

Sarah.

MEMORANDUM

TO: CELA WATER COMMITTEE - Sarah, Kate, Anne, Isabel

FROM: TOBY VIGOD

DATE: FEBRUARY 11, 1986

RE: STANDARD SETTING

Attached please find the latest minutes and draft paper entitled, "Public Involvement in the Setting of Human Health Standards for Drinking and Ambient Waters".

My comments are due by the 21st. If possible, could you call me or send back a marked up version with your comments by the beginning of next week.

I think we're finally making some progress. Let me know what you think.



Ministry
of the
Environment

Ministère
de
l'Environnement

RECEIVED FEB 10 1986

Mr. J. Vigod

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MEMORANDUM

February 3, 1986

TO: Members of the Public Interest Liaison
Committee on Drinking Water Issues

FROM: P. J. Crabtree
Secretary
Public Interest Liaison Committee
on Drinking Water Issues

RE: Meeting Notes and Draft Paper

I am enclosing copies of the draft notes from the eighth meeting of the Committee held on December 19, 1985, and of the draft paper entitled "Public Involvement in the Setting of Human Health Standards for Drinking and Ambient Waters".

Please review both of these documents, and let me have your comments on them no later than February 21, 1986. After any changes have been made to the draft paper, the Chairman, Mr. Walter Giles, will brief his colleagues prior to the document being circulated for comment outside the Committee and the Ministry.

Peter Crabtree

PJC/cj
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Encl.



DRAFT

PUBLIC INTEREST LIAISON COMMITTEE
ON DRINKING WATER ISSUES

Notes from the eighth meeting of the Committee held at the Ministry of the Environment's Laboratories in Rexdale on Thursday, December 19, 1985.

Present:

J. W. Giles, Chairman, MOE
G. Bagshaw, Regional Municipality of
Niagara & M.E.A.
T. Davey, Environmental Writer
T. Fowle, AWWA
K. Millyard, Pollution Probe
T. Vigod, CELA
K. Newman, MOE
K. Roberts, MOE
A. Vajdic, MOE
P. J. Crabtree (Secretary), MOE

Absent:

O. Oleksuk
M. Howe

1. Matters Arising from Previous Notes

T. Fowle made the following point:

Page 2, second paragraph. The emphasis regarding the circulation of information on drinking water analyses was that an exceedance of a limit should not be automatically advertised; it may not represent a health hazard.

2. Public Involvement

T. Vigod generally supported the discussion paper entitled "Public Involvement in the Setting of Standards/Objectives for Drinking Water" (P.I. Discussion Paper), but questioned the constitution of the proposed standards advisory committee. She felt that an extended PILCODWI would not be appropriate. K. Millyard agreed.

The Chairman said he saw this discussion as providing groundwork for standard setting across the board, not limited to drinking water. K. Roberts said that a committee to address all standards would be large, in order to handle the full range of media.

K. Millyard liked the concept of an advisory committee to oversee all standards, with separate sub-committees dealing with each medium (of which drinking water would be one). The sub-committee members would not necessarily be experts, but would have access to technical staff and contract expertise.

T. Fowle supported the need to look at all standards for contaminants in water and air, not limited to drinking water. Members also agreed that the advisory committee should set priorities for the standard setting process.

A. Vajdic pointed out the need for getting approval for a large number of standards quickly. K. Roberts stressed that this would call for regular meetings of the committee, and a commitment by its members to provide the necessary time.

T. Fowle proposed federal representation on the advisory committee to bring in the Health & Welfare perspective and responsibility. The Chairman outlined the present federal/provincial level of cooperation through CCREM, and K. Roberts referred to the existing working groups dealing with drinking water. T. Vigod suggested that a federal representative be invited to sit on the advisory committee; this would not change the fact that the standards developed would be provincial (for use in Ontario) rather than federal.

K. Millyard favoured the idea that progress in developing the standards be gazetted, in order to achieve the appropriate public involvement. He also wanted to ensure that there would be sufficient expertise in the committee process to review the criteria documents. A. Vajdic said the technical sub-committee would serve this purpose, and the criteria documents would be prepared by staff or consultants. The advisory committee would choose the members of the technical sub-committees, and would review and approve their work at a policy-related level. K. Newman suggested that the advisory committee be known as Standards Advisory Committee (SAC); members all agreed. As a general rule, SAC would have at least one representative on each sub-committee, to provide a liaison link.

The sub-committees would be responsible for developing ADI's for each chemical, and for recommending the split between media (air, water, food, others) as they relate to human health. At the same time, T. Vigod stressed the need for an ecosystem approach. K. Roberts' concern was that if the scope was too broad, membership of SAC and its sub-committees would be unmanageably large.

SAC would be responsible for initiating the public review process, for receiving and distilling the comments, and for finalizing its recommendations. T. Vigod proposed that when the P.I. Discussion Paper is revised to accommodate the decisions reached at this meeting, it be sent out to identified groups for comment, and be accompanied by a series of questions. It will contain a preamble to explain that the proposal, while it only addresses human health effects, is envisaged as part of an overall approach to standards that will also include environmental effects.

Discussion followed on possible mechanisms, for public circulation of the P.I. Discussion Paper; a press release will be used as one vehicle. Mailings to Ministry mailing lists will be made. Advertising was proposed for major cities (approximately 30) through public notice.

It was agreed that the P.I. Discussion Paper would be revised and an accompanying questionnaire on public comment procedures prepared and circulated to the PILCODWI members early in January 1986. Members were asked to return comments to the Secretary. After that, the Paper will be sent out for public review as outlined above.

Next Meeting

To be arranged at the call of the Chairman.

Prepared by:

P. J. Crabtree
February 3, 1986
00043

MEMBERS:

PUBLIC INTEREST LIAISON COMMITTEE ON
DRINKING WATER ISSUES

Enclosed is a final draft, based on comments and discussion at the last meeting of the above Committee, of the proposed Human Health Standard Setting Mechanism for Drinking and Ambient Water.

Following incorporation of additional adjustments and comments from the Committee it is proposed to release the document for public review by any or all of the following mechanisms:

- a) Press release by Minister, and announcement in the House.
- b) Mailing of copies to interested parties (lists provided by Pollution Probe, CELA, etc.) and organizations such as AWWA, MEA, etc.

The document will be accompanied by the attached questionnaire, to assist, but not limit, those responding with their input and comments.

PUBLIC INVOLVEMENT IN THE SETTING OF HUMAN HEALTH
STANDARDS FOR DRINKING AND AMBIENT WATERS.

Introduction:

The Minister has stated the Ministry of the Environment will become more open to public input and scrutiny. A major component in the Ministry's Drinking Water Protection Strategy has been identified as "Public Involvement". A priority area for such public involvement is in the setting of quality standards to protect public health in the area of water supplies. It is generally acknowledged (Liess, pers. comm.) that there is no existing formula for obtaining public involvement. It is however, vital to the standard setting exercise that meaningful input from the public be obtained. Furthermore, given the current, perceived public demand for enforceable standards, it is imperative that the standard setting procedure involve as little delay as possible. Any procedure should include full disclosure to the public on the protocols and mechanisms used, provide sufficient information and time-frame for wideranging comment, and indicate how comments were dealt with in achieving a final decision. This document outlines a mechanism to obtain public involvement in such a standard setting process.

Background:

Chemicals in the environment have the potential to cause effects on aquatic and terrestrial plants and animals.

Further, if effects only on man are considered there are numerous routes by which he may become exposed to contaminating chemicals in the environment e.g. from food, water and air. It is therefore necessary to adopt an "Acceptable Daily Intake" or "ADI" approach, to the development of standards for a particular route of exposure, e.g. from drinking water. In essence, this means that any valid toxicological data for a given chemical, are used to establish a level of intake of that chemical for man, which is considered to be acceptable i.e. of negligible health risk.

Using data on the distribution of the chemical in the environment, it is possible to assign a proportion of the ADI to each medium of exposure i.e. x% to air, y% to food etc. It is thus possible, once an ADI has been established, to develop levels of a chemical (standards) which would be acceptable in, for example, drinking water. The proportion of the ADI assigned to drinking water as the exposure route, divided by the amount of drinking water ingested, would be the "acceptable level" or "standard" of that chemical for drinking water.

The mechanism proposed in this document would apply to the setting of standards to protect human health on exposure to both drinking and ambient waters; the latter takes into consideration exposure by both drinking the untreated water and consuming aquatic products from the same body of water. It will be necessary to set additional standards for the protection of man by other exposure routes (food, air) and for the protection of aquatic and other terrestrial life forms. An 'ecologic' approach to environmental protection can be obtained by integrating human health protection standards with others, at some later point.

STANDARD - SETTING MECHANISM
- HUMAN HEALTH EFFECTS -
DRINKING AND AMBIENT WATER

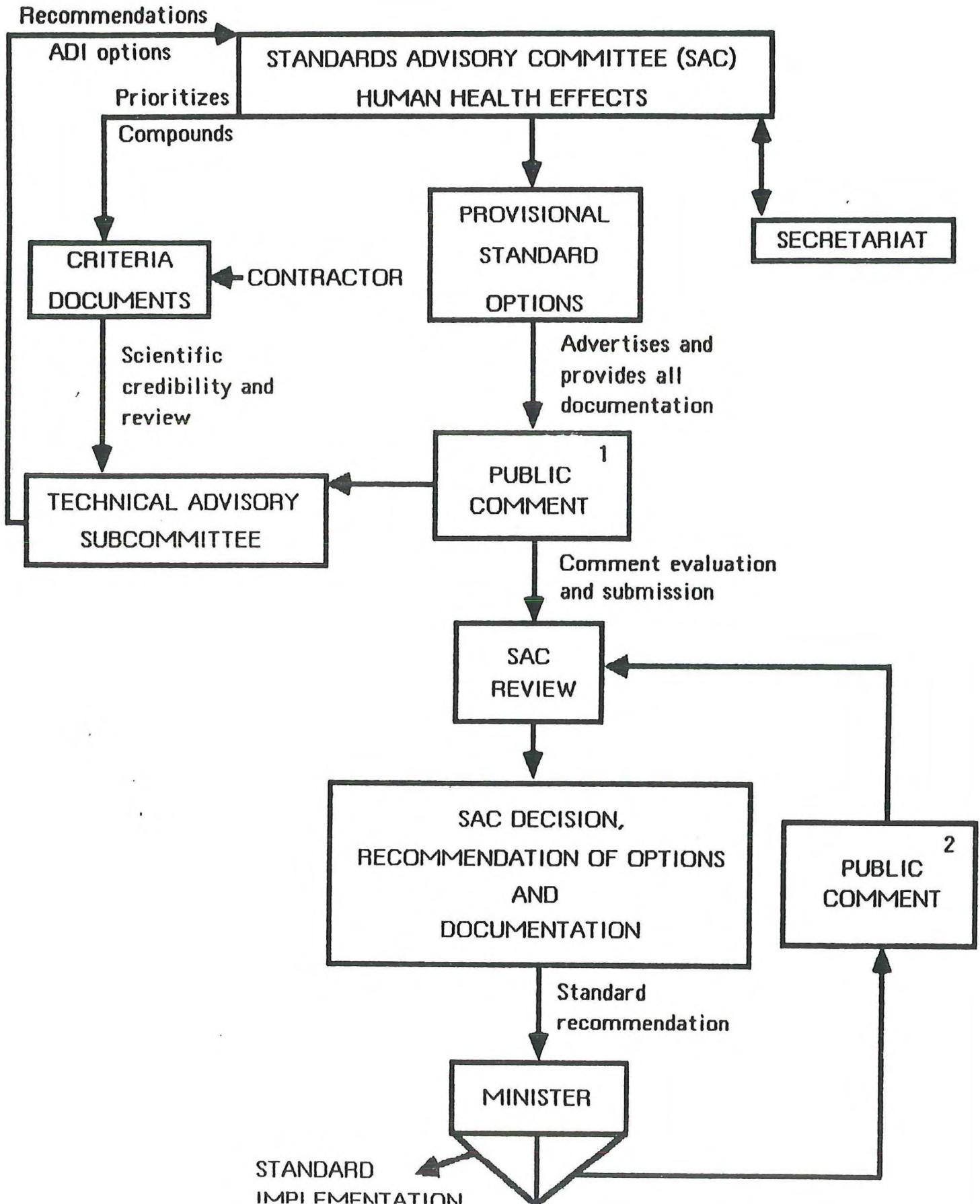
The flow chart for the proposed standard-setting mechanism is attached. The keystone for the mechanism is the "Standards Advisory Committee" (SAC) for human health effects in drinking and ambient water. Such a committee would be made up of individuals with established credentials, both "expert" and "non-expert", with various interests and areas of expertise. Members would provide representation from academia, health, water engineering, industry and other appropriate fields, and would act as a "peer review" body for standard-setting, which would be acceptable to the general public. Selection of candidates for the SAC might be based on recommendations to the Minister of the Environment from the Public Interest Liaison Committee on Drinking Water Issues (PILCODWI) which has representation from various public interest groups, the health field, professional engineering groups, the American Water Works Association, (AWWA) etc. The SAC would only function in its role successfully if its membership were perceived to be unbiased and truly representative of the public interest. Additionally, a paramount requirement for the success of the proposed mechanism would be a total commitment by the members of the SAC to participate in the process to ensure a continuity of function. Lack of commitment would result in the destruction of the credibility of the process.

The SAC, once established, would require the provision of a permanent secretariat by the MOE, which would be provided with funding and responsible for administration on behalf of the SAC. This would include advertising, letting of contracts, etc., recording minutes of meetings and arranging for the production of any documentation required by the SAC etc. In addition to the secretariat, MOE would provide "resource persons", as appropriate to the SAC or its subcommittees, to assist with information such as Ministry mechanisms and policies, water quality data, research material etc.

The sequence of activities in the standard-setting procedure would be as follows: (refer to Diagram 1).

1. The SAC, based on the frequency and levels at which a compound is found in drinking and/or ambient waters, potential health effects, public perception of hazard etc., would compile a list of compounds for which standards are to be developed, and assign each compound a priority. The criteria for selection employed by the World Health Organization, for establishing a list of substances for evaluation, might provide an appropriate procedure.

**DIAGRAM 1: STANDARD SETTING MECHANISM
HUMAN HEALTH EFFECTS
DRINKING AND AMBIENT WATER**



Footnotes to Diagram 1.

1. Public comment solicited by publishing material in the "Ontario Gazette"; making documentation available at MOE Regional and District Offices; distribution to public interest groups and University 'Environmental' departments. Comments would be in the written form or by some other interactive mechanism such as cross-examination, interrogation, seminars etc. These mechanisms would take place before the TASC alone, the TASC and the full SAC or the TASC and selected members of the SAC, as appropriate to the context of the comments.
2. Public comment obtained by any mechanism up to a full Public Hearing.

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2. According to the priority, the SAC would let contracts for the preparation of scientific criteria documents for each compound of concern; such documents would contain information on production, use, toxicity, sources and environmental significance as well as human and other toxicological effects.
3. A series of expert Technical Advisory Sub-committees, (TASC) selected by members of the SAC, with membership appropriate to the compound under discussion would be convened. Each TASC would have at least one liaison member from SAC. The subcommittee would make use of the criteria-document and would be charged with making recommendations on:
 - a) The ADI (acceptable daily intake) of the compound;
 - b) The potential distribution of the compound amongst the various routes of exposure;
 - c) Options on a standard for the compound for both drinking and ambient water.

The subcommittee would be required to review and comment on the criteria document and provide full documentation of its review and of the rationale and methodologies used in developing and presenting its final conclusions.

4. The documentation from the subcommittee, along with any additional pertinent input from its own members (socioeconomic and engineering impact, feasibility, etc..) would be used by the SAC to prepare a recommendation on a standard.

The SAC would be required to make all documentation available for public scrutiny at various locations in the province and would be responsible for appropriately advertising its availability. One mechanism for obtaining public scrutiny would be by publishing all material in the Ontario Gazette.

5. Following a 60-day period for comment, the SAC would send the submitted material to the Technical Advisory Sub-Committee. In addition, submissions could be by a number of interactive mechanisms such as cross-examination, interrogations, second-round written comments, conferences, etc., in which those commenting could present their views to the TASC or the TASC plus the SAC.

A final submission is then made to the SAC by the TASC, including the ways in which public comments were incorporated into the final ADI decision and options.

6. Based on step 5., the SAC, fully documenting the procedures, makes a final decision on the standard.

This recommendation, with an indication of the degree of unanimity within the SAC, with proposed options for action, is then transmitted to the Minister.

7. The Minister, based on the recommendation of the SAC can make a decision:
 - a) To implement the recommended standard with no further discussion;
 - b) To call for a public hearing on the standard, or to invoke any other appropriate mechanism for further public comments. It is envisaged that this route would only be taken in the event of major dissention among members of the SAC on a standard; or if a great deal of public interest had been manifested during the standard development; or if the application of the selected standard would result in considerable economic impact.

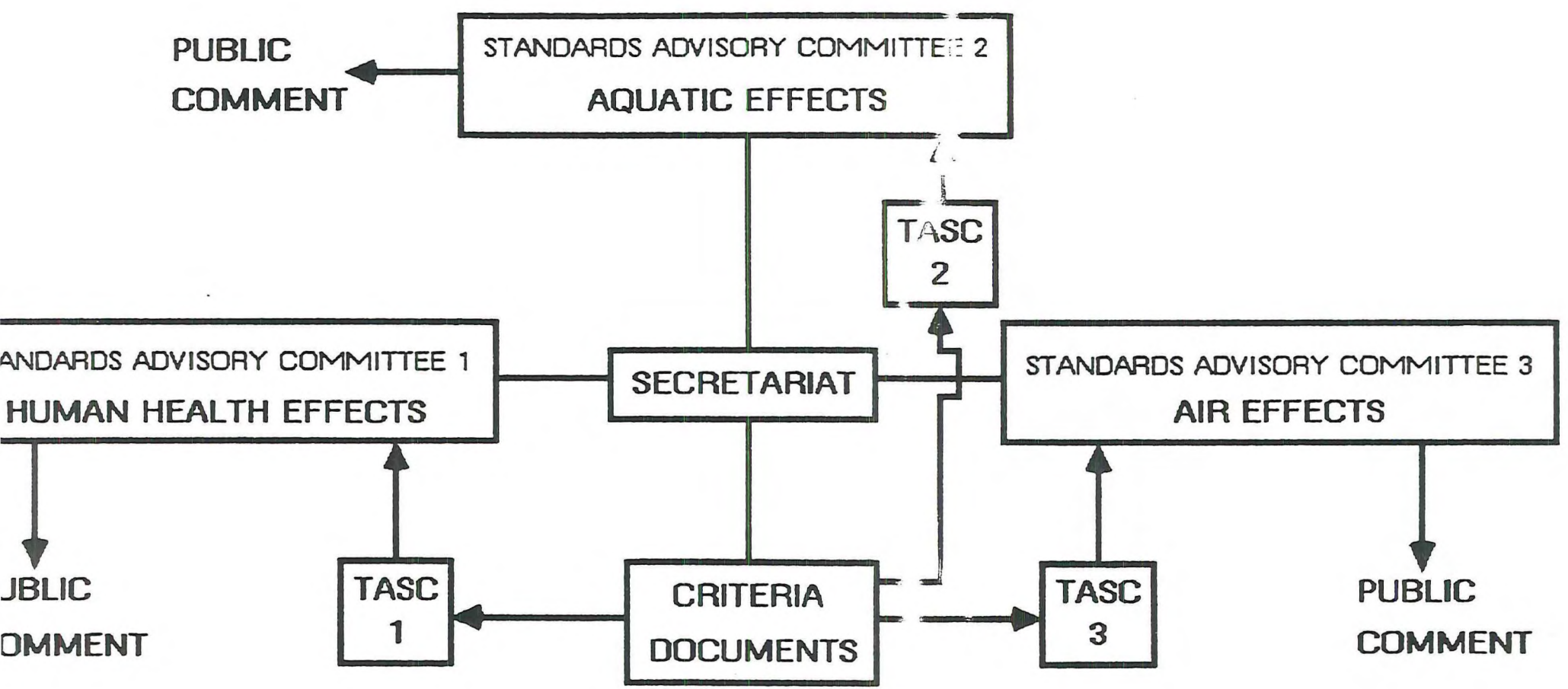
Should option "b" be taken, material generated during the hearing would be returned to the SAC for further review and standard recommendations.

Additional Comments:

1. It is felt that the initial tasks of the SAC would be:
 - a) To define the "level of risk" which is acceptable to the public in the use of drinking and ambient waters;
 - b) To define the criteria used to set the priority list of chemicals for standard-setting.
2. This particular mechanism was developed to set standards for drinking and ambient waters to protect human health. As mentioned in the "Background" preamble, chemicals can cause other environmental effects e.g. toxicity to aquatic plants and animals, and there are other routes by which man can be exposed to such chemicals, such as via food and air.

It is envisaged that a similar mechanism could be utilized to set standards for the aquatic environment, and for air etc. Indeed, it is possible to conceive of two or three parallel standard setting "paths" each with an SAC constituted to deal with the particular type of standard (Diag. 2.).

PROGRAM 2: PARALLEL TRACK CONCEPT OF STANDARD-SETTING FOR HUMAN HEALTH, AQUATIC AND OTHER EFFECTS



NOTE: each 'track' utilises common Secretariat and criteria documents

The secretariat would provide services to all TASC's as well as to the SAC. Additionally, the 'criteria documents' would be contracted on the basis of containing all the toxicity and environmental information available on the particular compound, and thus would provide pertinent information to this and any future SAC's, whether to set a human health standard related to water, or an air or aquatic standard.

QUESTIONNAIRE

MECHANISM FOR PUBLIC INVOLVEMENT IN THE SETTING OF HUMAN HEALTH STANDARDS FOR DRINKING AND AMBIENT WATERS

Attached you will find a document describing a proposed mechanism for setting standards for contaminants, to protect human health, in drinking and ambient water.

This document, developed by PILCODWI*, proposes a standard-setting mechanism which allows for considerable public input into the process.

As assistance in reviewing the document and mechanism, it may be helpful to keep in mind the following questions:

1. What would you like to see as the composition of the Standards Advisory Committee (SAC)? The membership should be capable of commanding considerable respect and establishing the public credibility of the process. Possible candidates might include representatives of Public Interest groups, Government Agencies, Universities, etc.
2. What problems can be foreseen with the proposal to establish "parallel tracks" for standard-setting i.e. one another for aquatic effects, (for human health in drinking and ambient water) etc, each with its own SAC? What alternative would you suggest? (Bear in mind that an SAC with expertise in all areas of toxicology and environmental effects would probably be unmanageably large).
3. Please comment on:-
 - a) The mechanism outlined for obtaining public input to the standard-setting process. Is there sufficient allowance for comment?
 - b) The sequence of events as outlined - is it logical and practical?
4. What types of public comment (written, oral, conference, etc.) would you like to see at the various stages? Are the stages indicated for public input logical? If not, where could additional comments be useful?
5. If the general concept appears acceptable to you, do you have any additional comments or suggestions?
6. If the general concept does not appear acceptable to you, what alternatives would you suggest?

* Public Interest Liaison Committee on Drinking Water Issues.

7. Please indicate the way that the proceedings of the SAC should be advertised: -

- Ontario Gazette
- Newspaper Advertisement
- Press Release
- Mailing List Of Interested Parties
- Postings in Libraries and Municipal Offices

Any other suggestions?

8. Do you agree that the Minister should have the ultimate decision, based on documentation received from the SAC, on whether or not a public hearing is necessary?