CHAPTER 8. HAZARDOUS AIR POLLUTANTS: APPROACHES AND CHALLENGES IN IDENTIFYING ASSESSMENT PRIORITIES

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This chapter provides information to support decisions by the International Agency for Research on Cancer (IARC) on prioritizing hazardous air pollutant assessments. The decisions may be based on a variety of alternative approaches and criteria, some of which are presented here for consideration along with other methods. A key criterion influencing the methods described here is the necessary focus on agents that may present the greatest potential threat to human health. For agencies charged with the protection of public health, it is of primary importance to prioritize activities to ensure that resources are expended to address the largest public health risks and to seek optimal risk reduction as required, in many instances, by legislative direction or executive order.

In the conventional model of risk assessment (NRC, 1983, 1994), hazard identification is followed by the development of estimates of toxic potency and human exposure, which results in estimates of risk for the end-points of concern. After this risk assessment, valuable resources can be allocated to research chemicals presenting the greatest risk instead of those with little or no potential for human exposure. Health risk assessment approaches provide insights on setting priorities for assessments and subsequent risk management activities. Here, selected data on risk potential are considered in the prioritization of chemicals for IARC review.

It is essential to recognize that a focus on only those chemicals for which toxicity and exposure data are available may fail to identify other chemicals that are highly important but for which data are scant or missing and the potential for risk is poorly understood. Identification of key missing information and priorities for toxicity testing and research may be a significant by-product of prioritization efforts as documentation of knowledge gaps can inform future prioritization efforts.

[1] This document has been reviewed in accordance with United States Environmental Protection Agency policy. The views expressed in this chapter are those of the author and do not necessarily reflect the views or policies of the agency. Appreciation is extended to Jamie Benedict, Larry Claxton, Ila Cote, David DeMarini, David Guinnup, Amy Mills, Susan Reith, Christine Ross, and William Russo for their assistance in collecting the information presented here and for their thoughtful comments and suggestions.

Scope of evaluation: hazardous air pollutants

Two major types of air pollutants are defined for regulatory purposes in the USA. One type, criteria air pollutants, has historically been the primary focus of air quality management programmes. These pollutants accumulate in the atmosphere as a result of emissions from numerous and diverse mobile and stationary sources. They have widespread exposures and include tropospheric ozone, carbon monoxide, particulate matter (PM) (of various size classifications), lead, sulfur dioxide, and nitrogen dioxide. Of these, there is some evidence or suggestion of carcinogenic potential for tropospheric ozone (Bell *et al.*, 2004), PM (Pope *et al.*, 2002), and lead (NTP, 2003). There are widespread human exposures to ozone and PM, with current exposure levels for these pollutants exceeding ambient standards in some areas in the USA (EPA, 2003a) and elsewhere. For lead, exposures may occur due to the cumulative influence of air, water, and dietary routes of exposure. Timing of scientific and regulatory evaluation is also relevant. In the USA, the most recent evaluation of PM was completed in 2012, carbon monoxide in 2011, nitrogen dioxide and sulfur dioxide in 2010, and ozone and lead in 2008. Hence, PM, ozone, and lead may be reasonable candidates for IARC evaluation over the next several years to inform scientific and regulatory evaluations in the near future. Billions of dollars per year are being spent in the USA alone to achieve and maintain acceptable air quality related to these pollutants.

The second major type of air pollutant, the hazardous air pollutants (HAPs), has historically been a focus for source-specific emissions standards. In the USA, the 1970 Clean Air Act directed the United States Environmental Protection Agency (EPA) to identify and develop emissions standards to protect public health with an ample margin of safety. From 1970 to 1990, several HAPs were identified (e.g. mercury, benzene, beryllium, arsenic, coke oven emissions) and regulations were developed. Concerns about non-criteria pollutants increased substantially in the 1980s, due in part to the thousands of people killed and injured by a large accidental emission of methyl isocyanate from an industrial facility in Bhopal, India. It became evident that substantial public exposure could be occurring in the USA, through a toxics release inventory mandated by provisions of the Emergency Planning and Community Right-to-Know Act of 1986 and expanded by the Pollution Prevention Act of 1990. In 1990, the United States Congress identified 188 chemicals and compound groups as HAPs under Section 112 of the Clean Air Act. The list was developed from an evaluation of state and local agency efforts in the USA to control non-criteria pollutants, coupled with the potential for the agents to be present in ambient air, among other factors. This list has been the focus in the USA of technology-based emissions standards and, subsequently, residual risk evaluations intended to ensure protection of public health.

Prioritization approaches and data input

Four approaches and data are described and evaluated: (1) emissions data from the Toxics Release Inventory; (2) information from the Integrated Risk Information System; (3) potential risk data for a subset of HAPs based on emissions information evaluated in the United States National Air Toxics Assessment; and (4) a subjective evaluation.

Toxics Release Inventory

The Toxics Release Inventory (TRI) provides insights on the potential for human exposures (in the USA) to more than 650 chemicals emitted to the air, water, and waste sites from facilities that meet certain criteria (e.g. employ at least 10 workers, manufacture or use in excess of 10 000 pounds of a chemical in a year) (http://www.epa.gov/tri). Emissions from smaller facilities that also emit chemicals (e.g. dry cleaning facilities) are not included.

The most current TRI data indicate that for many chemicals the largest environmental releases are from fugitive and point-source air emissions. In addition, the quantity of emissions to the air of these various agents spans > 7 orders of magnitude; hence, the potential for human exposure is also highly variable among these agents. It is important to note, however, that emissions do not relate directly to exposure and risk.

Integrated Risk Information System

The EPA's Integrated Risk Information System (IRIS) collects information in support of prioritization efforts (http://www.epa.gov/iris). The IRIS programme reviews scientific information for priority environmental pollutants. It develops hazard characterization and dose–response evaluations for cancer and non-cancer health end-points through a process that includes internal and external expert peer review. Through IRIS, EPA provides the highest quality science-based human health assessments to support environmental decision-making by EPA and other organizations.

Since 1997, the IRIS programme has sought nominations for high-priority chemicals and other substances for assessment or reassessment from EPA regulatory and other programmes, regional offices, other United States federal agencies, and the public. The chemicals identified through this process reflect, in aggregate, priorities resulting from EPA programme activities.

The criteria used by the EPA Office of Research and Development to evaluate nominations include:

- Statutory, programmatic need for EPA
- Other stakeholder need
- Availability of scientific information
- Existing assessment available
- Widespread exposures, cross-media concern, and other factors.

Many of the IRIS assessments in progress at any time are for HAPs, and their presence on this list is an indicator of high priority to EPA. The chemicals nominated or being reviewed under the IRIS programme represent candidates for IARC evaluation.

National Air Toxics Assessment

The EPA conducted a National Air Toxics Assessment (NATA) for 1996 and again for 2005 (http://www.epa.gov/ttn/atw/natamain/). This national-scale assessment identified 33 air pollutants (a subset of 32 air toxics on the Clean Air Act list of 188 air toxics, plus diesel PM) of greatest potential concern in terms of their contribution to population risk.

Health effects tables support the NATA process by providing cancer hazard characterization and potency estimates, as well as non-cancer characterization. The web site includes a description of the information collected and cautions about the use of NATA summary information, which is subject to change.

Information from modelled population exposure, when coupled with health effects information on hazard and dose–response, has been used to estimate potential population health risks. The calculated distribution of lifetime cancer risk for the United States population, based on 1996 exposure estimates to all sources combined, is available at http://www.epa.gov/ttn/atw/nata/rcharts/figure06.pdf (along with important cautions about interpretation of modelling results). These results suggest that the lifetime cancer risks from individual pollutants range over several orders of magnitude, and in aggregate for the 29 chemicals or compound groups with cancer potency values, the lifetime cancer risks exceed 1 in 10 000 for a subset of the population most exposed to these chemicals.

A subjective synthesis

Analyses of information on emissions, health data, and health risk provide insights on potential priorities for IARC and other purposes. The information sources noted above present a means for looking across chemicals to evaluate their potential for risk and, to some extent, the possible availability of new information that might influence existing risk estimates. It must be cautioned that these analyses are limited and uncertain due to the methods used to collect the original data (TRI, NATA), evaluate existing data (IRIS), and conduct population modelling (NATA). In some ways, the most valuable information obtained from these analyses is that emissions and potential exposures vary widely and there are many gaps in our knowledge of health effects; therefore, looking at the emissions with the highest exposure potential is a reasonable approach.

Recognizing the chemicals that are most important to environmental regulatory programmes may be useful as such perspectives reflect consideration of risk magnitude and confidence in the data used to support decision-making. The carcinogens most important to air toxics regulatory programmes include benzene, metals (arsenic, cadmium, chromium, beryllium, nickel), industrial chemicals or releases (1,3-butadiene, ethylene oxide, perchloroethylene, benzidine, hydrazine, 1,4-dioxane, acetaldehyde, naphthalene, polycyclic organic matter, ethylene dichloride, ethylene dibromide, *p*-dichlorobenzene, bis(2-ethylhexyl)phthalate, formaldehyde, acrylonitrile, methylene chloride, trichloroethylene and 1,1,2,2-tetrachloroethane, chloroprene, ethylbenzene, and vinyl acetate), and persistent chlorinated chemicals such as dioxin, polychlorinated biphenyls, and chlorinated pesticides. Although many of these chemicals have been evaluated numerous times, repeated evaluations are important as new information becomes available so that regulatory programmes have access to the most recent data and analyses. It is helpful to align the evaluations by IARC with new study data collected by the United States National Toxicology Program (http://ntp-server.niehs.nih.gov/) and with evaluations by IRIS and the Agency for Toxic Substances and Disease Registry (http://www.atsdr.cdc.gov/).

Some chemical groups such as the ketones, asbestos subgroups, various aldehydes, and phthalates are also obvious assessment candidates. Due to their relatively high cancer potency, metals as a group are generally of higher priority.

In addition, pollutant emissions from emerging or changing technologies are a priority, for example nanomaterials, emissions from new diesel engines, and gasoline PM. New information sources are also becoming available; the development of chemical dossiers by the Registration, Evaluation, Authorisation and Restriction of Chemical Substances (REACH) programme in Europe (http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm) may provide information of substantial importance in identifying additional candidate chemicals for assessment.

There are many HAPs produced through atmospheric chemistry that may be important targets for IARC assessment. Claxton *et al.* (2004) reviewed the research on genotoxicity of ambient outdoor air and demonstrated that many compounds that would not be identified by TRI or NATA may be very important to public health. For example, they stated that the mutagenicity of PM organics is due to at least 500 identified compounds from varying chemical classes. These compounds present a challenge, and an opportunity, for assessment programmes.

It is important to keep in mind that available data focus on those pollutants we know the most about. There are many more chemicals emitted from industrial, residential, or commercial uses, emitted from gasoline and diesel engines, or produced through atmospheric chemistry, than we have satisfactory data for about emissions, exposures, and health effects. Recognition of these limitations and staying vigilant to identify emerging health concerns is of significant value in prioritizing assessment activities.

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