Chapter 4 Use of the guidelines in protecting public health

When strategies to protect public health are under consideration, the air quality guidelines need to be placed in the perspective of total chemical exposure. The interaction of humans and the biosphere is complex. Individuals can be exposed briefly or throughout their lifetime to chemicals in air, water and food; exposures may be environmental and occupational. In addition, individuals vary widely in their response to exposure to chemicals; each person has a pre-existing status (for example, age, sex, pregnancy, pulmonary disease, cardiovascular disease, genetic make-up) and a lifestyle, in which such factors as exercise and nutrition play key roles. All these different elements may influence a person's susceptibility to chemicals. Various sensitivities also exist within the plant kingdom and need to be considered in protecting the environment.

The primary aim of these guidelines is to provide a uniform basis for the protection of public health and of ecosystems from adverse effects of air pollution, and to eliminate or reduce to a minimum exposure to those pollutants that are known or are likely to be hazardous. The guidelines are based on the scientific knowledge available at the time of their development. They have the character of recommendations, and it is not intended or recommended that they simply be adopted as standards. Nevertheless, countries may wish to transform the recommended guidelines into legally enforceable standards, and this chapter discusses ways in which this may be done. It is based on the report of a WHO working group (*1*). The discussion is limited to ambient air and does not include the setting of emission standards.

In the process of moving from a “guideline” or a “guideline value” to a “standard”, a number of factors beyond the exposure–response relationship need to be taken into account. These factors include current concentrations of pollutants and exposure levels of a population, the specific mixture of air pollutants, and the specific social, economic and cultural conditions encountered. In addition, the standard-setting procedure may be influenced by the likelihood of implementing the standard. These considerations may lead to a standard above or below the respective guideline value.

Definitions

Several terms are in use to describe the tools available to manage ambient air pollution. To avoid confusion, definitions are needed for the terms used here – guideline, guideline value and standard – within this specific context.

Guideline

A guideline is defined as any kind of recommendation or guidance on the protection of human beings or receptors in the environment from adverse effects of air pollutants. As such, a guideline is not restricted to a numerical value but might also be expressed in a different way, for example as exposure–response information or as a unit risk estimate.

Guideline value

A guideline value is a particular form of guideline. It has a numerical value expressed either as a concentration in ambient air or as a deposition level, which is linked to an averaging time. In the case of human health, the guideline value provides a concentration below which no adverse effects or (in the case of odorous compounds), no nuisance or indirect health

significance are expected, although it does not guarantee the absolute exclusion of effects at concentrations below the given value.

Standard

A standard is considered to be the level of an air pollutant, such as a concentration or a deposition level, that is adopted by a regulatory authority as enforceable. Unlike the case of a guideline value, a number of elements in addition to the effect-based level and the averaging time have to be specified in the formulation of a standard. These elements include:

- the measurement strategy
- the data handling procedures
- the statistics used to derive the value to be compared with the standard.

The numerical value of a standard may also include the permitted number of exceedings.

Moving from guidelines to standards

The regulatory approach to controlling air pollution differs from country to country. Different countries have different political, regulatory and administrative approaches, and legislative and executive activities can be carried out at various levels such as national, regional and local. Fully effective air quality management requires a framework that guarantees a consistent derivation of air quality standards and provides a transparent basis for decisions with regard to risk-reducing measures and abatement strategies. In establishing such a framework, several issues should be considered, such as legal aspects, the protection of specific populations at risk, the role of stakeholders in the process, cost–benefit analysis, and control and enforcement measures.

Legal aspects

In setting air quality standards at the national or supranational level, a legislative framework usually provides the basis for the evaluation and decision-making process. The setting of standards strongly depends on the type of risk management strategy adopted. Such a strategy is influenced by country-specific sociopolitical considerations and/or supranational agreements.

Legislation and the format of air quality standards vary from country to country, but in general the following issues should be considered:

- identification and selection of pollutants to which the legislative instrument will apply;
- the process for making decisions about the appropriate standards;
- the numerical value of the standards for the various pollutants, applicable detection methods and monitoring methodology;
- actions to be taken to implement the standard, such as the definition of the time frame needed/allowed for achieving compliance with the standard, considering emission control measures and necessary abatement strategies; and
- identification of responsible enforcement authorities.

Depending on their position within a legislative framework, standards may or may not be legally binding. In some countries the national constitution contains provisions for the protection of public health and the environment. In general, the development of a legal framework on the basis of constitutional provisions comprises two regulatory actions. The

first is the enactment of a formal legal instrument, such as an act, a law, an ordinance or a decree, and the second is the development of regulations, by-laws, rules and orders.

Air quality standards may be based solely on scientific and technical data on public health and environmental effects, but other aspects such as cost–benefit or cost–effectiveness may be also taken into consideration. In practice, there are generally several opportunities within a legal framework to address these economic aspects as well as other issues, such as technical feasibility, structural measures and sociopolitical considerations. These can be taken into account during the standard-setting procedure or at the level of designing appropriate measures to control emissions. This rather complicated process might result in several standards being set, such as an effect-oriented standard as a long-term goal and less stringent interim standards to be achieved within shorter periods of time.

Standards also depend on political choices as to which receptors in the environment should be protected and to what extent. Some countries have separate standards for the protection of public health and the environment. Moreover, the stringency of a standard can be influenced by provisions designed to take account of higher sensitivities of specific receptor groups, such as young children, sick or elderly people, or pregnant women. It might also be important to specify whether effects are considered for individual pollutants or for a combined exposure to several pollutants.

Air quality standards can set the reference point for emission control and abatement strategies on a national level. It should be recognized, however, that exposure to some pollutants is the result of long-range transboundary transport. In these cases adequate protection measures can only be achieved by appropriate international agreements.

Air quality standards should be regularly reviewed, and need to be revised as new scientific evidence on effects on public health and the environment emerges.

Standards often strongly influence the implementation of an air pollution control policy. In many countries, the exceeding of standards is linked to an obligation to develop action plans at the local, regional or national level to reduce air pollution levels. Such plans often address several pollution sources. Standards also play a role in environmental impact assessment procedures and in the provision of public information on the state of the environment. Provisions for such activities can be found in many national legal instruments.

Within national or supranational legislative procedures, the role of stakeholders in the process of standard-setting also needs to be considered. This is dealt with in more detail below.

Items to be considered in setting standards

Within established legal frameworks and using air quality guidelines as a starting point, development of standards involves consideration of a number of issues. These are in part determined by characteristics of populations or physical properties of the environment. A number of these issues are discussed below.

Adverse health effects

In setting a standard for the control of an environmental pollutant, the effects that the population is to be protected against need to be defined. A hierarchy of effects on health can be identified, ranging from acute illness and death through chronic and lingering diseases and

minor and temporary ailments, to temporary physiological or psychological changes. The distinction between adverse and non-adverse effects poses considerable difficulties. Of course, more serious effects are generally accepted as adverse. As one considers effects that are either temporary and reversible, or involve biochemical or functional changes whose clinical significance is uncertain, judgements must be made as to which of these less serious effects should be considered adverse. With any definition of adversity, a significant degree of subjectivity and uncertainty remains. Judgements as to adversity may differ between countries because of factors such as different cultural backgrounds and different background levels of health status.

In some cases, the use of biomarkers or other indicators of exposure may provide a basis for standard-setting. Changes in such indicators, while not necessarily being adverse in themselves, may be predictors of significant effects on health. For example, the blood lead concentration can provide information on the likelihood of impairment of neurobehavioural development.

Special populations at risk

Sensitive populations or groups are defined here as those impaired by concurrent disease or other physiological limitations, and those with specific characteristics that make the health consequences of exposure more significant (such as the developmental phase in children or reduction in reserve capacity in the elderly). In addition, other groups may be judged to be at special risk because of their exposure patterns or due to an increased effective dose for a given exposure. Sensitive populations may vary from country to country owing to differences in the number of people lacking access to adequate medical care, in the existence of endemic disease, in the prevailing genetic factors, or in the prevalence of debilitating diseases, nutritional deficiencies or lifestyle factors. It is up to the politician to decide which specific groups at risk should be protected by the standards (and thus which should not be protected).

Exposure–response relationships

A key factor to be considered in developing standards is information about the exposure–response relationship for the pollutant concerned. For a number of pollutants an attempt has been made to provide exposure–response relationships in the revised version of the guidelines. For particulate matter and ozone, detailed tables specifying the exposure–response relationship are provided. The information included in these tables is derived from epidemiological studies of the effects of these pollutants on health. Such information is available for only a few of the pollutants considered in the guidelines. For known "no-threshold compounds" such as the carcinogen benzene, quantitative risk assessment methods provide estimates of risk at different exposure concentrations.

When developing standards, regulators should consider the degree of uncertainty about exposure–response relationships provided in the guidelines. Differences in the population structure, climate and geography that can have an impact on the prevalence, frequency and severity of effects may modify the exposure–response relationships provided in the guidelines.

Exposure characterization

An important factor to be considered in developing standards is that of how many people are exposed to concentrations of concern and the distribution of exposure among various population groups. Current distributions of exposure should be considered, together with those that are likely to occur should the standard be met. Besides using monitoring data, results of exposure modelling can be used at this stage. The origins of pollutants, including long-range transport and its contribution to ambient levels, should also be evaluated.

The extent to which ambient air quality estimates from monitoring networks or models correspond to personal exposure in the population is also a factor to be considered in the standard-setting. This will depend on the pollutant in question (for example, personal exposure to carbon monoxide is poorly characterized by fixed-site monitors) as well as on a number of local characteristics, including lifestyle, climatic conditions, spatial distribution of pollution sources and local determinants of pollution dispersion.

Other important exposure-related concerns include:

- how much of total human exposure is due to ambient, outdoor sources as opposed to indoor sources; and
- where multiple routes of exposure are important, how to apportion the regulatory burden among the different routes of exposure (such as lead from air sources versus lead from paint, water pipes, etc.).

These factors may vary substantially across countries. For example, indoor air pollution levels might be quite substantial in countries in which fossil and/or biomass fuels are used in homes.

Risk assessment

In general, the central question in developing air quality standards to protect public health or ecosystems is the degree of protection associated with different pollution levels at which standards might be established. In the framework of quantitative risk assessment, various proposals for standards can be considered in health or ecological risk models. These models provide a tool that is increasingly used to inform decision-makers about some of the possible consequences associated with various options for standards, or the reduction in adverse effects associated with moving from the current situation to a particular standard.

The first two steps in risk assessment, namely hazard identification and, in some cases, development of exposure–response relationships, have been provided in these guidelines and are discussed in greater detail in later chapters. The third step, exposure analysis, predicts changes in exposure associated with reductions in emissions from a specific source or groups of sources under different control scenarios. Instead of exposure estimates, ambient concentrations (based on monitoring or modelling) are often used as the inputs to a risk assessment. This is in part because of the availability of information on concentration–response relationships from epidemiological studies in which fixed-site monitors were used.

The final step in a regulatory risk assessment is the risk characterization stage, whereby exposure estimates are combined with exposure–response relationships to generate quantitative estimates of risk (such as how many individuals may be affected). Regulatory

risk assessments are likely to result in different risk estimates across countries, owing to differences in exposure patterns and in the size and characteristics of sensitive populations and those at special risk.

It is important to recognize that there are many uncertainties at each stage of a regulatory risk assessment. The results of sensitivity and uncertainty analyses should be presented so as to characterize the impact of major uncertainties on the risk estimates. In addition, the methods used to conduct the risk assessments should be clearly described and the limitations and caveats associated with the analysis should be discussed.

Acceptability of risk

The role of a regulatory risk assessment in developing standards may differ from country to country, owing to differences in the legal framework and availability of information. Also, the degree of acceptability of risk may vary between countries because of differences in social norms, degree of adversity and risk perception among the general population and various stakeholders. How the risks associated with air pollution compare with those from other pollution sources or human activities may also influence risk acceptability.

In the absence of clearly identified thresholds for health effects for some pollutants, the selection of a standard that provides adequate protection of public health requires an exercise of informed judgement by the regulator. The acceptability of the risks and, therefore, the standard selected will depend on the effect, on the expected incidence and severity of the potential effects, on the size of the population at risk, and on the degree of scientific certainty that the effects will occur at any given level of pollution. For example, if a suspected health effect is severe and the size of the population at risk is large, a more cautious approach would be appropriate than if the effect were less troubling or if the exposed population were small.

Cost–benefit analysis

Two comprehensive techniques provide a framework for comparing monetarized costs and benefits of implementing legislation or policy: cost–effectiveness analysis and cost–benefit analysis. These two techniques differ in their treatment of benefits. In cost–benefit analysis, costs and benefits (for example, avoided harm, injury or damage) of implemented control measures are compared using monetary values. In cost–effectiveness analysis, the costs of control measures are reported in quantitative terms, such as cost per ton of pollutant or cost per exposure unit. That is, the benefits are described in their own physical, chemical or biological terms, such as reduced concentrations or emissions, or avoided cases of illness, crop losses or damage to ecosystems.

Analysis of control measures to reduce ambient pollutant levels

Control measures to reduce emissions of many air pollutants are known. Direct control measures at the source are readily expressed in monetary terms. Indirect control measures, such as alternative traffic plans or changes in public behaviour, may not all be measurable in monetary terms but their impact should be understood. Effective control measures should be designed to deal with secondary as well as primary pollutants.

Cost identification should include costs of investment, operation and maintenance, both for the present and for the future. Unforeseen effects, technical innovations and developments, and indirect costs arising during implementation of the regulation are additional complicating

factors. Cost estimates derived in one geographical area may not be generally transferable to other areas.

Air quality assessment has to provide information about expected air quality, both with and without implementation of control measures. Typically, the assessment will be based on a combination of air quality monitoring data and dispersion modelling. These two assessment methods are complementary, and must be seen as equally important inputs to the assessment process.

For the assessment, several types of data have to be acquired:

- measured concentrations for relevant averaging times (hourly, daily, seasonal) with information on site classification;
- emission data from all significant sources, including emission conditions (such as stack height) and with sufficient information on spatial and temporal variation; and
- meteorological and topographical data relevant to dispersion of the emissions.

Defining the scope and quantifying the benefits

The air quality guidelines are based on health and ecosystem endpoints determined by consensus. This does not imply that other effects on health and the ecosystem that were not considered in the guidelines may not occur or are unimportant. After assessing the local situation, other health- and ecosystem-related benefit categories should be considered in the analysis.

It is a difficult and comprehensive task to quantify the benefit categories included in a cost–benefit analysis. Some indicators of morbidity, such as the use of medication, the number of hospital admissions or work days lost, can be quantified. Other effects, such as premature death or excess mortality, present more difficult problems. Wellbeing, the quality of life or the value of ecosystems may be very difficult to express in monetary terms. In different countries, values assigned to benefit categories might differ substantially owing to different cultural attitudes. Despite these uncertainties, it is better to include as many of the relevant benefit categories as possible, even if the economic assessment is uncertain or ambiguous. A clear understanding of the way in which the economic assessment has been undertaken is important and should be reported.

Comparison of benefits with and without control actions

This step involves combining the information on exposure–response relationships with that on air quality assessment, and applying the combined information to the population at risk. Additional data needed in this step include specification of the population at risk, and determination of the prevalence of the different health effects in the population at risk.

Comparison of costs and benefits

Monetary valuation of control actions and of health and environmental effects may be different in concept and vary substantially from country to country. In addition to variations in assessing costs, the relative value of benefit categories, such as benefits to health or building materials, will vary. Thus, the result of comparing costs and benefits in two areas with otherwise similar conditions may differ significantly.

The measures taken to reduce one pollutant may increase or decrease the concentration of other pollutants. These additional effects should be considered, even if they result from exposure to pollutants not under consideration in the primary analysis. Pollutant interactions pose additional complications. Interaction effects may possibly lead to double counting of costs, or to disregarding some costly but necessary action. The same argumentation can be used when estimating benefits.

Sensitivity and uncertainty analysis

Sensitivity analysis includes comparisons of the results of a particular cost–benefit analysis with that of other studies, recalculation of the whole chain of the analysis using other assumptions, or the use of ranges of values. Specifically, a range of values may be used, such as for value of statistical life. Knowledge of the costs of control measures tends to be better developed than that of the benefits to health and ecosystems, and thus costs tend to be more accurately estimated than benefits. In addition, costs tend to be overestimated and benefits underestimated. One important reason for underestimating the benefits is not considering some important benefit categories because of lack of information. Another reason is the variability of the databases available for monetary assessment of benefits.

Many uncertainties are connected with the steps of cost–benefit and cost–effectiveness analysis, such as exposure, exposure–response, control cost estimates and benefits valuation. The results of sensitivity and uncertainty analyses should be presented so as to characterize the impact of major uncertainties on the result of the analysis. In addition, the methods used to conduct the analysis should be clearly described, and the limitations and caveats associated with the analysis should be discussed. Transparency of the analysis is most important.

Involvement of stakeholders and public awareness

The development of standards should encompass a process involving stakeholders that ensures, as much as possible, social equity or fairness to all involved parties. It should also provide sufficient information to guarantee understanding by stakeholders of the scientific and economic consequences. A review by stakeholders of the standard-setting process, initiated at an early stage, is helpful. Transparency in the process of moving from air quality guidelines to standards helps the public to accept necessary measures.

The participation of all those affected by the procedure of standard-setting – industry, local authorities, nongovernmental organizations and the general public – at an early stage of standard derivation is strongly recommended. If these parties are involved in the process at an early stage their cooperation is more likely to be elicited.

Raising public awareness of the health and environmental effects of air pollution is also an important means to obtain public support for necessary control actions, such as with respect to vehicle emissions. Information about the quality of air (such as warnings of air pollution episodes) and the entailed risks (risk communication) should be published in the media to keep the public informed.

Implementation

The main objectives of the implementation of air quality standards are: (*a*) to define the measures needed to achieve the standards; and (*b*) to establish a suitable regulatory strategy and legislative instrument to achieve this goal. Long- as well as medium-term goals are likely to be needed.

The implementation process should ensure a mechanism for regular assessment of air quality, set up the abatement strategies, and establish the enforcement regulations. Also, the impact of control actions should be assessed, both for public health and environmental effects, for example by the use of epidemiological studies and integrated ecosystems monitoring. Epidemiological studies of the effects of air pollutants on health should be repeated as control measures are implemented. Changes to the mixture of air pollutants and in the composition of complex pollutants such as particulate matter may occur, and changes in exposure–response relationships should be expected.

Assessment of air quality

Air quality assessment has an important role to play within the implementation of an air quality management strategy. The goals of air quality assessment are to provide the air quality management process with relevant data through a proper characterization of the air pollution situation, using monitoring and/or modelling programs and projection of future air quality associated with alternative strategies. Dispersion models can be used very effectively in the design of the definitive monitoring network

Monitoring methods

The monitoring method (automatic, semi-automatic or manual) adopted for each pollutant should be a standard or reference method, or be validated against such methods. The full description of the method should include information on the sampling and analytical method, on the quality assurance and quality control (internal and external) procedures and on the methods of data management, including data treatment, statistical handling of the data and data validation procedures.

Quality assurance/quality control procedures are an essential part of the measurement system, the aim being to reduce and minimize errors in both the instruments and management of the networks. These procedures should ensure that air quality measurements are consistent (and can be used to give a reliable assessment of ambient air quality) and harmonized over a scale as large as possible, especially in the area of the implementation of the standard.

Design of the monitoring network

An air quality monitoring network can consist of fixed and/or mobile monitoring stations. Although such a network is a fundamental tool for any air quality assessment, its limitations should be borne in mind.

In designing a monitoring network, a primary requirement is to have information about emissions from the dominant and/or most important sources of pollutants. Second, a pilot (or screening) study is needed to gain a good understanding of the geographical distribution of pollutants and to identify the areas with the highest concentrations. Such a screening study can be performed using dispersion models, with the emission inventory as input, combined with a monitoring study using inexpensive passive samplers in a rather dense network.

The selection strategy for site locations generally varies for different pollutants. The number and distribution of sampling sites required in any network depend on the area to be covered, the spatial variability of the emissions being measured, and the purpose for which the data should be used. Meteorological and topographical conditions as well as the density, type and strength of sources (mobile and stationary) must be considered.

Different types of monitoring station are likely to be needed to provide data at a regional or local level. In monitoring rural and urban areas, specific attention should be paid to sites affected by defined sources such as traffic and other "hot-spots". The representativeness of each site should be defined and assessed. Micro-scale conditions, including the buildings around the stations (street canyons), traffic intensity, the height of the sampling point, distances to obstacles, and the effects of the local sources must be kept in mind.

Air quality modelling

Air quality models are used to establish a relationship between emissions and air quality in a given area, such as a city or region. On the basis of emission data, of atmospheric chemistry, and of meteorological, topographical and geographical parameters, modelling gives an opportunity (*a*) to calculate the projected concentration or deposition of the pollutants in regions, and (*b*) to predict the air pollution level in those areas where air sampling is not performed. Measured concentrations should be used for evaluating and validating models, or even as input data. These measurements improve the accuracy of the concentrations calculated by models by allowing refinement and development of the modelling strategies adopted.

Abatement strategies

Abatement strategies are the set of measures to be taken to reduce pollutant emissions and therefore to improve air quality. Authorities should consider the measures necessary in order to meet the standards. An important factor in selecting abatement strategies is deciding the geographical scale of the area(s) that are considered not to meet the standard(s) and the geographical scale of the area for which control should be applied. In defining the geographical scale for abatement strategies, the extent of the transport of pollution from neighbouring areas should be considered. This may involve action at supranational, national, regional or local levels.

Supranational, national, regional and local actions form a hierarchy of approaches. Action at the supranational or national level is likely to be most effective in reducing background levels of air pollution. Local air quality management measures may be needed to address specific local problems, and such measures may need to be implemented urgently to deal with special pollution problems. National and supranational plans should specify the extent of the reduction in levels of air pollution that is required and the time-scale for achieving that reduction.

In addition to the comprehensive programme of emission control designed to reduce average pollution levels and the risk of high pollution episodes, short-term actions may be required for the period when the pollution episodes may occur. Such actions, however, should be considered to be applicable in a transitional period only or as a contingency plan. The objective of measures applied on a larger scale is to minimize the occurrence of local air pollution episodes. A link between control of emissions and ambient air quality is required and may need to be demonstrated. Emission-based air quality standards represent one possible step in this process.

Enforcement

The government of each country establishes the responsibilities for implementing air quality standards. Responsibilities for overseeing different aspects of compliance can be distributed among national, regional and local governments depending on the level at which it is necessary to take action.

Success in the enforcement of standards is influenced by the technology applied and the availability of financial resources to industry and government. Compliance with standards may be ensured by various approaches such as administrative penalties or economic incentives. Sufficient staff and other resources are needed to implement the policy actions effectively.

Periodic reports on compliance and trends in pollutant emissions and concentrations should be developed and disseminated to the public. These reports should also predict trends. It is important that the public be aware of the importance of meteorological factors in controlling pollution levels, as these may produce episodes of pollution that are not within the control of the regulatory authorities.

Reference

1. *Guidance for setting air quality standards. Report on a WHO Working Group*. Copenhagen, WHO Regional Office for Europe, 1998 (document EUR/ICP/EHPM 02 01 02).

