cultural, political and economic elements. One of the main objectives of risk communication is to prevent crises among the populace, establishing strategies and channels of communication that involve all players, including the affected population, in the development of solutions consistent with its needs.

The organizational restructuring of the Federal Commission for the Protection against Health Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios*—COFEPRIS) seeks to improve communication with the public with a risk communication strategy used from the analysis process through the health risk management stage, as well as in health emergencies.

This model generally describes the process to be followed under the risk communication strategy, with regard to the problem of lead contamination of children in pottery-producing areas in Mexico.

How Risk Assessment Is Used – U.S. Environmental Protection Agency
Brion Cook, Acting Division Director, Office of Pesticide Programs, U.S. EPA

EPA promotes public understanding of risks by providing understandable, accessible, and complete information on risks to the broadest audience possible. EPA promotes a safer environment through a combination of regulatory and voluntary efforts to round-out mutual goals in protecting children and the public's health. Like our scientific and regulatory processes, many of these initiatives also utilize public involvement and peer groups to give us necessary and adequate feedback. Risk assessment involves several components including, dose-response assessment, hazard identification and exposure assessment. The data collected from these components enable us to determine appropriate decisions to make regarding risk management.

Examples of how EPA manages chemicals that are a national risk can be seen in our lead-based paint, asbestos, PCB, and mercury programs. Risk assessment tools such as national data surveys and results from technical studies are presented to indicate a national environmental problem. From there, a combination of various risk management activities are undertaken. The activities may include regulatory controls, technical studies and research, federal agency coordination, and outreach.

The EPA Air Program accomplishes risk management through the use of regulatory programs (such as air quality index readings and national ambient air quality standards) and other related programs (such as the AIRNOW program).

For older pesticides and tolerance reassessments, risk assessments and risk management proposals and decisions are made available to the public through both a public repository (docket) and the EPA website (www.epa.gov/pesticides). The Agency actively seeks input to help refine risk assessments and to support its decision making. The Agency developed a six-phase public participation process for pesticides that contain older chemicals. This process facilitates and enhances transparency, and provides opportunities for broad public input on both risk assessment and risk-management.

EPA has a statutory mandate through the Food Quality Protection Act (FQPA), which established a single, health-based safety standard for new and existing pesticides and their residues in raw and processed food. In setting these residue tolerances, it requires an extra 10-fold safety factor "to take into account potential pre- and post-natal toxicity

and completeness of the data with respect to exposure and toxicity to infants and children" unless reliable data show that another factor may be used. EPA and the US Department of Agriculture (USDA) work together to implement FQPA. USDA plays a vital role by collecting improved data on foods consumed by infants and children as well as providing critical information to refine our preliminary risk assessments.

Plenary Discussion Period

With respect to comments that the CDC has put together panel to reconsider the definition of lead poisoning, one participant noted that in last six months there's been a trend to reject the public advisory committees recommendations for panel membership and rather representatives are appointed politically– such as professional experts from lead industry. There is a resulting concern that the outcomes of this panel will not necessarily protect children health.

One participant asked the USEPA if there are efforts to address concerns about mercury in vaccines. Brion Cook indicated that the EPA is doing work on mercury in products but they are not directly addressing the vaccine issue, the CDC would be the agency who would take a lead on this.

Nikki Sims-Jones was also asked about the availability of new dioxin and furans levels data for the North. She responded that the data is first being presented to community then will be available more broadly.

The USEPA was asked if through TOSCA anything can be done to prevent used building materials such as windows with lead paint being shipped and used in Mexico. Brion indicated that there are regulations under development that would ensure debris would go to land fill. This participant recommended that it be a recommendation from this workshop that there be trinational action to prevent this from happening.

Victor and Jose Carlos from the CEC discussed the role the SMOC program can play in facilitating trinational action on specific substances and reiterated that Lead is a substance that the three countries have expressed interest in developing a North American Regional Action Plan.

One participant commented that this workshop has provided much in the way of information on which to base advice to senior officials. This participant also shared a story that demonstrates the ability of to make a major impact with local action. In Canada, the municipality of Chelsea banned the cosmetic use of pesticides based on precaution and protecting the health of children. There were court challenges in Canada that went all the way to the Supreme Court where it was decided that the municipality had the right to protect the health of their children, that culture had changed in Canada to want more health protection. The decision noted that because Canada signed Rio including the precautionary principle, then municipalities could use it to make changes to bylaws.

One participant noted concern with the inclusion of cost-benefit analysis in risk assessment that often the costs and benefits are narrowly defined in favour of industry and not the communities.

One participant suggested that tobacco companies fund the conversion of plantations of tobacco to other crops and also finance the remediation of contaminated soil and water.

Another participant noted the importance of communicating the risks of asbestos to Mexican families because currently in some areas families are ending up consuming asbestos because it is used in fires when found in old buildings.

One participant commented that over the 3 days of the workshop we have all seen that in fact the three countries are not that different. We all have kids and aboriginals families that eat poisoned fish and live in polluted sights, who are exposed to lead at home and pesticides when they work, yet we had only 3 or 4 talks on how to tell the children about the risk. This participant recommended that the CEC host a workshop specifically on how to communicate risks to children.

One participant recommended that the CEC' Children's health team agenda address issues of food safety and risk communication particularly with respect to pesticides, antibiotics, hormones and transgenic foods especially for children's protection. This participant also recommended that this issue be addressed in the broader context of 'right to know' particularly in Mexico. Consumers should be given the right to choose with knowledge of the risks involved. In addition if a more detailed workshop on risk assessment takes place it should focus also on public access to the information used to conduct the risk assessment.

One participant offered thanks to the CEC for allowing their participation in the workshop and thanks to all the presenters. As a result of the last three days this participant felt very satisfied and armed with a much better understanding of risks to children. They recommended that these opportunities should continue and recommended that if there is to be a risk communication workshop it should also be done in a participatory manner. They noted the absence of the affected communities and feel they should also be included in future events.

One participant noted that there is an opportunity for the CEC to examine the practices of cost-benefit analysis and could generate recommendations of how to conduct CBA. This participant also commented that precaution must come before risk assessment to be precaution, otherwise it is simply risk management.

Another participant noted the importance of the tool of risk communication to take action rather than relying on a strictly regulatory approach.

WORKSHOP CONCLUSION

The workshop chair, Dr. John Buccini, led the final session of the workshop. The session began with a review of the workshop objectives. While participants agreed the objectives had been ambitious the group had gone a long way in achieving the objectives set out for the workshop. Significant learning and exchange had taken place and several practical recommendations for next steps had been generated. John Buccini and Victor Shantora of the CEC also expressed pleasure with the work that had taken place and commended presenters and participants.

The final session then proceeded with the presentation of recommendations based on the working session outcomes from day two. Participants then had the opportunity to discuss and confirm these recommendations, the proposed products of the workshop, and the proposed path forward. Thanks were offered from the floor to the Chair, the CEC, and the organizers.

Workshop Products

Participants agreed that the following should be produced and distributed to participants as a record of the workshop.

1. **WORKSHOP REPORT**
   This report is to include short summaries of presentations, summaries of plenary discussion periods including all interventions made by individuals (unattributed), the participant list with contact information and the working group recommendations as agreed to in the final session.

2. **WORKSHOP CDROM**
   This CD is to include copies of presentations made at the workshop, the background document prepared in advance of the workshop, and the workshop report. This CD will be sent to all workshop participants and will also be available to others by request. Its availability will be made known on the CEC website.

Path Forward

It was confirmed that the CEC Secretariat, led by the Children's Environmental Health Team would digest the report and recommendations from the workshop and make recommendations to ministers for CEC led follow up activities. It was also confirmed that in doing so this group would work with SMOC and the NAFTA TWG on Pesticides to ensure links are made where appropriate.

It was also noted that many practical recommendations made during the workshop could be taken on my individual organizations and many not necessarily require the CEC to take the lead. An important outcome of the workshop was to open lines of communication to facilitate collaboration and the exchange of information and ideas on

how to improve the ways we protect children from environmental risks. Participants are encouraged to continue the dialogue launched at this workshop.

APPENDIX 1 – AGENDA

North American
Commission for Environmental Cooperation

NAFTA
Technical Working Group on Pesticides

NORTH AMERICAN WORKSHOP ON RISK ASSESSMENT AND CHILDREN'S ENVIRONMENTAL HEALTH

19-21 February 2003
Hotel Fortin Plaza
Oaxaca, Mexico

AGENDA

WEDNESDAY 19 FEBRUARY

8:00-8:45 REGISTRATION

9:00-10:10 SETTING THE STAGE

9:00 Welcome
Victor Shantora, Acting Executive Director, Commission for Environmental Cooperation

9:20 Keynote Address: Assessing the Risk to Children's Health from Chemical Environmental Toxins
Irena Buka, MB, ChB, DCH, FRCPC, Associate Clinical Professor of Pediatrics
Chair, Expert Advisory Board on Children's Health and the Environment in North America

9:50 What is Risk Assessment?
John Buccini, PhD, Consultant, Workshop Chair

10:10-5:30 WHERE ARE WE NOW
This session will provide participants with the opportunity to learn about the current situation and current practices with respect to children's environmental health and risk assessment in North America. A short question period will follow each presentation.

10:10 The Use of Risk Assessment in COFEPRIS
Dra. Leonor Cedillo Becerril, Directora Ejecutiva, Comision Federal para la Proteccion Contra Riesgos Sanitarios

11:10 Break

11:40 Canadian Approaches to Health Risk Assessment of Chemicals in the Environment: Industrial Chemicals And Pesticides
Anthony W. Myres, PhD, Environment Contaminants Bureau, Health Canada
Christine Norman, MSc, Pest Management Regulatory Agency (PMRA), Health Canada

12:40 Lunch

1:40 Children's Environmental Risk Assessment - U.S. Environmental Protection Agency
Gary Kimmel, PhD, Developmental Toxicologist, Office of Research and Development, U.S. EPA
Jennifer Seed, PhD, Branch Chief, Office of Pollution Prevention and Toxics, U.S. EPA
Elizabeth Doyle, Branch Chief, Office of Pesticide Programs, U.S. EPA

2:40 Policy Interpretation Network on Children's Health and Environment
Moniek Zuurbier, MSc, Public Health Services Gelderland Midden, The Netherlands

3:00 Evaluating Potential Risks to Children's Health: Tiered Toxicity Testing & Risk Assessment of Industrial Chemicals
Richard A. Becker, PhD, DABT, Toxicologist & Senior Director, Public Health Team, American Chemistry Council

3:20 The Scientific and Ethical Challenges of Risk Assessment - An NGO Perspective
Kathleen Cooper, Researcher, Canadian Environmental Law Association

3:40 Break

4:10 Plenary Discussion Period
The plenary discussion period will provide participants with the opportunity to ask questions and to share ideas. A panel composed of the session speakers will be available for questions and to participate in the topics for discussion including: strengths and weaknesses of current use of risk assessment, similarities and differences in country approaches, and opportunities for collaboration.

6:00-7:00 COCKTAIL RECEPTION (Hosted by the CEC)

THURSDAY 20 FEBRUARY

8:30-9:00 REGISTRATION

9:00-10:40 NEW DEVELOPMENTS IN RISK ASSESSMENT: EMERGING SCIENCE, ISSUES, AND CHALLENGES

This session will provide the opportunity for participants to learn about new developments in the field of risk assessment and children's environmental health. A short question period will follow each presentation.

9:00 Exposure Assessment
Richard J. Jackson, MD, MPH, Director, National Centre for Environmental Health

9:15 Effects Assessment
Miriam Levitt, PhD, Vice President of Research, Policy and Programs, Canadian Institute of Child Health

9:30 Current Research for Children's Health Risk Assessment
Gail Charnley, PhD, Health Risk Strategies

9:45 Reducing Risks to Children Near Contaminated Sites in Mexico
Fernando Diaz-Barriga, PhD, Coordinador de Toxicologia Ambiental, Universidad Autonoma de San Luis Potosi

10:00 Plenary Discussion Period

10:30 Break

10:45-12:30 WHERE DO WE WANT TO GO FROM HERE

This session will allow participants to look forward and begin to examine where we want to go. Government, academic, industry, and non-government speakers will present their perspectives on emerging developments, future plans, opportunities for collaboration, and recommended focus for a path forward. A short question period will follow each presentation.

10:45 Developments in Risk Assessment- Children's Health
Anthony Myres, PhD, Environment Contaminants Bureau, Health Canada

11:00 How Are We Going to Improve the Use of Risk Assessment in COFEPRIS
Dra. Leonora Rojas Bracho, Directora Ejecutiva, Comision Federal para la Proteccion Contra Riesgos Sanitarios

11:15 Where Do We Go From Here - U.S. Environmental Protection Agency
Joanne Rodman, Acting Office Director, Office of Children's Health Promotion, U.S. EPA

11:30 Academic Vision of Risk Assessment: Present and Future
Dr. Irma Rosas, Coordinadora de PUMA, Universidad Nacional Autonoma de Mexico

11:45 Current Research and Best Approaches for Childhood Risk Assessment
George P. Daston, Ph.D, Research Fellow, Miami Valley Laboratories, Procter & Gamble

12:00 Where Do We Go From Here – An NGO Perspective
Renee Louise Robin, J.D., California Director, Children's Environmental Health Network

12:15 Plenary Discussion Period

12:45 Lunch

1:45-5:30 OPPORTUNTITIES FOR COLLABORATION WORKING SESSION

This working session will be an important part of the workshop where participants can build on the learning and sharing of information from the first two days, and work in groups to identify concrete recommendations for a path forward. There will be three concurrent break-out groups addressing the following areas for proposed North American cooperation:

1. ***Information Sharing***
   Share information on data sources, methodologies, and new developments
   Determine a path forward to document information sources
   Explore improved information exchange mechanisms
   More…

2. ***Building Capacity***
   Develop a skills profile for children's environmental health risk assessment
   Determine how more risk assessors can be trained
   Explore opportunities for staff exchanges
   More…

3. ***Harmonization Of Risk Assessment Terminology and Concepts***
   Explore the development of common language or an index of terminology
   Determine a path forward to document the different approaches to children's environmental health risk assessment
   More…

Participants will then be given the opportunity to present and discuss in plenary the results of the break-out working groups. As an outcome of this session, participants will be expected to develop clear recommendations for a path forward on North American cooperation on children's environmental health and risk assessment.

1:45 Work in Break-Out Groups

4:45 Report to Plenary and Discussion

5:30 End of Day

FRIDAY 21 FEBRUARY

8:30-9:00 REGISTRATION

9:00-11:45 HOW RISK ASSESSMENT IS USED IN DECISION MAKING, TRANSPARENCY, AND RISK COMMUNICATION

This session will provide participants with the opportunity to examine the context within which risk assessments are used to inform decision-making, including the role of precaution, transparency, and risk communication. A short question period will follow each presentation, and a plenary discussion period will provide participants with the opportunity to ask questions and to share ideas.

9:00 Risk Assessment and the Precautionary Approach: How far should children's health be cradled?
David VanderZwaag, Mdiv, JD, LLM, PhD, Professor of Law, Dalhousie Law School

9:20 Risk assessment implementation in Mexico, the path forward...
Alejandro Lorea, PhD, Environment, Safety and Hygiene Director, Asociacion Nacional de la Industria Quimica, A.C.

9:40 NGO Perspective
Beatriz Barraza Roppe, Director of Health Promotion, Colaborativo SABER, Environmental Health Coalition

10:00 Commission for Environmental Cooperation Update on Precaution
Victor Shantora, Acting Executive Director, Commission for Environmental Cooperation

10:10 Break

10:30 Risk Assessment in the Canadian Context: Dioxins and Furans in Pulp and Paper Mill Effluent, A Case Study
Nicki Sims-Jones, RN, MScN, Office of Children's Environmental Health, Health Impacts Bureau, Health Canada

10:50 Risk Management and Risk Communication in COFEPRIS
Lic. Laura Jarque Alonso, Directora de Comunicación de Riesgos, Comision Federal para la Proteccion Contra Riesgos Sanitarios

11:10 How Risk Assessment Is Used - U.S. Environmental Protection Agency
Brion Cook, Acting Division Director, Office of Prevention, Pesticides, and Toxic Substances U.S. EPA

11:30 Plenary Discussion Period

12:00-1:00 WORKSHOP CONCLUSION
The final session of the workshop will pull together the workshop outcomes and confirm a recommended path forward for collaborative North American activities. The session will begin with the presentation of draft recommendations based on the working session outcomes from day two and other workshop discussions. Participants will have the opportunity to discuss and confirm a set of workshop conclusions and recommendations for publication in the workshop report.

12:00 Plenary Discussion Period: Workshop Conclusions and Recommendations
Dr. John Buccini, Workshop Chair

12:50 Closing
Victor Shantora, Acting Executive Director, Commission for Environmental Cooperation

APPENDIX 2 – BREAKOUT SESSIONS

Working Session # 1: Information Sharing

This working session will focus on opportunities for sharing of data sources, methodologies and new developments among the three North American countries in support of child health risk assessment and risk management decision-making. The proposed focus of the discussion is on:

- Existing sources of data/information and opportunities for sharing
- Opportunities for sharing methods, emerging developments
- New sources of data/information that could be tapped into
- Mechanisms for information exchange, including means for improving the flow of information among the three countries as well as between the health and environment sectors

Risk assessors draw upon a range of information sources, including toxicological profiles, laboratory test data, exposure information, etc. This session will be a chance to review how and to what extent these types of data are being shared among risk assessors in the three countries, and opportunities for improvement. Enhanced information exchange between the health and environment sectors can also foster mutually beneficial improvements in risk assessment approaches, particularly with respect to methods for incorporating children's health concerns and vulnerabilities into risk assessment. This workshop is an initial step towards fostering trilateral exchange of data and methods. What are possible mechanisms that could be put into place to ensure ongoing interaction?

There may also be opportunities to draw upon additional data sources that could contribute to an understanding of the links between chemicals/pesticides and potential health impacts. Such data sources could include, for example, biomonitoring data, health surveillance data, information gained through longitudinal cohort studies (i.e. long-term epidemiological studies that follow a population over time, tracking both exposures and health outcomes), wildlife surveillance data, etc. The working group will have a chance to discuss some of these data sources and their potential relevance, and identify ways in which they might be channeled into risk assessment and/or risk management decision-making processes.

Another aspect of information sharing is making information available to interested parties, including the public. With better access to information, members of the public (parents, community leaders, healthcare professionals, etc.) are better equipped to take informed decisions to protect children's health, and are also more able to effectively participate in risk management decision-making processes. The working group may wish to address this question, with a view to identifying possible 'best practices' for providing public access to information that is used as inputs into risk assessment and risk management decision-making processes.

Suggested questions for discussion:

- To what degree is information (data sources, methodologies, new developments) being shared among the three North American countries? Between those concerned with health and those concerned with environmental protection? With the public?
- What are the strengths, weaknesses and challenges in this regard?
- What are some possible mechanisms for improving information exchange/access and for ensuring that it continues on an ongoing basis?

- If you had to recommend one activity to be taken within the next year to improve North American cooperation on this issue, what would it be? Who would need to be involved? What types of resources would be required?
- What are the 2-3 activities that you would recommend be taken within the next 3-5 years?

Working Session # 2: Building Capacity

A variety of capacities are needed at the country level to be able to effectively conduct risk assessment and risk management decision-making. The focus of this working session will be to identify gaps in existing capacities in North America, and potential means for addressing them through trilateral collaboration.

The CEC's *Cooperative Agenda for Children´s Health and the Environment in North America* establishes that there is currently a shortage of people with training in children´s environmental health risk assessment, limiting the capacity of governments to assess potential risks to children posed by chemicals, including pesticides. Mexico, in particular, has identified this as a priority need and has initiated a program of risk assessment training. Trilateral collaboration could help support the inclusion of a children's health focus within this ongoing training.

In addition to trained risk assessors, other types of capacities needed to support risk assessment and risk management decision-making include, for example: capacities for data gathering and interpretation; a sufficient supply of trained toxicologists and other experts whose work contributes to risk assessment; access to information on emerging methodologies and new developments, and the capacity to incorporate these into existing procedures; capacities for conducting exposure assessment; public awareness and access to information, to enable effective participation in decision-making processes; capacities in the healthcare sector to identify problems potentially associated with chemical/pesticide exposure, etc.

Suggested questions for discussion:

- What do you see as the priority needs for capacity building in your country? In North America?
- Are there resources (e.g. human resources, information, knowledge) that could be shared among the three countries to help overcome some of the existing gaps?
- What profile of skills is needed for children´s environmental health risk assessment?
- What steps could be taken to build these skills and expand the cadre of children's environmental health risk assessors? (e.g., staff exchanges, university training programs, development of relevant courses at universities and other training institutions, cross-border collaboration between universities, etc.)
- If you had to recommend one activity to be taken within the next year to improve North American cooperation on this issue, what would it be? Who would need to be involved? What types of resources would be required?
- What are the 2-3 activities that you would recommend be taken within the next 3-5 years?

Working Session # 3:
Harmonization of Risk Assessment Terminology and Concepts

This working session will focus on opportunities for harmonizing risk assessment terminology and concepts among the three North American countries in support of child health risk assessment and risk management decision-making. The objectives of the session are to:

1. Determine how we can best capture and document the learning that is taking place at this workshop (beyond the workshop report)
2. Find ways to enable the three countries to communicate more effectively by either creating a common language, or facilitating a mutual understanding of how each country 'talks' about risk assessment.

The group may also wish to address the question of how risk assessment information is presented to the public, with a view to exploring means of communicating in a common and easy to understand manner.

A common understanding of risk assessment terms and approaches among the three countries is a prerequisite for effective collaboration and sharing of information and results to ensure that children's vulnerabilities are taken into consideration when assessing risks. A common understanding terminology and concepts will facilitate the sharing of work, expertise, information and ideas, while maintaining the capacity and flexibility of governments to take their own decisions based on the analyses and in light of national/local circumstances.

Previous workshops and meetings on this topic have identified the lack of a shared understanding of the terminology being used to talk about the environmental health risk assessment for children. This has resulted in communication challenges. This workshop is a critical step in developing a common understanding of approaches and terminologies used in the three countries. However, it is only a first step.

Suggested questions for discussion:

- To what degree does the terminology and concepts of environmental health risk assessment differ among the three North American countries?
- What are the strengths, weaknesses and challenges in this regard?
- What are some possible mechanisms for documenting the learning that is taking place at the workshop and ensuring that it continues on an ongoing basis?
- What are some possible mechanisms for improving harmonization of terminology or a common understanding of terminology and ensuring that it continues on an ongoing basis? (i.e. glossary or dictionary or harmonized terms, or a glossary or dictionary to document how the different countries use different terms)
- If you had to recommend one activity to be taken within the next year to improve North American cooperation on this issue, what would it be? Who would need to be involved? What types of resources would be required?
- What are the 2-3 activities that you would recommend be taken within the next 3-5 years?

APPENDIX 3 – LIST OF PARTICIPANTS

NORTH AMERICAN WORKSHOP ON RISK ASSESSMENT AND CHILDREN'S ENVIRONMENTAL HEALTH

TALLER DE AMÉRICA DEL NORTE SOBRE EVALUACIÓN DE RIESGOS Y SALUD AMBIENTAL DE LA INFANCIA

Oaxaca, Oaxaca, México
19-21 February 2003

Liste finale des participants / Final List of Participants / Lista final de participantes

SVP veuillez informer le Secrétariat de toute erreur ou omission
Please inform the Secretariat of any mistake or missing name
Favor de informar al Secretariado de cualquier error u omisión

Canada

Annie Bérubé
Policy Analyst - Children Env. Health
Environment Canada
10 Wellington St. 22 Floor Rm. 2229
Hull (Québec)
Canada K1A 0H3
T: (819) 994-1657
F: (819) 953-4679
annie.berube@ec.gc.ca

Irena Buka
Paediatric Environmental Health
Specialty Unit,
3 West Child Health Clinic
16940 87th Avenue
Canada T5R 4H5
T: (780) 930-5942
F: (780) 930-5794
ibuka@cha.ab.ca

Bruce Caswell
Senior Manager, Environment,
Health and Safety – Canadian
Chemical Producers' Association
Suite 805, 350 Sparks St.
Ottawa (Ontario)
Canada K0A 1K0
T: (613) 237-6215 ext 241
F: (613) 237-4061
bcaswell@ccpa.ca

Julie Charbonneau
Policy Manager
Health and Environment
Environment Canada
10 Wellington St. 22 Floor
Hull (Québec)
Canada K1A 0H3
T: (819) 953-3392
F: (819) 953-7632
julie.charbonneau@ec.gc.ca

Kathleen Cooper
Researcher
Canadian Environmental
Law Association
301 - 130 Spadina Ave.
Toronto (Ontario)
Canada M5V 2L4
T: (416) 960-2284
F: (416) 960-9392
kcooper@cela.ca

Jim Houston
Environmental & Informatics Adviser
International Joint Commission
234 Laurier Ave. West, 22nd floor
Ottawa (Ontario)
Canada K1P 6K6
T: (613) 995-2984
F: (613) 993-5583
houstonj@ottawa.ijc.org

Miriam Levitt
Vice President of Research
Policy and Programs
Canadian Institute of Child Health
384 Bank Street, Suite 300
Ottawa (Ontario)
Canada K2P 1Y4
T: (613) 230-8838 ext 232
F: (613) 230-6654
mlevitt@cich.ca

Anthony Myres
Special Advisor
Environmental Contaminants
Health Canada
Ottawa (Ontario)
Canada K1A 0L2
T: (613) 954-1759
F: (613) 952-9798
tony_myres@hc-sc.gc.ca

Christine Norman
Head, Occupational Exposure
Assessment Section
Health Canada - Pest-Management
Regulatory Agency
2720 Riverside Dr. AL 6606DI
Ottawa (Ontario)
Canada K1A 0K9
T: (613) 736-3472
F: (613) 736-3489
cnorman@hc-sc.gc.ca

Jean Perras
Chair – National Advisory
Committee - Canada
3, Chemin des Castors
Chelsea (Québec)
Canada J9B 1B8
T: (819) 827-5036
leblanc.perras@videotron.ca

Sandra Schwartz
Director, Toxic Substances Program
Pollution Probe
63 Sparks St. Suite 101
Ottawa (Ontario)
Canada K1P 5ª6
T: (613) 237-3485
F: (613) 237-6111
sschwartz@pollutionprobe.org

Nicki Sims-Jones
Senior Policy Analyst
Health Canada
AL 6604 Sir Charles Tupper Bldg.
2720 Riverside Dr.
Ottawa (Ontario)
Canada K1A 0K9
T: (613) 948-2589
F: (613) 957-1886
nicki_sims-jones@hc-sc.gc.ca

Mary Ellen Starodub
Toxicology Consultant
Human Health and Environmental
4-1011 White Oak Drive
Toronto (Ontario)
Canada L7T 2L3
T: (905) 632-3313
F: (905) 632-1515
mestarodub@cogeco.ca

Anna Tilman
Chair
Storm Coalition
7 Whitefield Ct.
Aurora (Ontario)
Canada L4G 5L8
T: (905) 713-0562
annatilman@sympatico.ca

David VanderZwaag
Professor of Law
Dalhousie Law School
6061 University Ave.
Halifax (Nova Scotia)
Canada B8H 4H9
T: (902) 494-1045
F: (902) 494-1316
david.vanderzwaag@dal.ca

Frank Wandelmaier
Senior Science Policy Advisor
Pest Management Regulatory Agency
D749 Sir Charles Tupper Building
2720 riverside Drive
Ottawa (Ontario)
Canada K1A 0K9
T: (613) 736-3668
F: (613) 736-3659
frank_wandelmaier@hc-sc.gc.ca

Sol Wandelmaier
Medical Doctor
Independente
50 MacMabb
Ottawa, ON
Canada
T: (613) 744-5804
E: swandelm@cyberus.ca

UNITED STATES

Martha Berger
Director, International Affairs
U.S. EPA
Office of Children's Health Protection
1200 Pennsylvania Ave. NW
2512 Ariel Rios North
Washington DC
USA 20460
T: (202) 564-2191
F: (202) 564-2733
berger.martha@epa.gov

Brion Cook
Director
National Program Chemicals Division
U.S. EPA
1200 Pennsylvania Ave. NW
Washington DC
USA 20460
T: (202) 566-1970
F: (202) 566-0471
cook.brion@epa.gov

George Daston
Research Fellow
Procter & Gamble
Po Box 538707
11810 E. Miami River Rd.
Cincinnati, Ohio
USA 45253
T: (513) 627-2886
F: (513) 627-0323
daston.gp@pg.com

Brenda Foos
Toxicologist
U.S. EPA
1200 Pennsylvania Ave. NW
Washington DC
USA 20460
T: (202) 564-2707
F: (202) 564-2788
foos.brenda@epa.gov

Adam Goldberg
Policy Analyst
Consumers Union
1666 Connecticut Ave. Suite 310
Washington DC
USA 20009
T: (202) 462-6262
F: (202) 265-9548
goldad@consumer.org

Larry Lowry
Co-Director, South West Center
for Pediatric Environmental Health
The University of Texas Health Ctr.
11937 US Highway 271
Tyler, Texas
USA 75708-3154
T: (903) 877-5717
F: (903) 877-7982
larry.lowry@uthct.edu

Parastoo Anita Mesri
Investigadora
Facultad de Derecho
de la Universidad de Georgetown
1807 326th St. NW
Washington DC
USA 20007
parastooanita@hotmail.com

Michael Metzger
Branch Chief
U.S. EPA
1200 Pennsylvania Ave. NW
Washington DC
USA 20460
T: (703) 305-5883
F: (703) 305-5147
metzger.michael@epa.gov

Mark Miller
MD, MPH
University of California San Francisco
1640 Bidwell Ave.
Chico, California
USA 95926
T: (510) 622-3159
F: (530) 894-8296
mmiller@oehha.ca.gov

Thomas Natan
Research Director
National Environmental Trust
1200 18th St. NW 5th Floor
Washington DC
USA 20036
T: (202) 887-8828
F: (202) 887-8877
tnatan@environet.org

James Quackenboss
Scientist
U.S. EPA
944 East Harmon
Las Vegas, Nevada
USA 89119
T: (702) 798-2642
F: (702) 798-2261
quackenboss.james@epa.gov

Joanne Rodman
Acting Office Director
U.S. EPA
Office of Children's Health Protection
1200 Pennsylvania Ave. NW
Washington DC
USA 20460
T: (202) 564-2188
F: (202) 564-2733
rodman.joanne@epa.gov

Virginia Ruíz
Attorney
Farmworker Justice Fund Inc.
1010 Vermont Ave. NW #915
Washington DC
USA 20005
T: (202) 783-2628
F: (202) 783-2561
vruiz@nclr.org

Angel Valencia
Representante de CITI
Y Fundación Tekia
Consejo Internacional
de Tratados Indios
456 N. Alaska St.
Palmer, Alaska
USA 99645
T: (907) 745-4474
F: (907) 745-4484
iitcak@ak.net

Renée Louise Robin
California Director
Children's Environmental Health
Network
1604 Solano Ave.
Berkley, California
USA 94707
T: (510) 526-0081
F: (510) 526-3672
rlrobin@cehn.org

Beatriz Roppe
Director of Health Promotion
Colaborativo SABER
4581 Adair Street
San Diego, California
USA 92107
T: (619) 225-8247
F: (619) 225-8045
bearoppe@pacbell.net

Jennifer Sass
Senior Scientist
Natural Resources Defense Council
1200 New York Avenue, NW, Suite 400
Washington, DC
USA
T: (202) 289-2362
F: (202) 289-1060
jsass@nrdc.org

MÉXICO

Indra Angel Guggenbuehl
Colectivo Ecolojista Jalisco
Ley 2985 Departamento 1
Residencial Juan Manuel
Guadalajara, Jalisco 44680
México
T: 011 52 333 615 0948
F: 011 52 333 684 7749
iangel_2001@yahoo.com

Fernando Bejarano
Coordinador
RAPAM (Pesticide Action Network, Mexico)
Amado Nuevo 23-2
Col. San Juanito, Texcoco
Estado de México 56121, México
T: 011 52 595 954 7744
F: 011 52 595 954 7744
rapam@prodigy.net.mx

Adolfo Bolaños Stanley
Jefe Departamento
COFEPRIS
Monterrey 33 Noveno Piso Col. Roma
México DF 06700
México
T: 011 52 555 514 8582
F: 011 52 555 514 8574
adbos22@salud.gob.mx

Mariano Cebrian
Head of the Section
CINVESTAV – IPN
Ave. IPN #2508
Col. San Pedro Zacatenco
México DF 07360, México
T: 011 525 95 954 7744
F: 011 52 555 747 7111
mcebrian@mail.cinvestav.mx

Leonor Cedillo Becerril
Directora Ejecutiva
Comision Federal para la Proteccion
Contra Riesgos Sanitarios
Monterrey #33 Col. Roma
México DF 06700, México
T: 011 52 555 514 8574
F: 011 52 555 514 8574
lcedillo@mail.ssa.gob.mx

María Cristina Cortinas de Nava
Asesora
Grupo Parlamentario del Partido Verde
Ecologista de México
Mar de la Tranquilidad 36 Edif. 1-204
México DF 04899
México
T: 011 52 555 673 8525
ccortinasd@yahoo.com.mx

Nidia Coyote Estrada
Subdirectora
COFEPRIS
Monterrey 33 Noveno Piso Col. Roma
México DF 06700
México
T: 011 52 555 514 8582
F: 011 52 555 514 8574
nidiacoyote@hotmail.com

Fernando Díaz-Barriga
Coordinador - Toxicología Ambiental
Universidad Autónoma
De San Luis Potosí
Av. Venustriano Carranza No. 2405
San Luis Potosí, San Luis Potosí
México 78210
T: 011 52 444 826 2354
F: 011 52 444 826 2354
fdia@uaslp.mx

Patricia Díaz-Romo
Coordinadora de proyecto
Proyecto Huicholes y Plaguicidas - Asociación
Mexicana de Arte y Cultura Popular
Apartado Postal 1156
Oaxaca Oaxaca 68000
México
T: 011 52 951 514 2901
huicholesyplaguicidas@hotmail.com

Gonzalo G. García Vargas
Jefe, Departamento de Toxicología
Universidad Autónoma de Coahuila
Gregorio García 198 Sur
Torreón, Coahuila 27000
México
T: 011 52 871 717 6404
F: 011 52 871 717 6404
Ggarcia_vargas@hotmail.com

Roció González
Subdirectora del Programa
Hospital Saludable
División GRA/TE Equidad
Av. José Vasconceles 221
Col. San Miguel Chupultepec
Delegación Miguel Hidalgo
México DF, 11850
México
T: 011 52 555 211 7538/7788
F: 011 52 555 553 0583
Rocio_go@yahoo.com

Inocencio Higuiera-Ciapara
Investigador
CIAD, A.C.
Kmtro.0.6 Carr. a la Victoria
Hermosillo Sonora 83000
México
T: 011 52 662 289 2400
F: 011 52 662 289 2400
higuera@cascabel.ciad.mx

Irina Ize Lema
Subdirectora de Investigación para
La Evaluación de Riesgos Ambientales
Instituto Nacional de Ecología
Periférico Sur #5000 piso 4
México DF 04530
México
T: 011 52 555 424 5402
F: 011 52 555 424 5402
arize@ine.gob.mx

Laura Jarque Alonso
Directora de Comunicación
De Riesgos
COFEPRIS
Monterrey 33
México DF 06700
México
T: 011 52 555 514 8587
laujarque@yahoo.com

Alejandro Lorea
Environment, Safety
and Hygiene Director
Asociación Nacional
De la Industria Química, A.C.
Providencia 1118
México DF 03100
México
T: 011 52 555 230 5100
F: 011 52 555 559 2208
alorea@aniq.org.mx

Andrea Márquez Guzmán
Coordinación
Red por los Derechos de la Infancia
En México
Av. México Coyoacan No. 350
Col. General Anaya
México DF 03340
México
T: 011 52 555 604 2458
F: 011 52 555 604 2466
amarquez@derechosinfancia.org.mx

Adelaida Martínez Chapa
Gerente de Estudios y Evaluación
COFEPRIS
Monterrey 33
México DF 06700
México
T: 011 52 555 514 8587
laujarque@yahoo.com

Regina Montero Montoya
Investigador Titular "A"
Inst. Investigaciones Biomédicas, UNAM
Circuito Interiod de Cd. Universitaria
México DF., 70228
México
T: 011 52 555 622 3158
F: 011 52 555 550 0048
dorinda@servidor.unam.mx

Delia Namihira Guerrero
Coordinadora de Investigación
Centro de Especialidades Médicas
Del Estado de Veracruz – CEMEV
Campo Nuevo 30
Lomas Altas
Xalapa, Veracruz
Mexico
T: 011 52 228 812 7614
F: 011 52 228 814 4551
Delian3@yahoo.com

MA. Ines J. Navarro Gonzalez
Jefe de Proyecto
Instituto de Ingenieria, UNAM
CD. Universitaria Coyoacán
México DF, 04510
México
T: 011 52 555 622 3320, x12
F: 011 52 555 616 2798
ing@pumas.iingen.unam.mx

Jaime Fernando Navia Atezana
Presidente
Grupo Interdisciplinario
De Tecnología Rural Mapropriada
CC El Parian Local 17
Patzcuaro Michoacan 61609, México
T: 011 52 434 342 6216
F: 011 52 434 342 3216
direccion@gira.org.mx

Silvia Neydar Vazquez
Verificador
Secretaría de Salud
Monterrey No. 33
Esquina Calle Oaxaca
México DF 06700
T: 011 52 555 514 8573
F: 011 52 555 514 8574
lroiasbr@mail.ssa.gob.mx

Monica Olvera
Gerente General
Asociación Mexicana de la
Industria Fitosanitaria
Tintoreto 32 Edif. A Despacho 2
Col. Nochebuena Mixcoac
México DF 03720
México
T: 011 52 555 598 9095
molvera@amifac.org.mx

Alvaro Roman Osornio Vargas
Jefe del Departamento de Salud
y Ambiente del PUMA
Universidad Nacional Autónoma
De México – Cto. De la Investigación
Cientifica, C.U.
México DF 04510
México
T: 011 52 555 622 5212
F: 011 52 555 622 5207
arov@servidor.unam.mx

Silvia Victoria Ramírez
Gerente de Alimentes
SSA/DGSA
Monterrey 33, Col. Roma
México DF
México
T: 011 52 555 514 8575

Matiana Ramírez Aguilar
Investigador Asociado
Instituto Nacioanal de Salud Pública
Refineria Azcapotzalco 17
Col. Reynosa T. Azcapotzalco
México DF 02200, México
T: 011 52 555 556 4224 ext 109
F: 011 52 777 311 1148
jminclan@prodigy.net.mx

Leonora Rojas Bracho
Directora Ejecutiva
Comision Federal para la Proteccion
Contra Riesgos Sanitarios
Monterrey #33 Col. Roma
México DF 06700, México
T: 011 52 555 514 8574
F: 011 52 555 514 8574
lrojasbr@mail.ssa.gob.mx

Irma Rosas Pérez
Coordinadora de PUMA
UNAM - Cto. De la Investigación
Cientifica, C.U.
México DF 04510
México
T: 011 52 555 622 5212
F: 011 52 555 622 5207
puma@servidor.unam.mx

Guadalupe Salas
Coordinador de Asustos Regulatorios
SYNGENTA AGRO, S.A. de C.V.
Calzada de Tlalpan 3058
Col. Santa Ursula Coapa
México DF 04850
México
T: 011 52 555 422 6261
F: 011 52 555 679 3959
guadalupe.salas@syngenta.com

Samuel Salinas Alvarez
Coordinador de investigación
Proyecto Huicholes y Plaguicidas
Chipancingo 5-112
Col. Hipodromo Condesa
México DF 06140
México
T: 011 52 555 566 1902
F: 011 52 555 584 1308
samsalal@prodigy.net.mx

Samuel Salvador Ortiz
Asesor Legal
Pueblo Huitchol
Universidad de Guadalajara
Mutualismo 1192
Col. Gusa
Zapopan, Jalisco
T: 011 52 553 861 2654/826 7946
F: 011 52 553 826 7946
wixarika@yahoo.com.mx

Tayra Pérez Sandi
Huicholes y Pleguicidad
20 Agosto 53 – 15
San Diego Churubusco
Coyoacán 04120
México
T: 011 52 555 545 0888
rayma@internet.com.mx

María Elena Silva Lojero
Directora – Instituto Internacional
De Seguridad de Riesgo
Calle Culiacán 79, 2° piso
Col. Condesa
México DF 06140
México
T: 011 52 555 265 1303
mslojero@gnp.com.mx

Gabriela Valdés Herrera
Gerente de Criterios Sanitarios
COFEPRIS
Monterrey 33 Noveno Piso Col. Roma
México DF 06700
México
T: 011 52 555 514 8582
F: 011 52 555 514 8574
gabyvaldes@salud.gob.mx

Victor Manuel Torres Meza
Subdirector
COFEPRIS – SSA
Monterrey 33 Colonia Roma
México DF 06900
México
T: 011 52 555 514 8580
vtorres@salud.gob.mx

THE NETHERLANDS

Moniek Zuurbier
MSc. Environmental Health
INCHES
Post Box 5364
Arnhem
The Netherlands
T: 31 263 773 780
F: 31 263 773 992
moniek.zuurbier@hvdgm.nl

CEC SECRETARIAT
393 St-Jacques St. W., #200
Montreal (Québec)
Canada H2Y 1N9

José Carlos Tenorio
Project Manager
Pollutants and Health, SMOC
T: (514) 350-4372
jctenorio@ccemtl.org

Paul Miller
Project Manager
Pollutants and Health, Air Quality
T: (514) 350-4326
pmiller@ccemtl.org

John Buccini
CEC Consultant
31 Sycamore Drive
Ottawa (Ontario)
Canada K2H 6R4

Tanis Frame
CEC Consultant
2821 Manitoba Street
Vancouver (British Columbia)
Canada V5Y 3B3
T: (604) 733-3651
Tanis.frame@telus.net

Erika Hercules
Assistant
Pollutants and Health
T: (514) 350-4362
ehercules@ccemtl.org

Liliana Paz Miller
Coordinator
Meeting Services
T: (514) 350-4313
lmiller@ccemtl.org