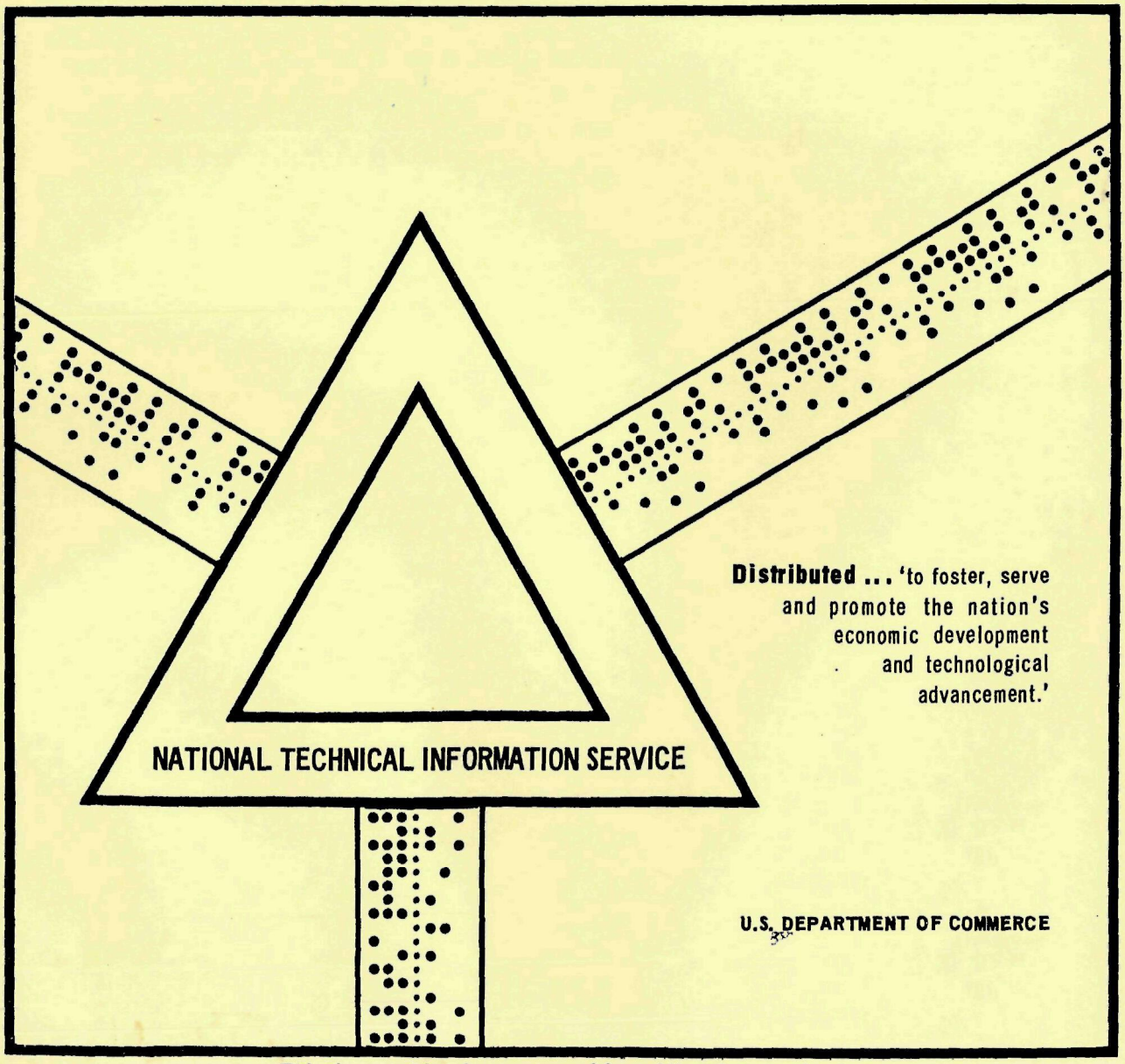
PB 199 904

BASIS FOR ESTABLISHING GUIDES FOR SHORT-TERM EXPOSURES OF THE PUBLIC TO AIR POLLUTANTS

National Academy of Sciences-National Research Council
Washington, D. C.

May 1971



Basis for Establishing Guides

for

Short-Term Exposures

of the

Public to Air Pollutants

by

The Committee on Toxicology
of the
National Academy of Sciences - National Research Council
Washington, D. C.

May 1971

Prepared under Contract No. CPA 70-57 between the National Academy of Sciences, Advisory Center on Toxicology and the Air Pollution Control Office of the Environmental Protection Agency.

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National Academy of Sciences - National Research Council
2101 Constitution Avenue
Washington, D. C. 20418
1971

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Preface

The continuing introduction of chemicals into channels of distribution for industrial, military, space exploration, and various other applications creates the possibility of relatively brief exposures of both occupational and non-occupational groups of people to air pollution from such chemicals.

Such occupational exposures were the subject of a report issued in 1964 by the Committee on Toxicology of the National Academy of Sciences-National Research Council titled "Basis for Establishing Emergency Inhalation Exposure Limits Applicable to Military and Space Chemicals." It was prepared at the request of the federal agencies sponsoring the Committee and its Advisory Center on Toxicology to meet a need within their organizations for guidance on the protection of the health of their civilian or military personnel who might briefly be exposed to atmospheric pollutants arising from the federal facilities. The report dealt only in general terms with possible similar exposures of the public.

The Clean Air Act as amended in 1970 places responsibility for public exposures to air pollutants with the Commissioner of the Air Pollution Control Office of the Environmental Protection Agency.

The assistance of the Committee on Toxicology and its Advisory Center on Toxicology of the National Academy of Sciences-National Research Council was requested in providing guidance on the establishment of standards for various pollutants occasionally released for short periods of time into the atmosphere. Their recommendations, as set forth in this report, will serve as the basis for a series of "Guides for Short-Term Exposures of the Public to Air Pollutants," each of which will be limited to specific materials.

Ralph C. Wands
Director
Advisory Center on Toxicology

SUMMARY

A. Short-term exposures of the public to air pollutants are described in two categories; those which are predictable as to time and place of their occurrence, and those which are unpredictable.

Limits for short-term exposures of either category should not be established for durations longer than 24 hours. Limits for both categories should always be subject to review as new data and new concepts are generated.

B. The factors to be considered in setting limits for predictable and unpredictable short-term public exposures are discussed. These factors include the nature and extent of effects on humans, plants and animals, and materiel. Other subjects discussed are nuisance effects, the availability of monitoring procedures, physical and chemical characteristics of the pollutant, and the presence of other pollutants.

C. The establishing of standards for short-term exposures of the public to atmospheric pollutants cannot be reduced to an arbitrary mathematical relationship. The process requires experienced judgment in evaluating pertinent information and selecting a balance of risks.

D. The kinds of data required for setting limits for predictable and unpredictable exposures are identified. Interpretation of the data and the safety factors involved in applying the data to man are discussed.

E. Short-Term Public Limits for predictable exposures and Public Emergency Limits for unpredictable exposures are defined. Predictable short-term exposures must be controlled to the point where their effect on the public health and welfare will be no greater than is acceptable under prevailing criteria and standards for ambient air quality.

Precautionary measures must be taken to reduce the possibility of unpredictable short-term exposures and to minimize their effects if they do occur. These exposures should be limited so as to be rare and unique in the lifetime of an individual and should not produce effects of a severe or irreversible degree.

Nuisance effects such as unpleasant odors might be tolerated for the brief periods with which these Guides are concerned.

F. Some of the judgmental considerations by a regulatory body for minimizing the potential overall risk to the public from short-term exposures are discussed.

I. Introduction

The Committee on Toxicology during the last several years has included in its services to the Federal Government recommendations for safe concentrations of air pollutants to which persons under direct Federal supervision might safely be exposed for brief periods of time during emergencies such as the accidental release of volatile or gaseous chemicals. The present report is an application of this experience to the protection of the public health. It contains the rationale in setting standards for short-term exposures of the public and will be followed by series of reviews on specific substances.

"Guides for Short-Term Exposures of the Public to Air Pollutants" will be developed from the concepts presented herein and will be designed to provide guidance in the control of both single and occasionally repeated, brief exposures of human communities to air pollutants. This document emphasizes protection against the adverse effects on human health and recognizes that some temporary irritation or nuisance may be acceptable on occasion. For many pollutants human health will be the only concern, however, it is recognized that for some the primary concern will be their effects on vegetation or materiel.

In developing these guidelines, consideration must be given to the presence and related effects of other pollutants and to the incorporation of appropriate safety factors.

II. Assumptions Underlying Guide Preparation

The effects of short-term or acute exposures to relatively high doses of air pollutants may be qualitatively and quantitatively different from those of long-term or chronic exposures. There may be little or no similarity between the two sets of effects. Accordingly, the protection of the public health requires careful consideration of short-term exposures in addition to and differentiated from the long-term exposures which are the subject of Air Quality Criteria and similar ambient air quality control documents.

A. Definition of Short-Term Exposures

A short-term exposure to an air pollutant is defined as exposure experienced by an individual to a pollutant released from a single source for a brief time.

The duration of such an exposure may be as much as 60 minutes under favorable conditions, although under stagnant atmospheric conditions it may last up to 24 hours or longer. There seems to be little practical significance in establishing standards for less than 10-minute

exposures, since variations in the dynamic processes of air movement and mixing lead to considerable uncertainty in predicting the amount of pollutant that might be inhaled by an exposed individual immediately after its release.

Short-term exposures will involve only a discrete downwind area and will therefore affect a limited segment of the population in the vicinity of the source. Such exposures will probably, but not necessarily, occur in a sparsely populated area.

Short-term exposures are in addition to any ambient conditions on air pollution such as those described in the documents "Air Quality Criteria" and similar publications issued by the Air Pollution Control Office for use in setting air quality standards.

B. Predictable Short-Term Exposures

Predictable short-term exposures are those occurring at predictable times and may arise from single or from occasionally repeated events. Such predictable exposures require acceptance of the concept that the general public may be required to be exposed briefly to relatively high concentrations of air pollutants (in the course of approved activities which cannot be carried out without such pollution) and that such exposures may occur again.

Such exposures occurring at predictable times can in no sense be considered as accidents. There is no justification for submitting the public to any appreciable risk in a predictable exposure. Advance provisions should be made prior to such releases of pollutants to control the public exposure. Under any set of normal operating conditions, such as rocket launching or blowing tubes in a steam boiler, it should be possible to predict reliably the timing, the duration of exposure, the concentration of pollutant, and the movement of the contaminated air mass. In many instances the time of release can be chosen to coincide with weather conditions which are optimum for minimizing the exposure.

Predictable exposures that regularly occur with high frequency will be subject to emission or ambient air quality standards rather than to short-term public exposure limits.

C. Unpredictable Short-Term Exposures

Situations will occur in which pollutants are released in an uncontrolled manner at unpredictable times and places as the result of accidents such as damage to transportation equipment or fire in a chemical storage facility. Even for such circumstances it should be possible to predict with fair accuracy the variety of probable conditions of an

accident and hence to predict the corresponding exposure parameters.

Safeguards should be taken against such accidents so that the probability of such an unpredictable release affecting an individual will be rare in his lifetime. Such an exposure would be considered an accident in its effect upon a given individual, and within this limitation, there is some justification for acceptance of a reasonable risk of reversible injury from potential public exposures.

III. Factors for Consideration in Guide Preparation

Although primary consideration must be given to factors affecting human health, secondary consideration must be given to the effects of short-term pollution episodes on plants, animals, and materiel. One or more of these latter categories may be more sensitive than humans and, thus, may constitute the limiting circumstances. Consideration of factors other than human health may require different criteria or standards.

A. Human Factors

Most of the reliable data on the toxicity of any material are the results of carefully controlled experiments on animals. Occasionally, data may be available on controlled exposures of human volunteers. Comprehensive epidemiological data can only rarely be found. Therefore, the prediction of the effects of human exposures to toxic materials requires a large measure of educated and experienced judgment.

The use of data from animal testing for predicting the effects of a substance on humans carries with it several sources of uncertainty which include:

(a) differences between individuals of the same animal species,
(b) differences between animal species,
(c) extrapolation of the data from animals to humans,
(d) differences between humans,
(e) non-uniformity of the contaminated air mass,
(f) deviations from the predicted movement of the contaminated air mass.

B. Plant and Animal Factors

There are numerous well-known examples of susceptibility of plants and animals greatly in excess of that of humans to the same pollutants. Many plants are readily damaged by traces of ethylene which have no effect upon humans or animals. Grazing animals, especially sheep and cattle, are severely affected by airborne arsenic, lead, and molybdenum

particulates that are deposited on forage and then ingested. Instances of this type are sufficiently common to justify their consideration when developing standards for short-term exposures.

C. Materiel Factors

There have been a few episodes in which brief releases of air pollutants have had significant effects upon materials in addition to generally reversible effects on the health of the exposed humans, plants, and animals. The release of gaseous sulfur compounds has caused discoloration of buildings painted with lead based paints. Corrosive gases and vapors will attack stone and metal; although the effect may not be immediately noticeable, these exposures can produce significant damage when sufficiently prolonged or repeated. The possibility of such effects should also be taken into account in arriving at short-term exposure standards.

D. Nuisance Factors

Undesirable esthetic effects such as unpleasant odors or reduced scenic visibility, and associated economic losses, should be considered in connection with predictable exposures. They are not deemed to be important factors in standards to be applied to short-term unpredictable exposures.

E. Analytical Factors

The maintenance and monitoring of air quality standards requires that suitable methods be available for sampling and analyzing air for the pollutant in question. If adequate procedures are not available the immediate need for research and development should be emphasized. Recommendations for "zero" levels are technically meaningless. If it is desirable to control a material to the lowest possible level, a phrase should be used such as "non-detectable by the most sensitive method of analysis available."

F. Physical and Chemical Factors

The physical form of a pollutant, i.e., gas, vapor, dust, or mist, may have a pronounced effect upon the route and extent of its attack. Particles up to 10 micra in diameter can be inhaled into the lungs, whereas larger particles are filtered out in the upper respiratory passages. Such properties as solubility and chemical composition will also alter the nature and degree of the effect of a pollutant. Consequently, it is essential that the pollutant be well characterized.

G. Interaction Factors

Exposure of the public to atmospheric pollutants is seldom, if ever, to a single compound. The effects of any pollutant involved in a short-term episode may be modified by interaction with one or more ambient pollutants. The interaction may be physical, as in the case of adsorption of gases on solid particulates; it may be chemical, as in photochemical smog; it may be biological, where the toxic effects are modified either in degree or in nature as in thickening of the alveolar barrier by NO_2. It is,therefore, important that information be obtained on the composition of the ambient air at the anticipated site of the short-term exposure.

IV. Cause and Effect Relationships

As far as is known all living systems have some ability to withstand injury from toxic materials. This resistance may be due to mechanisms which prevent absorption of the toxicant, rapidly excrete it, metabolize and detoxify it, or increase the rate of repair of injured tissues. These mechanisms are sometimes inherent in the organism and are sometimes enhanced or acquired in response to toxic stress. Whenever the capacity of these protective mechanisms is exceeded by the applied toxic stress the effect will become observable. Beyond this point of no biologically significant effect from a finite dose, the extent of the effect, i.e., the degree of injury, will increase with an increasing dosage of toxicant with death of the organism as the upper limit. The relationship between causative dosage and resultant effect is not necessarily a constant proportionality over the entire range. This lack of proportionality in dosage-effect relationships makes extrapolations much beyond the range of available data unreliable.

A. Acquisition of Data

The data necessary to evaluate the relationship between exposure to a pollutant and its effects on the population at risk are not always available. For many air pollutants further study will be needed and the following kinds of information are desired as a minimum. Experimental data should be derived from studies on at least two susceptible species. They are presented in relationship to human health concerns, but the principles involved apply to other concerns.

1. The most sensitive target organ(s) or body system(s) to be affected by the short-term air contaminant;

2. A full characterization of the nature of the effect upon the target(s);

3. The range of the time-concentration relationship for the target(s) from no effect to severe effects;

4. The rate of recovery from reversible effects;

5. The nature and severity of injury at which the effect ceases to be reversible;

6. Identification of cumulative effects, if any;

7. The combined effects, if any, of the toxicant with other air pollutants and the concentrations at which the combined effects occur;

8. Identification of types of functional abnormalities and pathological states among the potentially exposed population which may render such individuals more susceptible to the pollutant.

B. Interpretation of Data

The interpretation of the information derived from animal experiments requires mature, experienced, scientific judgment from a variety of professional disciplines. The evaluation should consider the conditions under which the data were obtained and, in particular, their relevance to the conditions of human exposure. How closely do the test species and the target organ compare in morphology, sensitivity of response, and metabolism with that of man? Were the observed animal responses the consequences of exposure conditions to which the public may be subjected?

C. Translation of Animal Data to Man and Determination of Safety Factors

Development of Guides for Short-Term Public Exposures requires that animal data must be translated as quantitatively as can be estimated to human response. The response of the "most sensitive" species should be used to arrive at the preliminary baseline for ultimate determination of the appropriate exposure level. The use of data from animal experiments, tissue culture, and the like may yield values surrounded by considerable uncertainty. If data from human exposures are available they may result in levels of considerable reliability. Obviously, reliable human information is the one of choice and should be obtained and utilized whenever possible except when the response indicated from animal experiments is life-threatening (e.g. cancer).

There are genetic variations among humans that may have a potential effect on their susceptibility to air pollutants. Examples are: allergic asthma, familial pulmonary emphysema and serum antitrypsin deficiency;

susceptibility to lead poisoning and deficiency of the enzyme glucose-6-phosphate dehydrogenase in the red blood cells; male susceptibility to chronic granulomatous disease and leucocyte deficiency of glucose-6-phosphate dehydrogenase; sickle cell anemia and enhanced risk from effects of carbon monoxide.

In the absence of dependable values for maximum no-effect doses, resort must be had to the incorporation of safety factors. These safety factors should be of a magnitude commensurate with (1) the severity of the response, (2) degree of hypersusceptibility related to (a) preexisting disease, such as respiratory disease, (b) heredity, (c) nutritional state, or (d) age, (3) extent of physical exertion, and (4) uniqueness of man's response, e.g., hypersensitivity of the respiratory tract.

V. Selection of Standards: Short-Term Public Limits (STPL's) and Public Emergency Limits (PEL's)

A. Definitions

Short-Term Public Limits are those for predictable exposures known to be safe for man. They differ from air quality standards only in that the concentration may be higher since the exposure is shorter and less frequent.

Public Emergency Limits relate to unpredictable exposures and they differ from short-term limits in that the levels selected are those known to cause only minor and fully reversible injury. They are levels such as those the public would voluntarily tolerate if necessary as a part of civil defense, or defense of neighborhood property as in the case of a fire.

B. Balance of Risks

Selecting an upper limit for the concentration of an air pollutant for a short-term exposure of the public entails a choice of the least risk to the public health of all the risks to the public associated with the operation releasing the pollutant. It thus involves a study not only of the effects such as those which have already been described but also an equally careful review of the source of the pollutant and the reasons for its presence.

Studies may be needed in order that the Commissioner can relate the risk to health of short-term exposures to the alternate risks which might accrue to the public if the operation were to be abandoned or conducted at varying degrees of control.

An example is the firing of a rocket motor during research, development, training, or launch operations by a federal agency such as

PB 199 404

STANDARD TITLE PAGE FOR TECHNICAL REPORTS	1. Report No. APTD-0684	2. Gov't Accession No.	3. Recipient's Catalog No.

4. Title and Subtitle
Basis for Establishing Guides for Short-Term Exposures of the Public to Air Pollutants

5. Report Date
May 1971

6. Performing Organization Code

7. Author(s)

8. Performing Organization Rept. No.

9. Performing Organization Name and Address
The Committee on Toxicology of the National Academy of Sciences - National Research Council
2101 Constitution AVenue
Washington, D. C. 20418

10. Project/Task/Work Unit No.

11. Contract/Grant No.
CPA 70-57

12. Sponsoring Agency Name and Address
Division of Health Effects Research
Air Pollution Control Office
Environmental Protection Agency
Durham, North Carolina 27701

13. Type of Report & Period Covered

14. Sponsoring Agency Code

15. Supplementary Notes

16. Abstracts
The basic rationale used in the preparation of a series of guides for short-term exposure to air pollutants are presented. The assumptions underlying guide preparation are given. The factors and considerations in guide preparation are outlined. The evaluation of the relationship between exposure to a pollutant and its effect on the population are discussed. Also included is a discussion of the selection of short-term Public Limits and Public Emergency Limits.

(Appr. Ref. Doc.)

17. Key Words and Document Analysis. (a). Descriptors
Air pollution
Contaminants
Toxicology
Exposure
Standards
Public Health

17b. Identifiers/Open-Ended Terms
Public Emergency Limits
Short-Term Public Limits
Air Pollution effects (humans)

17c. COSATI Field/Group 13B, 6T

18. Distribution Statement	19. Security Class (This Report)	21. No. of Pages
Unlimited	UNCLASSIFIED	16
	20. Security Class. (This Page) UNCLASSIFIED	22. Price

FORM NBS-667(1-70)

DISCLAIMER

This report was furnished to the Air Pollution Control Office by

The Committee on Toxicology of the National Academy of Sciences - National Research Council
2101 Constitution Avenue
Washington, D. C. 20418

in fulfillment of Contract No. CPA 70-57

the National Aeronautics and Space Administration or the Department of Defense. When the risks have been evaluated, the Commissioner can provide the agency with the appropriate options to reduce those risks to the public to acceptable levels by setting short-term limits for predictable exposures.

An example involving the private sector is the testing of a new firefighting technique or the training of firemen. The extent of public exposure to smoke, the firefighting agent, and its pyrolysis products are predictable. Among the risks to be evaluated and balanced would be the health and other effects which are the subject of these Guides, and the risk to the public of being deprived of adequate fire protection.

Associated with both of the foregoing examples is another risk which is the possibility of the accidental release of the rocket fuels or firefighting agents as the result of a spill. These would be unpredictable exposures and would be the subject of Public Emergency Limits.

C. Acceptable Risks

The risk to the public health must be appraised from the view of establishing what, if any, is an acceptable level of effect. One of the important factors to be considered is the duration and frequency of the exposure. Certainly, any severe or permanent disability cannot be tolerated. Even a minor effect such as a mildly unpleasant odor or slight irritation of the eyes and nose becomes sufficiently objectionable, if of frequent occurrence, to be a consideration in the selection of a Short-Term Public Limit. There is no justification for subjecting the public to any appreciable risk in a predictable exposure.

The risks associated with unpredictable exposures require for their full evaluation a consideration of the probability of an accident. Such risks can never be reduced absolutely to zero but by proper planning of operations and equipment design they can be minimized. Exposure to an accidental release of an air pollutant should be a rare and unique event in the lifetime of any individual. In some instances the objective may be sufficiently important to justify accepting some probability of an accident associated with some degree of risk of reversible effects from exposure to a pollutant. There should be no acceptance of any possibility of irreversible injury from accidental exposure to a pollutant.