



THE WHO ENVIRONMENTAL HEALTH CRITERIA PROGRAMME*

by

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* Information paper prepared for a meeting of the Sub-Committee on the Toxicology of Metals of The Permanent Commission and International Association of Occupational Health, Tokyo 18-23 November 1974.

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1. Introduction

Considering that criteria and standards for the quality of the environment are essential for planning and implementing national programmes in environmental health, the World Health Organization has given considerable attention to this subject during the last two decades. The International Standards for Drinking Water were first published in 1958, revised in 1963 and again in 1970¹. Annual meetings of the Joint FAO/WHO Expert Committee on Food Additives and Contaminants have been convened since 1956². The FAO/WHO meetings on pesticide residues³ held since 1961 have evaluated more than 100 substances. The Joint ILO/WHO Committee on Occupational Health in its 6th Report⁴ evaluated national recommendations and standards for occupational exposure to airborne toxic substances but found that safe concentration zones could be recommended for international adoption for only 26 substances. A new programme of the International Agency for Research on Cancer on the evaluation of the carcinogenic risk of chemicals to man has been in progress since 1970⁵. Air quality criteria and guides for sulphur dioxide and suspended particulates, carbon monoxide and photochemical oxidants were published in 1972⁶. As regards ionizing radiation, WHO has closely collaborated with the International Labour Organization, the United Nations Committee on the Scientific Effects of Atomic Radiation, the International Atomic Energy Agency, the International Commission on Radiation Protection and the International Commission on Radiation Units and Measurements. Other activities included the evaluation of the effects of noise, heat stress⁸ and altitude, and environmental health criteria for urban planning⁹.

An accelerated, expanded and integrated programme on environmental health criteria has been developed more recently in response to a number of World Health Assembly Resolutions¹⁰ taking into account the relevant recommendations of the UN Conference on the Human Environment in Stockholm in 1972¹¹ and of the Governing Council of the United Nations Environment Programme (UNEP)¹².

2. Concepts of criteria and standards for environmental quality

It is obviously impractical to try to eliminate the health risks from chemicals and other environmental hazards by ensuring that no pollutants escape or that no hazardous chemicals or devices are used. The alternative approach is to reduce the levels of environmental pollutants and hazards below the values which are thought to be harmful to health. This second approach depends on the knowledge of how changes in concentration of a chemical, or in the intensity of a physical hazard, influence man's health. It has become common to use the term "criteria" to designate "the relationships between exposure to pollutants (or other environmental factors) and the risk or magnitude of undesirable effects under specified circumstances defined by environmental and target variables."¹³

In practice it is usually difficult to obtain reliable information on exposure and response in man. The effects of environmental exposure may be immediate (within a few weeks) following a short-term, single or repeated exposure; this type of effect has generally been studied in conventional toxicological experiments on animals. Epidemiological studies, on the other hand, are usually concerned with the chronic effects of long-term exposure. There is much less reliable information on the chronic effects of acute exposure, or on the acute effects of long-term exposure. Such information is difficult to obtain because cause and effect are often separated in time, sometimes for 20 years or more as is the case with chemical carcinogens. Other complications relate to the presence of various modifying factors in the environment and their interaction, and to the biological variability of the target. In addition, if contact with the hazardous agent is spread over a long time, it is possible that exposure or effects, or both, will be cumulative; on the other hand it is also possible that chronic low-level exposure is counteracted by the processes of biological repair so that considerable total exposure may be without appreciable effect.¹⁴

Difficulties also exist with regard to the definition and measurement of exposure. The mere presence of pollutants in the environment should not be identified with "exposure" which has been defined as "the amount of a particular physical or chemical agent that reaches the target"¹⁵, to which we should add "under specified circumstances", to remove the objections that this definition raised, for example at a WHO Scientific Group¹⁶, that the concept of exposure should include concentration (or intensity of a physical factor), length of time and frequency, in addition to the amount of the substance that reaches the target.

Leaving aside the question of how to obtain reliable and meaningful data on exposure/effect relationships, we are still left with the problem of setting exposure limits such that the health of man is protected. There are two possible approaches. One is based on the concept of a threshold, i.e. the level of exposure at which no adverse effect can be expected, no matter how long the exposure is. There is considerable support for this concept in occupational health experience where systematic reduction in levels of exposure resulted in reduction of frequency of occurrence and seriousness of effects of a specific environmental agent, and in the elimination of demonstrable specific occupational disease when exposure was kept below established threshold levels.^{17,18} The other approach that has been used particularly in limiting the dose of ionizing radiation is based on the assumption that any exposure may involve some degree of risk; in other words, only the zero level of exposure is completely safe. If this is the case, the setting of exposure limits should be guided by the principle that "any unnecessary exposure should be avoided, and that all doses should be kept as low as possible, economic and social considerations being taken into account" and "that doses should be justifiable by the expected benefits"¹⁹. The practical application of this principle in radiation protection has recently been reviewed.²⁰ Although for most biological effects of chemicals it is assumed that a threshold or a no-adverse effect level exists, this has been questioned for mutagenesis and carcinogenesis. A recent review of the problem may be found in the report of a WHO Scientific Group²¹ which concluded that "the possible existence of a threshold for the effects of both chemical carcinogens and mutagens should be envisaged". However, "the difficulties of determining thresholds for a population are great" and "mathematically derived conclusions that it is impossible to demonstrate a no-effect level experimentally cannot be ignored". If this conclusion is accepted, a careful risk/benefit analysis should be made in each case before acceptable exposure limits can be established for substances which may be carcinogens and/or mutagens. This may be a very difficult task, particularly for environmental pollutants because in most cases the populations or individuals at risk are not the same as those who may benefit from an activity that results in environmental pollution. The most difficult consideration in establishing exposure limits is the possibility of interaction among the various environmental factors. Synergism, of course, presents the most serious problem, although it may be observed only at certain exposure levels, while at very low levels there may be no evidence of any synergistic or antagonistic action.¹⁴

Determination of criteria is essentially a scientific task. The setting of exposure limits and particularly of legal standards for environmental quality is a matter of policy decision. When setting standards, cost/benefit considerations become important as well as the technological feasibility of achieving the standards and other priorities a country may have in the field of health protection. It should also be made clear what standards we wish to set: for desirable conditions, for minimum requirements, for maximum permissible conditions, or for specific conditions such as emergencies¹⁴.

* "target (or receptor): the organism, population or resource to be protected from specific risks"¹⁵

3. Objectives of the WHO environmental health criteria programme

The main objective of this programme, for which a substantial support has been received from the United Nations Environment Programme (UNEP), is to assess existing information on the relationships between exposure to environmental hazards and effects on man's health by preparing balanced and critical reviews of work done in the WHO Member States on health effects research into specific priority pollutants, and to provide guidelines for the establishment of "primary protection standards",* wherever possible; such reviews are called "criteria documents".

Other objectives are:

- a. to identify new or potential pollutants by technological surveillance and forecasting; and by preparing "preliminary reviews" of substances which are likely to be increasingly used in industry and/or in chemical consumer products;
- b. to identify gaps in knowledge on health effects of recognized or potential pollutants, and to stimulate national and international research in areas where information is inadequate;
- c. to promote the harmonization of toxicological and epidemiological methods so as to obtain internationally comparable results.

4. Scope and contents of criteria documents

Since the environmental health criteria documents are addressed primarily to environmental health administrators responsible for decision making, the documents do not aim at covering all the information available on a given substance; only the information that is considered valid and relevant to the establishment of exposure (dose)-effect relationships are included.

As a rule environmental health criteria documents contain information on the chemical and physical properties of the pollutant, on sources of environmental pollution, on environmental exposure levels (in air, water, food, in the working environment and other conditions of exposure); on environmental distribution, transport, transformation and bio-concentration; on uptake, distribution in and elimination from the organism; on metabolism and biochemical effects; experimental toxicity studies, including interactions (such as synergism and antagonism); epidemiological and case (clinical) studies; estimates of the total human exposure from all sources and on quantitative aspects of exposure-effect relationships; maximum permissible levels as established in different countries for various environmental media, including occupational exposure; and guidelines for the establishment of "primary protection standards".

Preliminary reviews of potential pollutants are similar in scope and contents but the process for their preparation is different (see section 6); particular attention is given to the estimates of the future production and use and to research needed to fill the gaps in toxicological knowledge; no attempt is being made to provide guidance on the primary protection standards.

* i.e. "an accepted maximum level of a pollutant (or its indicator) in the target, or some part thereof, or an accepted maximum intake of a pollutant or nuisance into the target under specified circumstances"¹⁵

Both criteria documents and preliminary reviews are based on published scientific papers and reports and on information obtained from recognized scientific groups and research institutes. Unpublished data collected, evaluated and transmitted to WHO by governmental authorities and research institutes may also be included. Abstract literature is a useful source of information, but criteria documents and preliminary reviews should not be based on it. For each reference to a published paper or a report referred to in a criteria document or a review, a hard copy or a microfiche is kept in the WHO secretariat.

5. Priorities

Considering that some half a million chemicals are currently used and that about 10,000 or so are produced annually in amounts between 500 and 1,000,000 kilogrammes²³ and that in addition a variety of physical hazards have to be considered, a practicable programme for the preparation of criteria documents must be based on clearly defined priorities. The list of priorities for the WHO programme in this area has been established by a WHO scientific group¹⁶ and it is based on the following considerations¹³:

- "a. severity of adverse effects on the population; irreversible or chronic effects, those which have adverse genetic implications, and those which are embryotoxic and teratogenic, are considered to be of particular importance;
- b. persistence of the agent in the environment, resistance to environmental degradation and accumulation in man or in the food chain;
- c. metabolic degradation or synthesis in biological systems which may produce metabolites either more or less toxic than the parent compound;
- d. ubiquity and abundance of the agents in man's environment particularly those occurring naturally or produced inadvertently;
- e. size, type and demographic characteristics of population exposed, the frequency and magnitude of exposure, and selected exposure of highly vulnerable groups of the population."

The full list¹⁶ contains some 70 chemical and physical hazards, and it will be periodically reviewed.* In preparing this list it has been realised that each country must interpret environmental health problems in terms of its own national situation and establish its own priorities, which may not have been covered by this list. Based on this list a short-list has been prepared covering the 1973-1976 period (Table 1).

The metallic elements that have been given priority in the WHO programme are shown in table 2.

6. Preparation of criteria documents and preliminary reviews

The WHO programme on environmental health criteria depends on international collaboration in the use of the information and capabilities available in the member states and in other international organizations. Three different procedures are applied in the preparation of criteria documents and preliminary reviews.

* See Annex A

Table 1: Priorities for the Preparation of WHO Criteria Documents and Preliminary Reviews

	to be initiated* in	
	1973	1974
Criteria documents	manganese nitrates, nitrites nitrosamines PCBs mycotoxins cadmium mercury lead oxides of nitrogen asbestos noise	nickel vanadium sulfates, H ₂ SO ₄ aerosol flourine selected chlorinated biocides and chlorine arsenic beryllium chromium SO ₂ and suspended particulates carbon monoxide ozone and oxidants selected polycyclic hydrocarbons carbon disulfide
Preliminary reviews	Sb, Bi Se, Mo, Te Ti, Ge, Sn organic dusts selected products of petroleum industry	Li Ba La, Al, Ga, Zn Fe, Co, Pd, Pt selected plastics and plasticizers

* and completed by 1976/77

Note: selected compounds of the elements listed will also be considered.

a. Preparation of new criteria documents:

As a rule the criteria documents are prepared in four stages:

1. the preparation of national contributions, i.e. reviews of relevant research results obtained in a given country;
2. the consolidation of national contributions into draft criteria documents. This is done on a contractual basis with individual experts or WHO collaborating centres;

Table 2:

Metallic elements which received
priority in the WHO environmental health
criteria programme*

Periodic systems	Criteria documents	Preliminary reviews
I	<u>Cu</u>	Li
II	Be, Zn, Cd, Hg	Ba
III		<u>La</u> , Al, Ga, In
IV	Pb	<u>Tl</u> , (Ge), Sn
V	<u>V</u> , (As)	Sb, Bi
VI	<u>Cr</u> , (Se)	<u>Mo</u> , (Te)
VII	<u>Mn</u>	
VIII	<u>Ni</u>	<u>Fe</u> , <u>Co</u> , <u>Pd</u> , <u>Pt</u>

* Based on the Table in Annex A

Note: Transition elements are underlined; the elements in brackets are not considered as metallic, although certain properties make them similar to metals in some respects and under certain conditions.

3. circulation of draft criteria documents to national institutes (designated by governments as focal points for collaboration with WHO in this programme) for comments and additions.*
4. review and assessment of draft documents by meetings of groups of internationally recognized experts;

The total time estimated for preparing such documents is about 18-24 months from the moment the outlines are circulated by WHO secretariat to the national institutes.

National contributions to the criteria documents are prepared in English or French. They consist of a review data on health effects of environmental pollutants in relation to the level of exposure as revealed by experimental, clinical and epidemiological studies, and of other relevant information from research carried out in each country and published in national or international scientific journals or official publications²⁴. In order to facilitate the integration of national contributions into draft criteria documents, detailed outlines are prepared by the WHO secretariat for each environmental agent considered, in order to avoid omission and preventing the inclusion of less essential information. The national institutes are requested to follow these outlines as closely as possible.

National institutes are also requested that all publications referred to in the review are attached as a hard copy (reprint) or a microfiche. If a paper has been published in a language other than English or French, the bibliographical reference should contain a short summary of the paper in English or French, in addition to the reprint.

b. Preparation of criteria documents based on existing documentation:

This procedure has been recommended¹³ in cases where much preparatory work has been done and where criteria-like documents (either WHO or national) already exist. The document is prepared in four stages:

- a. preparation of a draft criteria document based on an outline prepared by WHO secretariat. This work is done on contract with recognized experts or specialist institutes;
- b. circulation of draft documents to national institutes for comments and additions;
- c. revision of draft documents based on national comments. This is done either by the WHO secretariat or as part of the contractual agreement under a;
- d. review of final draft documents by meetings of groups of internationally recognized experts;

The total estimated time for the preparation of documents using this method is 12-18 months.

The meeting of experts is also expected to provide guidance on the primary protection standards and to give recommendations on other research needed to improve the data base for the establishment of criteria.

* This stage may be omitted if a sufficient number of national reviews had been received at stage 1.

c. Preliminary reviews:

Expert assessment of a large number of chemicals and other hazards is required to facilitate sound judgement on the need for the preparation of international environmental health criteria documents and for further research efforts. This is the objective of preliminary reviews which will give a better perspective to the whole programme and facilitate the choice of priorities.

A short-cut procedure is used in this case consisting of two stages:

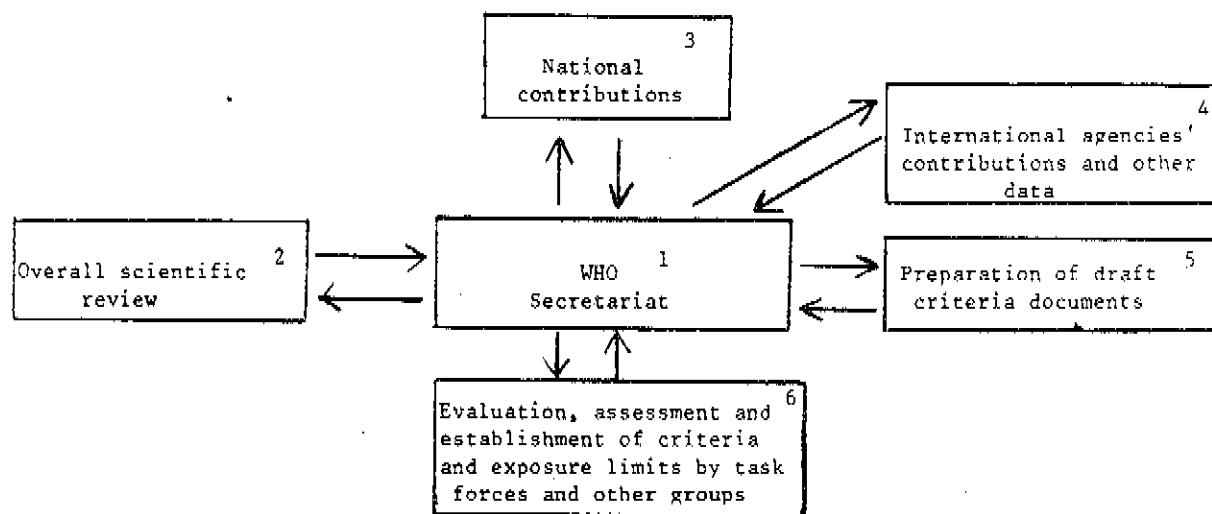
1. preparation of draft preliminary reviews according to an outline prepared by the WHO secretariat* This is done by contracts with recognized experts.
2. a review of this draft by a meeting of internationally recognized experts.

Estimated time for the preparation of the preliminary reviews is 8-12 months for one substance (or a group of 2-3 substances.)

Figure 1 shows schematically the arrangements for the preparation of criteria documents.

Figure 1

Schematic diagram indicating the steps in
the WHO Environmental Health Criteria Programmes 13



Overall scientific reviews indicated in box 2 of Figure 1 are planned to meet periodically every 2-3 years to review the progress of the programme and particularly the priorities for further work.

As indicated in box 4 of Figure 1, WHO will continue and intensify its collaboration with other organizations of the United Nations family who can contribute to this programme, other inter-governmental organizations such as the Organization for Economic Cooperation and Development (OECD), the Council for Mutual Economic Assistance (CMEA) and the Commission of the European Communities (CEC).

* See Annex B

Many non-governmental organizations in official relations with the WHO and others can also contribute, and working relations will be continued and strengthened with organizations such as the Permanent Commission and International Association of Occupational Medicine (IAOM), the International Council of Scientific Unions (ICSU), the International Commission of Radiological Protection (ICRP) and others.

The arrangements for collaboration with national and international bodies also apply to the other three objectives of the WHO environmental health criteria programme discussed in section 3.

7. Progress made in implementing the programme

The Director General has invited all Member States and a number of international organizations to collaborate in this programme, while WHO regional offices have approached Member States in the region to ascertain their participation. So far arrangements have been made with about 30 member states.

National contributions were requested on the effects of manganese and its compounds nitrates, nitrites and nitrosamines, poly-chlorinated biphenyls and mycotoxins, and the consolidation of information received is in progress. Draft preliminary reviews have been completed for cadmium, mercury, lead, carbon disulfide and noise. In preparation are the draft criteria documents for oxides of nitrogen; asbestos; oxides of sulphur (including sulphates and sulphuric acid aerosol) and suspended particulate matter; ozone and oxidants.

Preliminary reviews have been completed for selenium, molybdenum and tellurium and evaluated by a task group which met in July 1974. The group recommended that selenium be further studied in view of preparing a criteria document. Draft preliminary reviews have also been prepared for titanium, germanium and are in preparation for tin and selected products of the petroleum industry.

The meetings of experts to review draft documents and preliminary reviews of substances listed in the 1973 column of table 1 are planned for the first half of 1975.

A study group was also convened in Geneva in September 1974 to review the available methods for identifying new and potential environmental pollutants and other hazards and some areas which need immediate attention, such as the environmental health impact of changes in energy production, trends in materials technology (including the use of platinum metals, lanthanides and some other transition metals) and new developments in chemical pest control.

8. References

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ANNEX A

SUGGESTED PRIORITIES FOR ENVIRONMENTAL HEALTH CRITERIA
FORMULATION AND REVIEW (1973-76)

Priority	(1) Preparation of new criteria documents	(2) Review, extension and evaluation of existing WHO documents	(3) Review and assessment of national criteria documents by WHO as they become available	(4) Preliminary expert assessment and further research
A	oxides of nitrogen nitrates, nitrites and nitrosamines manganese polychlorinated biphenyls noise and vibrations	cadmium lead mercury photochemical oxidants and reactive hydro- carbons	arsenic beryllium chromium copper nickel selenium vanadium zinc	antimony bismuth cobalt lithium palladium platinum tin ammonia mercaptans marine biotoxins organic dusts laser beams
B	mycotoxins microwaves	carbon monoxide sulfur dioxide and suspended particulates asbestos carbamate pesticides polycyclic organic matter	estrogens goitrogens phytotoxins	barium germanium lanthanum molybdenum titanium tellurium
C	sulfite-sulfate-sulfuric acid aerosols	chlorinated pesticides thermal environment, climatic factors, and altitude	chlorine and hydro- chloric acid phenols phthalates surfactive agents growth promoters ultraviolet and solar radiation	aluminum gallium indium iron strong alkalis talc and silicates inert dusts acrolein alkyl-chlorides benzene, toluene, and xylene formaldehyde fluorocarbons organobromine compounds organic isocyanates coal tar volatiles and asphalt other volatile hydrocarbons mineral spirits petroleum distillates epoxy resins styrene and polystyrenes industrial and consumer enzymes anticorrosives barometric pressure changes infrared radiation

General outline for the preparation of criteria documents and preliminary reviews on environmental chemicals*

1. Overview of environmental health problems related to the substance considered.
2. Chemical composition and properties
 - 2.1 chemical and physical properties
 - 2.2 nature and content of impurities in the substance considered**
 - 2.3 analytical methods:
 - 2.3.1 sampling procedures, sample preparation, analytical methods in general, their sensitivity, limits of detection, interferences
 - 2.3.2 analytical methods used for specific sources and environmental media (air, water, soil, plants, food, working environment; biological tissues and fluids)
 - 2.4 references
3. Sources of environmental pollution
 - 3.1 natural occurrence
 - 3.2 industrial production, production data and projections - past, present and future
 - 3.3 use patterns - by industries and by the general public, extent of use, controlled or uncontrolled
 - 3.4 disposal of wastes
 - 3.5 accidental releases during transport, etc.
 - 3.6 references
4. Environmental exposure levels
 - 4.1 levels in air, water, soil, plants, food
 - 4.2 occupational and other situations of exposure (e.g. home)
 - 4.3 estimate of effective human exposure from all environmental media (daily or weekly intakes)
 - 4.4 references
5. Environmental distribution and transformations
 - 5.1 transportation and distribution between media
 - 5.2 environmental transformations and degradation processes
 - 5.3 interaction with other physical, chemical or biological factors
 - 5.4 bioconcentration
 - 5.5 references

* This outline has to be appropriately modified for certain types of substances (e.g. typical air pollutants)

** This section is included when appropriate

6. Kinetics of distribution in mammalian organisms (absorption, storage, elimination), metabolism; biochemical effects
 - 6.1 dermal, respiratory tract, gastro-intestinal tract contact
 - 6.2 uptake and distribution, blood, lymphatics, storage organ or tissues, target organ or tissues
 - 6.3 body burden and critical organ burden - levels in body tissues and fluids
 - 6.4 elimination, including excretion into milk or transplacentally, rate of excretion
 - 6.5 metabolic transformation and rate of elimination of products
 - 6.6 biological half life
 - 6.7 individual variations - strain and species comparisons
 - 6.8 biochemical effects
 - 6.9 references

7. Experimental toxicity studies with pure or commercial products
 - 7.1 experimental animals
 - 7.1.1 acute studies, LD₅₀ data, no adverse effect level, interactions; species comparisons
 - 7.1.2 sub-acute and chronic studies
 - 7.1.2.1 reversible changes, physiological, biochemical, morphological
 - 7.1.2.2 irreversible changes, pathological and histopathological, toxicity to specific organs, carcinogenicity, mutagenicity, fetotoxicity and teratogenicity
 - 7.1.2.3 interactions with other physical or chemical factors
 - 7.1.2.4 interactions with disease factors - genetic, nutritional, infectious etc.
 - 7.1.3 biochemical and physiological mechanisms of toxicity
 - 7.2 experiments on human subjects (healthy volunteers or cooperating patients)
 - 7.3 references

8. Epidemiological and case studies
 - 8.1 epidemiologic studies - mortality, morbidity
 - 8.1.1 occupational groups
 - 8.1.2 general population groups
 - 8.1.3 high (accidental) exposure groups
 - 8.2 clinical studies, pathological findings and progression of disease
 - 8.3 evaluation of other factors increasing the risk: pre-existing disease, genetic, nutritional, other factors
 - 8.4 references

9. Dose-response relationships
 - 9.1 intra-species variation in response
 - 9.2 inter-species variation in response, suspected causes of variation, host factors, external factors, nutritional, environmental, synergistic, additive, antagonistic
 - 9.3 references

10. Maximum permissible levels in different media (literature data)
 - 10.1 MPL's in air, water, food, working environment
 - 10.2 risk/benefit evaluations
 - 10.3 references

11. Guidelines for the establishment of primary protection standards
(this section does not apply to preliminary reviews)