A HEALTH-CENTRED FRAMEWORK FOR ESTABLISHING AMBIENT AIR QUALITY STANDARDS

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Contents

1. Introduction 5

1.1 Background 5

1.2 Structure of the working paper 6

2. History and the evolution of the NAAQS in India 7

3. Framework for revision of the NAAQS 9

3.1 Overall framework 9

3.2 Planning 10

3.2.1 Scientific Review Committee 10

3.2.2 Working groups 11

3.3 Periodicity 12

4. Working group 1: Integration of health evidence 14

4.1 Defining the scope of the review 14

4.2 Conducting a structured literature review 15

4.3 Selection of studies for integration of health evidence 15

4.4 Developing a concentration-response function 16

4.5 Formulation of safe limits for individual pollutants 18

5. The roles of the other working groups 19

5.1 Working group 2: Air quality data and modelling 19

5.1.1 The role of working group 2 19

5.1.2 Background and forecasted levels of pollution 19

5.1.3 Current approach 19

5.1.4 Recommended approach 19

5.2 Working group 3: Assessment of standards for ecologically sensitive zones 20

5.2.1 The role of working group 3 20

5.2.2 Lack of Indian studies 20

5.2.3 Recommended approach 20

5.3 Working group 4: Benefit – cost analysis 20

5.3.1 The role of working group 4 20

5.3.2 Global approaches 21

5.3.3 Recommended approach 21

5.4 Working group 5: Monitoring methods 22

5.4.1 The role of working group 5 22

5.4.2 Current approach 23

5.4.3 Recommended approach 23

5.5 External peer-review ... 23
6. Policy assessment and rule making ... 24
6.1 Policy assessment ... 24
6.2 Rulemaking ... 24
6.2.1 Preparation of the NAAQS draft ... 24
6.2.2 Public participation ... 24
6.2.3 Release of the NAAQS ... 25
7. Conclusion ... 26

1. INTRODUCTION

1.1 Background

Air quality standards are primarily health-based standards that define the ambient concentration of air pollution to which the public can be exposed without suffering harm to their health. In India, the Central Pollution Control Board (CPCB) is tasked with setting the National Ambient Air Quality Standards (NAAQS) under the Air (Prevention and Control of Pollution) Act of 1981 [1]. The NAAQS were first established in 1982 for four pollutants (suspended particulate matter, nitrogen dioxide, sulphur dioxide and carbon monoxide) and subsequently revised in 1994 and 1998 to include several more. The current iteration of the NAAQS were notified in 2009 and were aligned with the World Health Organization's (WHO) interim air quality guidelines [2]. The most recent revision of the WHO guidelines for ambient air quality in September 2021 rendered the NAAQS as substantially weaker in comparison [3]. The alignment of the NAAQS with these global guidelines will require integration of the wealth of new health data generated since 2009 on the deleterious effects of air pollution on health both locally and globally.

The 2009 NAAQS revision were notified through the Gazette of India with no contextual information provided on the composition of the committee tasked with the revisions, or on the kind of data or information used by the committee to draw its conclusions on the acceptable levels of exposure to various pollutants. In August 2021, the CPCB convened a committee to review and update the NAAQS [4]. The committee's wide-ranging remit includes an assessment of the health risks of air pollution, establishing guidelines for monitoring, identifying non-attainment areas, and revising the Air Quality Index (AQI) through which health risks are communicated to the public [5].

While the proposed revision of the NAAQS is a step in the right direction, at the time of this paper's publication it remains unclear how evidence on the harmful effects of air pollution to health would be weighed by the committee, whether the committee has adequate disciplinary diversity, how it would consider economic and social factors in its decision-making, and how it would engage with the public. These concerns have been previously highlighted in several government policy documents as well, including the National Environment Policy (NEP) of 2006, and the National Clean Air Programme (NCAP) of 2019 [6],[7]. The NEP for instance noted the need to set up a "permanent machinery" of experts to review standards as and when needed, based on an understanding of the risk to human health, technological feasibility, and economic viability, in line with the broader goals of "economic and social development". It also cited the need to engage with various stakeholders, including affected communities and industry. While this document is now dated, the principles articulated in it remain valid as no subsequent environmental policy has been articulated by the Government. The NCAP's national-level policy document also highlighted the need to establish guidelines regarding the periodicity and remit of such reviews [7].

Based on the need to establish scientifically robust health-based standards, this working paper evaluates the global best practices for setting or revising air quality standards. Through this, we suggest a structured approach to revising the current and future NAAQS – through an inclusive, expert-driven institutional process, with appropriate timelines, evidence integration, and public participation for the Indian context.

1.2 Structure of the working paper

This paper is organised into seven chapters

Chapter 2 provides an overview of the history and evolution of the NAAQS in India, highlighting the significant revisions that constituted each update.

Chapter 3 provides the broad framework for revising the NAAQS with four significant steps i.e., planning, science assessment, policy assessment, and rulemaking. In this chapter, we go over the planning step, including the creation of the scientific review committee, working groups, periodicity, and the timeline for the revisions.

Chapter 4 details the roles and responsibilities of working group 1 i.e., Integration of health evidence on harmful effects of air pollution. We propose a process, institutional framework and decision-making approach for establishing air quality standards based on health considerations.

Chapter 5 details the roles and responsibilities of working groups 2-5, including tasks such as handling air quality data and modelling, conducting benefit-cost analysis, assessing standards for ecologically sensitive zones, and suggesting measurement techniques for air quality monitoring.

Chapter 6 explains the proposed policy assessment and the rule-making steps. We also discuss how the findings from the working groups can be integrated into the decision-making, and the key policy-relevant questions that must be raised to ensure that the proposed NAAQS are scientifically sound, protective of public health and the environment, and achievable through feasible and cost-effective measures.

With respect to rule-making, we highlight the need for public consultation and how it provides an opportunity for a plurality of stakeholders to contribute to decision-making process, ensuring transparency, accountability, equity and inclusivity, thereby enhancing the legitimacy and acceptance of the final standards.

Chapter 7 concludes that the process of setting ambient air quality standards in India should adopt an approach that prioritises public health, emphasises scientific robustness, periodicity, interdisciplinarity, and transparency to align with global best practices.

2. HISTORY AND THE EVOLUTION OF THE NAAQS IN INDIA

Air quality standards were first mentioned in the WHO Technical Report Series No 157, 1958 [8]. The report noted that insufficient data were available at the time to arrive at standards that would protect human health. Subsequently, in 1972, a report on "Air quality guidelines and guidance for urban air pollutants" was published by the WHO, and it dealt with the harmful effects of photochemical oxidants, nitrogen dioxide (NO_2), suspended particles, carbon monoxide (CO), and sulphur dioxide (SO_2) [9]. Indian experts were involved in the expert committees that developed both reports.

In the same year, at the Stockholm Conference for the Human Environment, 113 countries pledged to enact policies to protect natural resources. In response, the Indian Government enacted the Air (Prevention and Control of Pollution) Act, of 1981, the first national legislation to address the problem of air pollution in India. The Act entitled the Central Pollution Control Board to lay down national minimum air quality standards as per section 16 (2) (h) of the act.

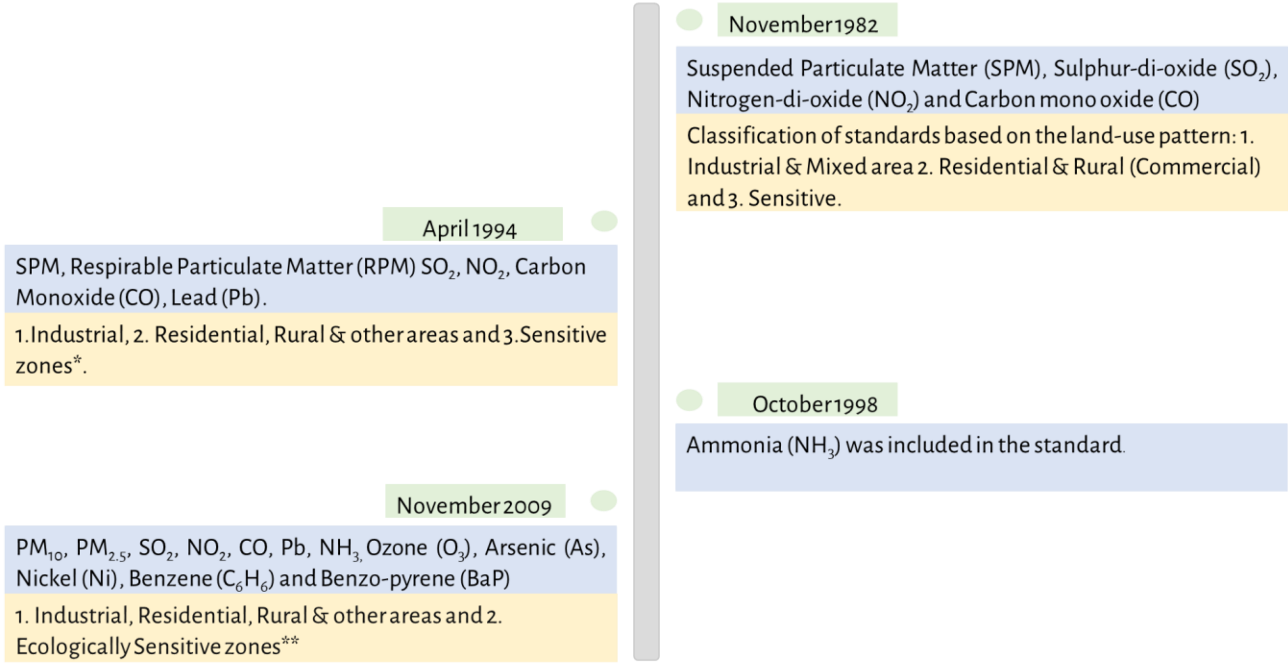
India's first NAAQS were notified in November 1982 for four pollutants - Suspended Particulate Matter (SPM), SO_2, NO_2 and CO. The standards were prescribed for 8-hour averages and no details on monitoring methods were included[1]. A detailed schematic on the evolution of the NAAQS in India is provided in Figure 1. Classification of standards were based on land-use patterns, namely (1) industrial & mixed area, (2) residential & rural (Commercial), and (3) sensitive. The sensitive regions included hill stations, national parks, and areas surrounding monuments. As per the 1982 standards, monitoring was to be conducted uniformly over 12 months with a frequency of not less than once a week. The standards were considered to have been met if the levels during this monitoring period were within the prescribed limits for 95% of the time over the course of the year.

The second update was notified in 1994 for six pollutants including respirable suspended particulate matter (RSPM) or PM_{10} and lead (Pb) [10]. The standards were classified by (1) industrial area, (2) residential, rural & other areas, and (3) sensitive area. Mixed and commercial areas were removed from the 1982 standard and a new land use terminology called "other areas" was included. It was also mentioned that states can notify sensitive areas within their respective jurisdictions within six months from the date of notification of the NAAQS. The frequency of monitoring was also increased from once a week to twice a week with the standards considered to have been met if the level of pollutants were within permissible limits for 98% of the time in a year. Thus, legal compliance with the NAAQS was assessed based on data that comprised a minimum of 28.5% of days in a year.

The third update was notified in October 1998, when ammonia was added to the list [11]. The fourth and most recent update was notified in 2009 with a further increase to the list of criteria pollutants monitored under the NAAQS regime. Particulate matter was regulated as $PM_{2.5}$ and PM_{10}, and in addition ozone (O_3), arsenic (As), nickel (Ni), benzene, (C_6H_6) and benzo-pyrene (BaP) were added to the standards based on research conducted by the CPCB and the Indian Institute of Technology Kanpur, WHO guidelines, and limits notified by the European Union [12]. Monitoring methods were included for the first time in the 1994 standards and the methods remained the same for all the pollutants except for particulate matter in the 2009 revision. Currently, twelve pollutants are regulated under the NAAQS. In the last update, industrial, residential, rural and other areas were clubbed into a single category, with ecologically sensitive zones listed as a separate category [2].

[1] The 1982 standard document is available with the author. Received from the CPCB library upon request.

It is important to note that the third update (2009) was weaker than the second update (1994) in terms of the standards for ecologically sensitive zones, with states tasked with notifying ecologically sensitive zones (ESZ) based on CPCB peer group recommendations. The CPCB peer group recommended that ESZs be notified 10 km all around the periphery of 'health resorts'[2], biosphere reserves, sanctities (likely places of religious significance) and national parks, and 5 km all around the periphery of the archaeological monuments, centres of tourism, and pilgrimage centres in consultation with the respective departments [13].



*- State pollution control boards can notify sensitive and other areas in the respective states within six months of the date of notification.

**- As notified by the Central Government

Figure 1. Evolution of the Indian National Ambient Air Quality Standards

[2] The definition of "health resorts" was not found in the peer group recommendation document provided by CPCB on request by the authors.

3. FRAMEWORK FOR REVISION OF THE NAAQS

3.1 Overall framework

In India, the NAAQS are composed of six components i.e.,

1. Land use patterns e.g., residential, industrial and ecologically sensitive zones,
2. Pollutants e.g., PM_{10} and SO_2,
3. Averaging time e.g., annual, daily, 8-hourly and hourly average,
4. Levels e.g., 50 µg/m^3 and 2 mg/m^3,
5. Form e.g., The 24-hour or 8 hours averaged values should meet the NAAQS guideline levels 98% of the time in a year, and
6. Monitoring methods e.g., gravimetric sampling for particulate matter measurement.

Hence revising the NAAQS means reviewing all six components. An integrated framework along with the involvement of experts from diverse backgrounds can make the process scientific and robust.

The framework that we suggest includes four significant steps, i.e., planning, science assessment, policy assessment and rulemaking (Figure 2). The subsequent sections will explain each step - in detail. Each section contains information on the activities to be conducted and the agency/experts responsible for performing the activity.

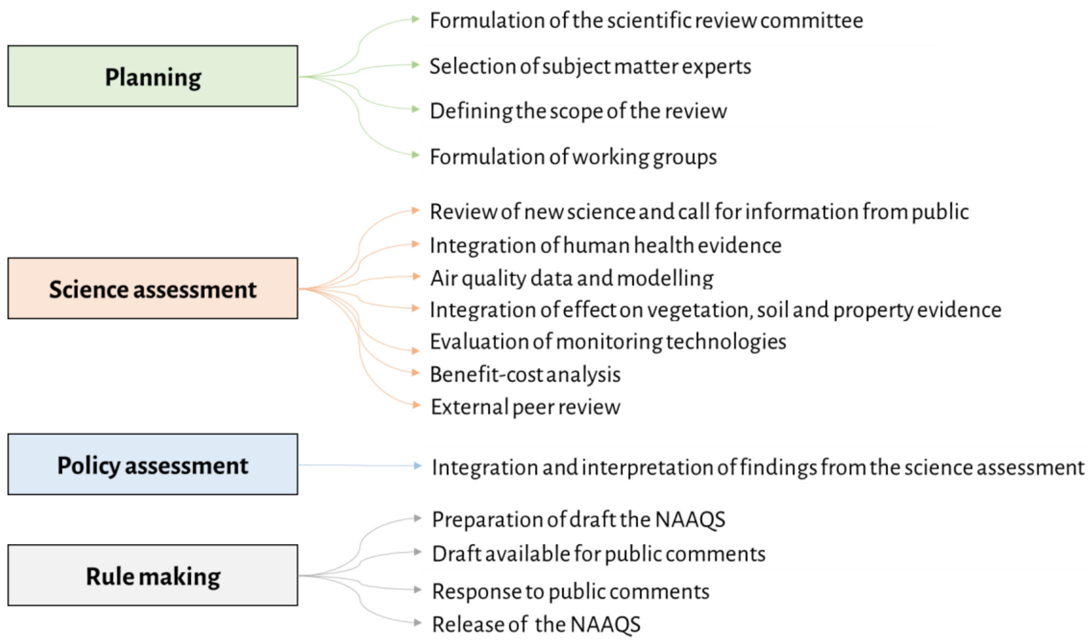


Figure 2. Suggested framework for revision of the NAAQS

3.2 Planning

The planning phase of the NAAQS review begins with the formulation of the Scientific Review Committee (SRC). The SRC can set up permanent machinery in the CPCB similar to the Clean Air Scientific Advisory Committee (CASAC) in USEPA [14]. Reviewing all the indicators discussed above for two categories of the standards requires multi-disciplinary expertise and hence it is suggested to form the SRC co-chaired by the CPCB and the Indian Council of Medical Research (ICMR). This committee will be responsible for completing the review of air quality standards at pre-defined intervals.

3.2.1 Scientific Review Committee

The SRC is intended to keep track of new scientific developments on air pollution and inform policy discussions. The members of the SRC and the working groups can be appointed by the CPCB to serve for a term (typically five years).

The SRC can include representatives from:

1. CPCB,
2. ICMR,
3. Ministry of Environment, Forests & Climate Change (MoEF&CC),
4. Ministry of Health and Family welfare (MoHFW),
5. State Pollution Control Boards (SPCBs),
6. Technical experts (Council of Scientific & Industrial Research (CSIR) institutions, technical universities, India Meteorological Department (IMD), and others),
7. Health experts (National Centre for Disease Control (NCDC), and other medical and public health institutions),
8. Environmental economics experts (National Council of Applied Economic Research (NCAER) and National Institute of Public Finance and Policy (NIPFP), and
9. Civil society organisations

Experts from technical institutions should be selected based on their expertise in the following fields: exposure assessment, risk assessment, atmospheric science and modelling, biostatistics, ecology, economics, monitoring methods, and instrumentation. Experts from health institutions should have expertise in environmental/clinical epidemiology, toxicology, and community medicine. It must also be noted that this expertise is often present outside of government and public universities and such expertise is vital to include in an SRC that is fit for purpose. Where necessary, additional 'consulting' members can be appointed to complement the expertise of the SRC.

For the selection of experts, the CPCB can publish a notice announcing opportunities for the experts to serve on the SRC. The selection of members can be done based on the expertise in the field, years of experience, prior engagement with policy processes, and relevant publications. The list of experts must be made publicly available to ensure transparency at every stage of the review process. Figure 3 illustrates the proposed structure of the SRC.

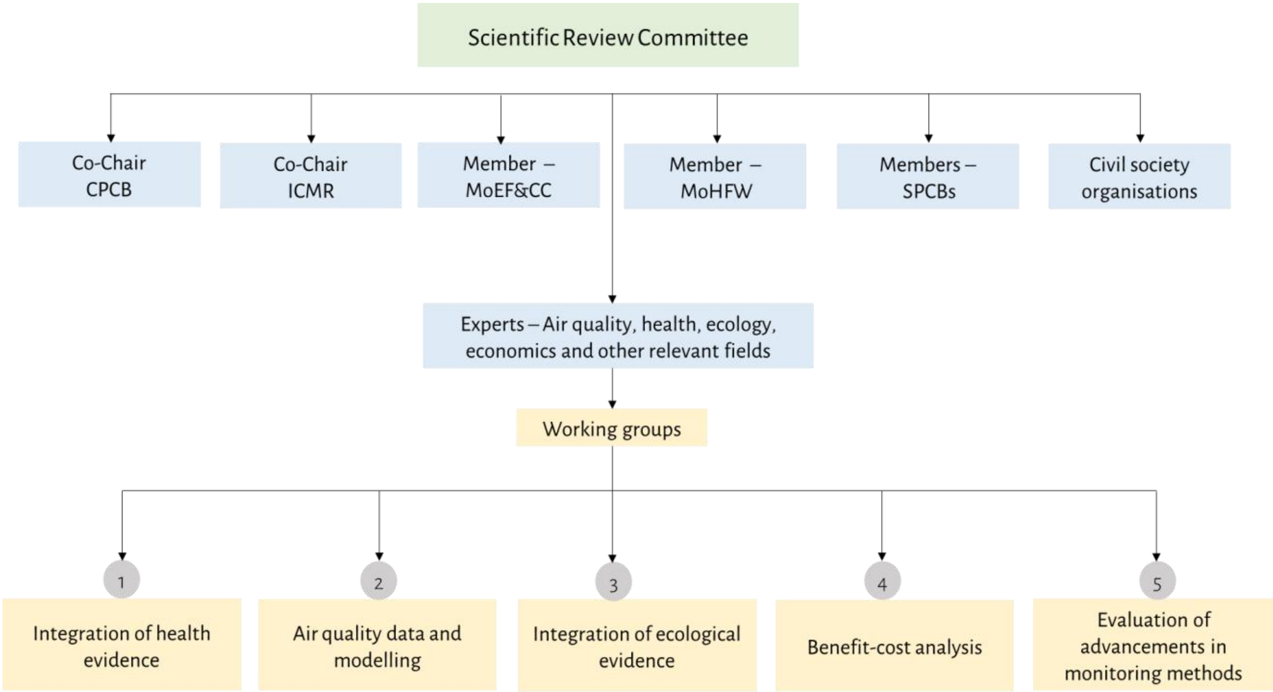


Figure 3. Structure of the Scientific Review Committee

3.2.2 Working groups

The technical and health experts can be grouped under different working groups. We suggest forming five working groups for integrating health evidence, evaluating the air quality data, cost-benefit analysis, integration of evidence for ecologically sensitive zone standards, and evaluation of advancements in monitoring methods. The expertise required and role of each working group are tabulated in Table 1.

Table 1. Function and expertise of each working group

Working Group	Output	Expertise
1	Integration of health evidence	• Environmental/clinical epidemiology • Exposure assessment • Risk assessment • Toxicology • Biostatistics
2	Air quality data and modelling	• Atmospheric science • Atmospheric modelling
4	Assessment for ecologically sensitive zone standards	• Ecology • Plant and animal toxicology
3	Benefit-cost analysis	• Epidemiology • Economics
5	Monitoring methods	• Environmental science • Environmental engineering • Electronics and Instrumentation engineering

3.3 Periodicity

As new scientific knowledge on the consequences on human health and the environment emerges, air quality standards should be regularly reviewed and revised. In India, the periodicity of the review of the NAAQS were around 12-14 years, with no stipulated time period for review. The NEP, 2006 recommended periodic revision of environmental standards, however, there needs to be a clear mandate in the Air Act for the periodic revision of standards [6].

At the global level, the WHO launched its first air quality guideline for Europe in the year 1987 followed by one in 2000. The first global update of air quality guidelines for four classical pollutants were published in 2006. In May 2015, the World Health Assembly, the decision-making body of the WHO adopted resolution 68.8 on health and the environment to address the health impact of air pollution. They also urged the member states to redouble work to protect their populations from health risks associated with air pollution. This resolution also considered the role of air quality guidelines and after 15 years the WHO revised the guideline values for four pollutants and included two more pollutants to its guidelines in 2021.

In the United States, the Clean Air Act mandates that a multi-stage, robust review of current science to be conducted every five years [15]. The USEPA does not conduct a single revision of all the pollutants at a specific time. It typically occurs on a pollutant-by-pollutant basis and each pollutant has its own separate timelines and processes.

In China, the periodicity of revision follows the same trend as in India. The NAAQS were first launched in China in the year 1982. They were revised in the year 1996, followed by that in the year 2000. The latest revision was carried out in the year 2012 [16].

In recent times, the Indian Union government has taken proactive steps to address air pollution's health impacts by initiating studies under key programs such as the NCAP and the National Programme on Climate Change and Human Health [7], [17]. Additionally, researchers nationwide are actively engaged in generating valuable insights through various projects, including the Global Environmental and Occupational Health (GEOHealth), the Cardiovascular Health Effects of Air Pollution in Andhra Pradesh, India (CHAI) study, and the Household Air Pollution Intervention Network (HAPIN) initiative, among others [18]–[20].

These research projects collectively aim to provide robust evidence pertaining to air pollution's effects on health, shedding light on both the extent of exposure and the resulting physiological responses. By accumulating and appropriately synthesising an increasing body of scientific knowledge, India will be better equipped to establish crucial scientific benchmarks for periodically revising the NAAQS, ensuring that air quality regulations remain aligned with the latest scientific findings.

Hence, we suggest a periodic review once every five years. In Figure 4, we propose a timeline and institutions responsible for the different steps of the review process.

Figure 4. Proposed timeline and responsible institutions for the review of the National Ambient Air Quality Standards

4. WORKING GROUP 1: INTEGRATION OF HEALTH EVIDENCE

Health or epidemiological evidence on the harmful effects of air pollution is foundational to setting air quality standards. Integrating such evidence into a review of the standards involves defining the scope of work (i.e., the pollutants and associated health outcomes to be considered), reviewing the evidence available, and interpreting the data collected to define new standards that protect health adequately. In this section, we describe the process involved in each step and propose the supporting institutional mechanism. A summary of the process and the proposed institutional mechanism is provided in Figure 5. For the integration of health evidence, the working group will include experts in the field of environmental/clinical epidemiology, exposure assessment, risk assessment, toxicology and biostatistics.

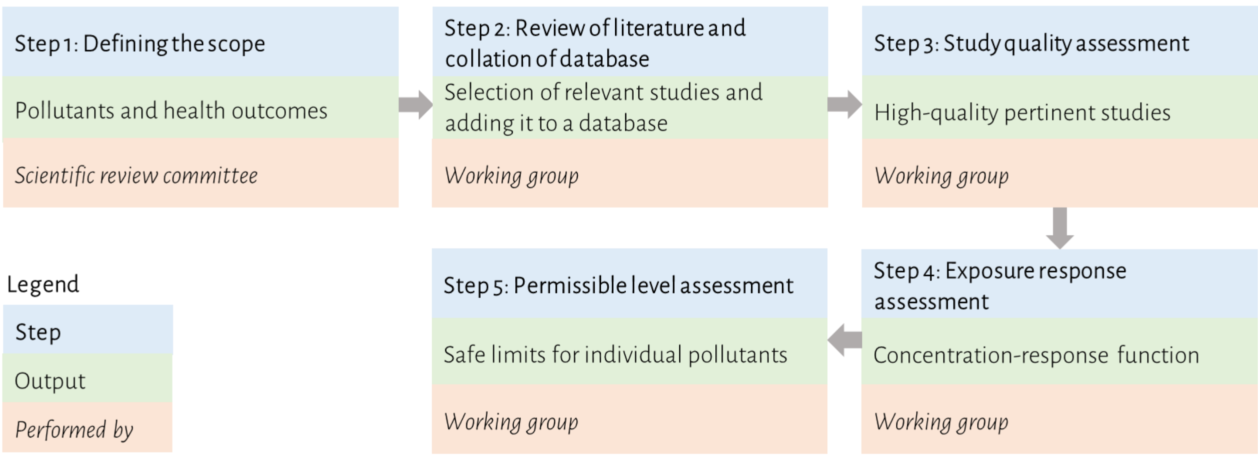


Figure 5. Framework for integrating health evidence

4.1 Defining the scope of the review

The scope of the review is essentially defined by the pollutants and the health outcomes chosen for examination. The pollutants and the health outcomes can be chosen based on the evidence obtained from Indian and international studies.

1. Strong evidence has been established in India between ambient PM and all-cause mortality, lower respiratory infections, chronic obstructive pulmonary disease, ischemic heart disease, lung cancer, adverse pregnancy and stroke. An illustrative list of relevant studies is provided in the Annexure.
2. In the absence of Indian evidence, the working group can use the evidence of causation obtained by international agencies such as the WHO, Health Canada, Committee on the Medical Effects of Air Pollutants (United Kingdom), USEPA, and the International Agency for Research on Cancer.
3. In the absence of both Indian and international evidence, the committee can exercise discretion on whether to include certain pollutants based on the precautionary principle.
4. Finally, the scientific review committee can reach a broad consensus on the scope through deliberation.

4.2 Conducting a structured literature review

After defining the scope, the next step will be to conduct a literature review. In this step, the research studies in the field of exposure assessment and epidemiology will be reviewed. Generally, international agencies follow the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach while conducting systematic reviews. This method of conducting the review is largely subject to the time and resources available [21]. Other international bodies like the Office of Health Assessment and Translation (OHAT) also provides guidelines for systematic review and evidence integration [22].

In the context of India, there has been a steady growth in the evidence base in the time period since the last review. However, given the significant gaps that still exist, it is recommended that a structured review process be adopted to effectively capture and assess the recent findings.

The structured review can be accomplished by:

1. Specifying the search strategy and then iteratively refining it to locate relevant papers in online databases such as PubMed, Google Scholar, Web of Science, etc.
2. The citations of the selected publications can be used to do a relational search.
3. The papers retrieved can be screened by title and abstract, and the pertinent publications can be considered for review.

Indian studies or those pertinent to the Indian context can also be identified by reviewing the studies included in the global systematic reviews conducted by organisations like the WHO, the EU, or the USEPA. In addition to the structured review by experts, the committee might request information from outside experts and the public to enhance the results by incorporating all the relevant studies and gain public trust.

The selected articles can be deposited in a database that is searchable and publicly accessible. It will be a valuable resource for future review processes including the revision of the Air Quality Index (AQI), for standard-setting by the CPCB and SPCBs, and for regulatory agencies like the Commission for Air Quality Management (CAQM). The public availability of the database will also allow researchers, policymakers, concerned citizens, and others to understand the basis for the standards, engage with the process, and use the evidence in different ways to advocate for improvement in air quality.

4.3 Selection of studies for integration of health evidence

The articles included in the database will be subject to study quality evaluation by subject matter experts in the working group. The role of the experts in this step is to select the most scientifically credible and relevant studies from the database. To do that, experts should consider peer-reviewed journal articles based on the design, approach, conduct, documentation, strengths, and limitations. In addition, experts can look at the mechanism of addressing confounders, effect modifiers and other biases in these studies. Most importantly, studies addressing vulnerable populations under ambient exposure conditions can be given higher importance. The following factors can be considered in assessing vulnerability:

1. Children in the developmental stage and elderly who have difficulty recovering from the health effects.
2. Other intrinsic factors like sex, genetic factors, and pre-existing health conditions.

3. Non-biological factors such as income level, physical activity level, greater internal dose (e.g., athletes), higher exposure duration (e.g., outdoor workers), and higher exposure levels (e.g., residents near major roadways and industries).

An illustrative list of studies related to exposure to PM on vulnerable populations like children and women has been provided in the Annexure.

4.4 Developing a concentration-response function

From the selected studies, epidemiological information can be collected to inform the shape of the concentration-response function for the various pollutant-health outcome pairs. A concentration-response function represents the relationship between the concentration of the pollutant to which the population is exposed and the risk associated with changes in exposure i.e., in general, it quantifies the health effect per unit change in exposure to the air pollutant [23].

A structured approach should be followed while collecting relevant information. International agencies adopt the Population, Exposure, Comparator, Outcome, and Study design (PECOS) approach to collect evidence and a similar approach may be followed [3].

The approach should answer the following question: In a given study, for any population (P), what is the increase in the risk of health outcome (O) per unit increase (C) in pollutants of long term (in months to years) or short-term (in the order of hours to days) exposure to the ambient level of the selected pollutant (E) for the exposure duration of interest (S)? The following section explains the criteria for selecting study design based on the evidence hierarchy. The basis for choosing appropriate studies in the Indian context is provided in Box 1.

Rigorous, high-quality epidemiological studies are the basis for sound decision-making on developing or revising air quality standards. The strength of the evidence is based on the epidemiological study design. In developing countries like India, the necessity for increased high-quality epidemiological studies, including systematic reviews, meta-analyses, and cohort studies, is evident due to their potential to provide context-specific, reliable, and comprehensive health evidence essential for formulating air quality standards. These studies account for local pollutant sources, population characteristics, and health disparities, filling data gaps and ensuring standards effectively address region-specific challenges. As air pollution significantly impacts public health in India, rigorous studies aid in accurately quantifying health risks, strengthening the scientific foundation of standards, and enabling evidence-based policy decisions that ultimately improve the well-being of the population.

Box 1: Choosing appropriate studies based on the study design and availability of studies in the Indian context

In India, most studies are either of a cross-sectional or time-series design. Cross-sectional studies can be used to determine the prevalence of health outcomes attributed to exposure at the community level. However, cross-sectional studies have limited power to evaluate the time-varying confounders. Time-series studies are used to evaluate the association between day-to-day changes between exposure and outcomes at the population level. Such studies are significant for evaluating short-term (24-hour/8-hour) standards for pollutants.

In recent years, there have been an increasing number of cohort studies in India. Cohort studies are less prone to bias and hence evidence from such studies can be given priority while developing concentration-response functions. In addition to that, they are useful in understanding the progression of an outcome in relation to the risk factor.

In the absence of Indian studies, it may not be appropriate to draw conclusions based on the studies conducted in Western countries, where the level of ambient pollution is comparatively low. Instead, evidence from regions where pollution sources and levels are comparable to those in India (e.g., China, east Asia) may be considered relevant.

When dealing with pollutants such as CO, O_3, benzene, and others, which exhibit toxicity independent of the composition of their mixtures but rather depend on the specific pollutants themselves, considering studies from various countries can be acceptable. For these pollutants, their adverse effects on health are primarily attributed to their inherent chemical properties and reactivity rather than the specific mix or source of compounds present. This allows insights and findings from studies conducted in different geographical locations to be relevant and applicable to the assessment of health risks associated with these pollutants.

In addition to epidemiological studies, evidence can be derived from controlled human exposure studies. These studies examine the health consequences in human volunteers under controlled laboratory conditions with a known exposure, environment, and activity level. However, in India, controlled human exposure studies are not available, and thus we can rely on international studies. Studies with relevant pollutant exposures (i.e., prevailing ambient level) can be considered to establish the concentration-response function.

It is worth noting that randomized controlled trials (RCTs) are relatively uncommon in the field of air pollution epidemiology. Instead, cohort studies and case-control studies are frequently employed. The primary reason for this preference is the impracticality of conducting RCTs due to ethical and cost limitations.

4.5 Formulation of safe limits for individual pollutants

Following the synthesis and integration of evidence, the final step will be deriving the permissible level for the selected pollutants. For certain pollutants where there are enough studies to conduct a meta-analysis, the exposure metrics can be converted to a standard metric, like relative risk or hazard ratio, which can be compared across other health outcomes to arrive at a safe level. In India, existing studies are not adequate to conduct such an analysis except for particulate matter.

For the pollutants where inadequate studies have been conducted, we recommend the approach outlined below:

1. Develop the concentration-response function for the pollutant and a health outcome from the evidence collected.
2. Identify the lowest level of exposure and the minimal relevant health outcome (which can be determined by the experts based on the availability of information from the selected studies).
3. Identify the lowest common level across all the critical outcomes under the scope of the review.
4. Establish the permissible level by considering all the critical health outcomes associated with a specific pollutant.

For example, the safe limit based on all-cause mortality would still allow for a significant degree of asthma given the differing relationship between exposure and these outcomes. Here the level of the selected pollutant based on the asthma outcome would be taken as the recommended level for the NAAQS. On arriving at the recommended level (short and long-term) of pollutants the expert committee can submit the report to the scientific review committee for approval.

5. THE ROLES OF THE OTHER WORKING GROUPS

5.1 Working group 2: Air quality data and modelling

5.1.1 The role of working group 2

The role of working group 2 will be to provide information on the prevailing, background and forecasted levels of the selected pollutants.

5.1.2 Background and forecasted levels of pollution

Background concentrations are defined as that portion of the measured ambient level that is not attributable to anthropogenic emissions within the study area. Forecasted air pollution refers to the projected levels of air pollutants over a specific period of time. The methodology to assess the forecasted pollution includes using air quality models by integrating data from multiple sources like emission inventories, weather forecasts, and atmospheric monitoring.

5.1.3 Current approach

In India, the breakpoints established for the Air Quality Index (AQI) calculation are also based on the background pollution levels [5]. Hence, the practice of estimating the background pollution levels and incorporating them into the policy-making process was already in place. However, it is still unclear what methods were employed to assess the background air pollution levels. The site selection criteria for placement of background monitors and the details about the available background monitors are not available in the public domain. Studies have also highlighted the importance of establishing regional monitoring stations to measure background pollution levels [24].

5.1.4 Recommended approach

It is crucial to emphasise that there has been a significant increase in the accessibility of air quality data over the years, both from ground-based monitoring networks and satellite sources. The Government of India has implemented proactive measures in facilitating the development of new capabilities related to air quality forecasting and modelling.

Advances in air quality modelling have enabled us to better estimate the relationship between the sources of pollution to simulate the ambient pollution concentrations under different policy scenarios. They have also played a critical role in enhancing the understanding of multi-pollutant air quality assessments at local, regional, national, and global scales. The models can also be used to characterise background air pollution levels. For instance, chemical transport models can be used to estimate the more spatially and temporally resolved atmospheric compositions. It can also be used to isolate the contributions from specific emission sources to the pollutant concentrations via zero-out modelling techniques [25]. In this technique, the emissions from a particular source or sector are "zeroed out" or completely removed from the model's calculations. This allows us to observe the resulting change in air quality levels due to the absence of those emissions. By comparing the air quality simulation with the emissions and without them (after zeroing them out), we can quantify the impact of that particular emission source or sector on pollutant concentrations.

The working group can consider estimating both the natural and the transboundary sources of background pollution. For example, in the case of particulate matter, the natural sources may include dust from wind erosion, sea salt, forest fires, primary bio-aerosols and biogenic hydrocarbons. Pollutants from the transboundary sources can be of both natural and anthropogenic origin.

In addition, the working group can also provide information on the seasonal and diurnal variation of pollutants as it will be crucial in establishing the averaging time and the form. It is also crucial to provide information on the interaction between the pollutants as it is useful while conducting the benefit- cost analysis explained in section 5.3 below.

5.2 Working group 3: Assessment of standards for ecologically sensitive zones

5.2.1 The role of working group 3

The role of the experts from working group 3 will be to integrate the evidence related to the effects of air pollution on soil, water, crops, vegetation, materials, animals, wildlife, weather, visibility, climate, and damage to and deterioration of property.

5.2.2 Lack of Indian studies

Air pollution affects the environment through various mechanisms like acidification, eutrophication, and photochemical damage causing harm to forests, ecosystems and vegetation. However, the number of studies conducted in this aspect in India is very low.

5.2.3 Recommended approach

The concentration-response relationship can be developed between the pollutants and their impact on natural systems, and a similar method to that proposed in Chapter 3 can be employed to determine the acceptable limits. For certain pollutants, where there are not enough studies conducted to assess the effects, a factor of safety can be assumed by the expert committee to derive standards based on the residential and industrial zone standards.

For certain pollutants, based on the available evidence, if the permissible levels obtained based on the concentration-response function are higher than those in residential and industrial zones, then the committee might not consider the concentration-response function; instead, it should derive values based on the factor of safety. For example, if the established safe level for the residential, industrial and commercial standards of $PM_{2.5}$ is 10 $\mu g/m^3$ and the assumed factor of safety is 2, then the safe level for ecologically sensitive zones should be 5 $\mu g/m^3$. Further, we recommend distinct standards for residential and industrial areas as the exposure and vulnerability of these populations differ significantly.

5.3 Working group 4: Benefit – cost analysis

5.3.1 The role of working group 4

The role of working group 4 will be to assess the anticipated benefits, such as reduced healthcare costs and improved air quality, against the potential costs of implementing new standards, such as technology upgrades and compliance expenses.

5.3.2 Global approaches

The global best practices of standard setting consider three principal approaches: 1) cost-benefit standards 2) feasibility standards and 3) health-based standards [26]. Establishing standards considering only health-based evidence will be an absolute commitment to a zero-risk level and it may ultimately lead to a standard that may be economically unviable to implement. Hence, inputs from the benefit- cost analysis (BCA) will be crucial in arriving at the appropriate level for the NAAQS.

BCA has been a fundamental tool in public policy globally for a long period. It is widely recognised as an essential step within the process of framing policies. Particularly in the case of environmental policy, where BCA forms an inherent aspect of project design and implementation. Article 130R of the Single European Act, for instance, stipulates that the community's environmental policy must include "the potential benefits and costs of action or lack of action" [27].

However, in the US, the standard-setting process doesn't consider costs, but the USEPA conducts regulatory impact analyses (RIAs) for the proposed or revised NAAQS. These RIAs inform the public and local governments about the potential benefits and costs, although they're separate from the standard selection process [28].

BCA offers a structure for comparing the monetary benefits and costs of implementing the proposed safe air quality levels. The costs can be assessed in terms of pollution-reduction control strategies. The direct control measures can be quantified in monetary terms. Yet, indirect control measures, such as changes in public behaviour, might not be quantifiable in monetary terms. However, the working group can determine which sectors or policies can be assessed for the purpose of cost estimation.

5.3.3 Recommended approach

For the benefit estimation, a set of short and long-term health (e.g., healthcare expenditure, number of hospital admission, days of labour lost, and premature death)[3] and ecosystems (e.g., crop yield, effect on building and materials) endpoints can be arrived at by consensus within working groups 1 and 3. For example, the economic value of the health benefits with respect to mortality can be evaluated based on the “value of statistical life” derived from the willingness to pay method. Similarly, in the case of morbidity, years of life lost (YLLs) or quality-adjusted life years lost (QALYs) or disability-adjusted life years lost (DALYs) methods can be used [30].

The cost assessment can take into account various sectors and major pollution mitigation initiatives. For example, the working group can consider action plans proposed under NCAP for different sectors. The assessment can compare the preferred options relative to the baseline. Table 2 offers an illustration based on chosen the NCAP action plans within selected sectors to depict the handling of benefits and costs. The costs can include present and future investments, operation and maintenance and will vary in different geographical areas.

It is also important to consider that the reduction of one pollutant may increase or decrease the concentration of another pollutant. For example, the reduction of PM may increase the levels of ozone and the reduction of SO_2, NO_x and NH_3 will reduce the level of PM as they contribute to the formation of secondary particulate matter [31],[32].

[3] The list of co-morbidity outcomes is not exhaustive. The WHO is in the process of developing a methodology to estimate the economic costs associated with morbidity outcomes. This methodology can be referred to while arriving at the morbidity health outcomes [29].

Hence working group 2 should provide information on the interaction between the pollutant components based on the baseline and modelled estimates.

The output will be the benefits in monetary terms and the total monetary cost of implementing the proposed air quality levels. The benefits of the proposed safer levels should far outweigh the implementation costs, i.e., the highest benefit-to-cost ratio.

Table 2. Illustrative allocation of benefits and costs based with regard to the NCAP

BENEFITS		
Morbidity/mortality Outcomes		Other benefits for ecologically sensitive zones
Reduction in premature deaths	Reduction in number of hospital admissions	Reduction in loss of crops
Reduction in health expenditure	Reduction in loss of productivity	Reduction in deterioration of materials
COSTS		
Industries	Road dust and construction & demolition waste	Power
Stringent emission standards	Introduction of mechanical sweepers	Utilization of natural gas/ clean fuel
Installation of continuous emission monitoring systems	Greening and landscaping	Phasing out older coal power plants
Elimination of diesel generator sets	Wall-to-wall paving of roads	Expansion of renewable power initiatives
Transport and mobility	Agriculture	Waste management
Implementation of BS VI norms all over India	Implementation of ex-situ crop residue management	Implementation of decentralized waste disposal systems
Implementation of National Biofuel Policy	Initiatives for addressing the issue of crop residue burning	Transitioning towards a zero-waste pathway
Use of Hydrogen as transport fuel	Management of emissions from fertilizers and livestock	Training and capacity building

The complexity of BCA varies depending on how benefits and costs are treated. However, there is another simpler approach where the benefits can be an "increase in human well-being" and the cost can be a "reduction in human well-being". These simpler tools are capable of yielding comparable conclusions with a high level of confidence. In instances where certain data might be lacking for a traditional BCA, these alternative methods offer a similar outcome while being more flexible in terms of data requirements. Notably, software tools like BenMAP have emerged to calculate the magnitude and the economic value of health impacts with respect to changes in air quality [33]. The calculations rely on concentration-response relationships from working group 1, coupled with population, health and economic data, background or modelled pollution data from working group 2.

5.4 Working group 5: Monitoring methods

5.4.1 The role of working group 5

The role of working group 5 encompasses evaluating various monitoring technologies, developing standardised protocols, and ensuring the reliability and consistency of data collection.

5.4.2 Current approach

Compliance with the NAAQS is determined by monitoring ambient air quality as per the reference method. CPCB lists the reference methods as one of the components of the NAAQS. The procedure for sampling and analysis for the reference methods are provided in the Guidelines for the Measurement of Ambient Air Pollutants Volume I (Manual sampling and analyses) and Volume II (Real-time sampling and analyses) [34], [35].

In addition, the Bureau of Indian Standard's (BIS) IS 5182 series provides methods to monitor air pollutants, guidelines for a number of stations, and the distribution of the monitoring network [36]. The standards are prepared by the technical committee. The technical committee is composed of almost 50 members representing pollution control boards, industries, academic, and R&D institutions [37]. The National Physical Laboratory (NPL) is working on developing the type testing, calibration & certification facility. However, there is no clarity on how these independent bodies interact during regulatory decision-making.

5.4.3 Recommended approach

The SRC can consider taking inputs from the fully functioning technical committee at the BIS and other technical institutes like National Environmental Engineering Research Institute (NEERI) and NPL or consider electing representatives from the technical institutions to form working group 5. The committee should encompass additional expert groups established by the CPCB for air quality monitoring in the context of programs like NCAP or National Air Quality Monitoring Programme (NAMP), among others.

Working group 5 can suggest suitable methods of monitoring under different categories. Globally, regulatory agencies have classified air quality instruments into four categories 1. Certified reference 2. Certified equivalent 3. Certified indicative and 4. Indicative. The classification is based on the accuracy, the sensitivity of the instruments and the cost of purchase and operation [38].

Owing to the rise of technologies and the necessity for the creation of a vast monitoring network, it becomes essential to establish equivalent and indicative methods. Researchers recommend the implementation of a hybrid monitoring network that combines high-quality regulatory monitors with low-cost sensors to gain a comprehensive understanding of pollution's temporal and spatial distribution [39], [40]. Considering the fact that the applicability of technologies varies by location based on environmental factors, the CPCB may consider excluding monitoring methods from the NAAQS and provide the reference, equivalent, and indicative methods under a separate program as done by other international regulatory agencies. The technical institutes can collaborate under the direction of the CPCB to develop, evaluate, and promulgate the approved methods. The procedure for quality assurance and calibration can be provided under the same program. Following the detailed science assessment by the working groups, the SRC can review the reports and send them for external peer review.

5.5 External peer-review

It is advised that international experts and renowned national experts who are not members of the scientific review committee are invited to conduct external peer review. The objective of the international peer review would be to assess the extent to which the revision methodology adheres to global best practices and to identify opportunities for improvement. The peer review report and the response to the review comments should be made available to the public.

6. POLICY ASSESSMENT AND RULE MAKING

6.1 Policy assessment

The purpose of conducting policy assessment is to bridge the gap between the science and economic information from the science assessment and the judgments required of the CPCB when proposing a decision as to whether the standards should be retained, revised, or revoked with respect to each of the pollutants.

Reports by the four working groups can be reviewed in detail by the SRC. The review should answer the key policy-relevant questions as decided by the SRC in consultation with the experts in the working groups. For example, the questions could be structured as follows:

1. Does the currently available scientific evidence support the adequacy of the protection afforded by the current standards? If not, what is a safer limit?
2. Is the proposed value attainable considering the background and modelled levels of pollutants? If not, what is the lowest possible level that could be met that would still be protective of human health?
3. Has the proposed level passed the benefit – cost analysis by yielding a higher level of benefits than costs?
4. Is it appropriate to consider alternative standards?
5. Is there a need to revise the averaging time and form considering the diurnal and seasonal variation of pollutants?

6.2 Rulemaking

The rulemaking component consists of three steps viz preparation of the NAAQS draft, public participation, and the release of the NAAQS.

6.2.1 Preparation of the NAAQS draft

The scientific review committee can prepare and publish a notice of the proposed NAAQS considering the information from the science assessment and the policy assessment. The report should include information about an overview of the previous revision process, the objectives and scope of the current review, minutes of the meetings, findings from the five working groups, decisions made through the policy assessment and the proposed NAAQS. The report should be made publicly accessible to enable greater consultation.

6.2.2 Public participation

Public involvement can happen at different levels as discussed in USEPA, 2014 public participation guide [41].

1. Inform – At the "Inform" level of public participation, there is no active public engagement, but rather a focus on imparting information to the public about the process. This level aims to ensure that the public is aware about committee's proceedings, aligning with the commitment to keep them well-informed throughout the process of revision.

2. Consult – Gathering inputs from the public, stakeholders, and external experts who are not part of the review committee regarding matters pertaining to establishing air quality standards. This can be done by

making draft proposals accessible to the public and soliciting their feedback, conducting public hearings, administering surveys, and organising community meetings. For instance, the European Union seeks public and expert input through public consultations to aid the revision of the ambient air quality directives as part of its impact assessment process.

3. Collaborate – To establish a process for meaningful collaboration with the public and other stakeholders in decision making. This level commits to involving and consulting the public extensively on key activities and decisions and integrating their input to the greatest extent feasible.

4. Empower (decision-making) – The level aims to establish an informed decision-making process, where the committee can implement the outcomes of the public's decisions. However, ensuring meaningful input and knowledge dissemination is challenging, making true empowerment intricate.

The review mechanism discussed in this working paper takes the public collaborative approach by involving representatives from civil society organisations, interest groups and communities in the scientific review committee. In addition to this, it is essential to have public consultation on the proposed NAAQS. It aids various stakeholders (individuals, civil society organisations, and affected communities) to have a say in decisions that affect their health and wellbeing.

The prepared report should be made available to the public for a 60-day public comment period to solicit input from the public and other professionals in the field. The public should be made aware of the availability of reports for public comments through broadcast, print and social media and the official website of the chairing and the participatory agencies. The report should be made available in major vernacular languages to enable widest possible access to the information contained in it. The comments received from the public and the reply against each comment can be made available online for making the process of public consultation transparent.

6.2.3 Release of the NAAQS

The scientific review committee can respond to all substantial comments on the proposed rule at the time of the final rulemaking. Publication of the final regulation in the Gazette concludes the MoEF&CC's rulemaking procedure. The scientific review committee can upload all necessary proposal-related documents to the public domain.

7. CONCLUSION

Setting ambient air quality standards is a complex process that fundamentally necessitates an interdisciplinary approach with consideration of the health effects, economic costs and benefits, and policy landscape within which they are notified. The lack of public information on all previous reviews of the NAAQS, what evidence they considered, and how they arrived at their conclusions raises several questions which would have been easily answerable if there was a level of transparency associated with their determination. Prior revisions also failed to include a wide enough range of disciplinary expertise including epidemiology, economics and public policy. The approach laid out in this paper aims to enshrine a set of core principles in this process including periodicity, interdisciplinarity, and transparency while centring health in the setting of any new standards. Adopting such an approach would ensure that India's standard setting process aligns with global best practices while following a time-bound and structured approach that foregrounds public participation.

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