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INTERGOVERNMENTAL NEGOTIATING COMMITTEE FOR AN INTERNATIONAL LEGALLY BINDING INSTRUMENT FOR THE APPLICATION OF THE PRIOR INFORMED CONSENT PROCEDURE FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES IN INTERNATIONAL TRADE Eighth session Rome, 8-12 October 2001 Item 4 (j) of the provisional agenda^{*}

PROCEDURES AND FORMS USED TO ADDRESS MATTERS SUCH AS CONFLICT OF INTEREST, DISCLOSURE AND RECUSAL IN SCIENTIFIC BODIES OF OTHER ORGANIZATIONS AND CONVENTIONS

Background

1. At its sixth session, held in Rome from 12 to 16 July 1999, the Intergovernmental Negotiating Committee for an International Legally Binding Instrument for the Application of the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, decided to establish an Interim Chemical Review Committee, composed of twenty-nine government-designated experts appointed by the Intergovernmental Negotiating Committee. Consistent with the provisions of the Rotterdam Convention¹, the Interim Chemical Review Committee is, <u>inter alia</u>, required to: make recommendations on the inclusion of banned and severely restricted chemicals in the Prior Informed Consent Procedure; make recommendations on the inclusion of severely hazardous pesticide formulations in the procedure; and prepare draft decision guidance documents.

2. At its seventh session, held in Geneva from 30 October to 3 November 2000, the Intergovernmental Negotiating Committee noted the possible need for the Interim Chemical Review Committee to be protected through the use of conflict-of-interest procedures. The Committee requested the secretariat to collect information on procedures and forms used to address matters such as conflict of interest, disclosure and recusal in use by scientific bodies in other conventions. In addition, the Committee asked the secretariat to

* UNEP/FAO/PIC/INC.8/1.

¹ Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

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develop a draft disclosure and/or recusal form and procedure for consideration by the Committee at its eighth session along with a summary of the information collected (UNEP/FAO/PIC/INC.7/15, para. 110).

I. INFORMATION ON PROCEDURES AND FORMS USED TO ADDRESS MATTERS SUCH AS CONFLICT OF INTEREST, DISCLOSURE AND RECUSAL IN SCIENTIFIC BODIES OF OTHER ORGANIZATIONS AND CONVENTIONS

3. The interim secretariat contacted a number of secretariats of organizations or secretariats established under the aegis of international conventions, including the United Nations Secretariat, the Food and Agriculture Organization of the United Nations (FAO), the Office of the United Nations High Commissioner for Refugees, the International Committee of the Red Cross, the International Telecommunications Union (ITU), the International Labour Organization (ILO), the International Maritime Organization (IMO), the secretariat of the Convention on Biological Diversity, the Secretariat of the Vienna Convention on the Protection of the Ozone Layer, the World Intellectual Property Organization (WIPO), the World Health Organization (WHO), the World Trade Organizations provided information on forms and procedures that they had developed. These were the secretariat of the Montreal Protocol on Substances that Deplete the Ozone Layer of 1987, concluded under the Vienna Convention on the Protection of the Ozone Layer of 1985, FAO and WHO.

A. The Montreal Protocol on Substances that Deplete the Ozone Layer

4. The Secretariat for the Vienna Convention on the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer, as amended, developed terms of reference for the Technology and Economic Assessment Panel which operates under the Montreal Protocol. The terms of reference were approved by the Parties. The Panel analyses and presents technical information on the basis of available scientific, environmental, technical and economic information relevant to the review and assessment of control measures. The terms of reference of the Panel include a code of conduct intended to protect its members from conflicts of interests. The code of conduct defines the obligations of the members of the Panel when carrying out their duties and states, in particular, that "(members) shall perform their official duties and arrange their private affairs in such a manner that public confidence and trust in the integrity, objectivity and impartiality" of the Panel are conserved and enhanced. The members of the Panel are required to disclose their activities including business or financial interest in the production of ozonedepleting substances, their alternatives and products containing ozone-depleting substances that may call into question their ability to discharge their duties and responsibilities objectively. They are required to annually disclose such activities. The members are also required to disclose any financing for their participation in the meetings from a company engaged in commercial activities.

5. In accordance with its terms of reference the Panel is responsible for the interpretation while the members are responsible for the application of the code of conduct. Additional information collected through the Chair of the Panel confirmed that the implementation of the code of conduct is under the overall responsibility of the Panel.

6. Annex I to this document contains an extract of the terms of reference of the Technology and Economic Assessment Panel, including its code of conduct.

B. World Health Organization and Food and Agriculture Organization of the United Nations

7. WHO and FAO have also acquired some relevant experience on the matter. During recent years, these organizations have developed a form for the disclosure of information by experts participating in some of their groups or panels of experts. In view of the fact that some of the groups of experts operate under the framework of the Joint FAO/WHO Food Standards Programme and the Codex Alimentarius Commission, both organizations consulted closely when developing the relevant forms and procedures. In the case of FAO, the procedure in question was used by the Joint FAO/WHO Expert Committee on Food Additives and

was introduced recently to the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Toxicological Core Assessment Group on Pesticide Residues. Consideration is being given, however, to extending this procedure to other meetings of experts at FAO. In the case of WHO the procedure applies to the members of all expert advisory panels and committees.

8. The general purpose of the procedure is to ensure that the best possible assessment of scientific evidence is achieved in an independent atmosphere free of either direct or indirect pressures. To ensure the technical integrity and impartiality of the work, it is necessary to avoid situations in which financial or other interests might interfere with the outcome of that work. There are two aspects to the procedure in question. The first, is a requirement that the expert should declare any interests that could constitute a real, potential or apparent conflict of interest, with respect to his or her involvement in the work of a committee. The second, and perhaps more complex stage, is the determination by the organization concerned, on the basis of the declaration made, that a particular situation does give rise to a conflict of interest. In that case, the Director-General may decide not to appoint a particular expert or to request him or her not to participate in specific proceedings or debates.

9. The form being used by FAO with respect to experts of the Joint FAO/WHO Expert Committee on Food Additives is presented in annex II hereto, while that used by WHO is presented in annex III hereto.

II. BRIEF ANALYSIS OF POSSIBLE OPTIONS AND THEIR RELEVANCE TO THE NEEDS OF THE INTERIM CHEMICAL REVIEW COMMITTEE

10. The interim secretariat sought to obtain additional information on the practical implementation of the above options.

11. As regards the implementation of the option followed under the Montreal Protocol, the interim secretariat obtained some relevant information from the Chair of the Technology and Economic Assessment Panel. It is considered that the strength of the Panel is that it provides objective information on the technical and economic feasibility of alternatives and substitutes to ozone-depleting substances. It is further considered that this technical capacity cannot be seen in isolation from the participation in the panel of representatives from the industry, particularly the industry most involved in developing, commercializing and selecting technology. Thus, it would seem that "conflict-of-interest" is seen essentially as undisclosed affiliation or income, but that does not prohibit membership for those experts working for organizations with an interest in a policy outcome. The Chair of the Panel and of its working groups are alert to issues where an expert might be tempted to represent their organizational interest.

12. The practical implementation of the option followed at FAO and WHO reflects, in some respects, a comparable approach to the issue of the conflict of interest. Conflict of interest is seen as undisclosed affiliation or income. In addition, conflict of interest is a situation where, given the links between an expert and particular interests, there would be doubts as to the actual independence of that expert when considering a particular issue.

13. There is, however, a fundamental difference between the option followed at FAO and WHO and that followed under the Montreal Protocol. In the case of FAO and WHO panels of experts, the process for the appointment of experts is entirely under the control of the Directors-General of FAO and WHO. Consequently, where it appears that a situation of conflict of interests is likely to arise, the Directors-General are in a position themselves, to determine whether a particular expert should be appointed or not.

14. In general, both options – i.e., the option under the Montreal Protocol and the option followed at FAO and WHO - would seem to be of relevance to the situation of the experts serving in the Interim Chemical Review Committee. From a purely technical point of view, the option being implemented under the Montreal Protocol would seem to have the advantage of being easily transposable to the situation under the Rotterdam Convention without any major legal and institutional adjustments. This is so because this option is already being implemented in a legal and institutional context similar to that of the Rotterdam

Convention where experts are nominated or designated by individual Governments and appointed by the Conference of the Parties. In the case of the Montreal Protocol, it is also felt that the ability of the Technology and Economic Assessment Panel to provide objective information on the technical and economic feasibility of alternatives and substitutes to ozone-depleting substances cannot be seen in isolation from the fact that experts may have some links with the industry, especially industry most involved in developing, commercializing and selecting technology. The option being followed at WHO and FAO, peculiar to each of the organizations concerned, would require a number of fundamental adjustments in order to be applied to the intergovernmental context of the Interim Chemical Review Committee. With regard to these two options, and particularly the option followed at FAO and WHO, a number of specific issues deserve further consideration.

III. SPECIFIC ISSUES FOR CONSIDERATION

15. In seeking to identify a convenient option for the Interim Chemical Review Committee, a number of specific issues need to be considered in detail.

16. First, it is important to ascertain the criteria that could be used to assess whether a conflict of interests has arisen. On the basis of the information available, in the case of the Montreal Protocol, it is felt that the scientific capacity of the Panel would be hampered without representatives from industry, particularly industry most involved in developing, commercializing and selecting technology. Thus, the Panel sees "conflict-of-interest" essentially as undisclosed affiliation or income, but does not prohibit membership for those experts working for organizations with an interest in a policy outcome. The Chair of the Panel and of its working groups are also alert to issues where an expert might be tempted to represent their organizational interest. The option that is being followed at FAO and WHO reflects a similar concern for transparency in terms of knowing the interests of the experts. Where the interests of the expert are such as to cast doubts, actually or potentially, over his or her independence and objectivity, the secretariat enjoys a wide measure of discretion in making a determination as to the suitability of the expert. Thus the criteria applied by FAO and WHO might be slightly broader than those followed in the case of the Panel under the Montreal Protocol.

17. Second, another issue of a fundamental nature requiring due consideration is that the information provided by the experts is of a confidential nature and, for the system to function in an efficient manner, it might be desirable for the confidential nature of this information to be adequately preserved. The information obtained from the Technology and Economic Assessment Panel is not very conclusive in this respect, insofar as it would seem that the information provided by the Panel members is published in a report. In the case of FAO and WHO, the information provided is confidential and is not disclosed to any party.

18. Third, the practical institutional mechanisms which are required to implement any of the above options, would need careful consideration. As mentioned above, should the Intergovernmental Negotiating Committee wish to implement an option similar to the one followed under the Montreal Protocol this could be done in a fairly straightforward manner. Basically, the procedures as in force under this Protocol would apply, <u>mutatis mutandis</u>, to the Rotterdam Convention.

19. Should the Intergovernmental Negotiating Committee be of the view, however, that a procedure similar to that followed at FAO and WHO should be considered, then such option would need to be reviewed in some fundamental respects in order to adapt it from a context internal to a secretariat to an intergovernmental context. In doing so, consideration might need to be given to the fact that the information to be provided by the experts would be of a confidential nature.

20. As noted above, unlike the situation in FAO or WHO where the process for the appointment of experts is under the control of the Directors-General, the members of the Interim Chemical Review Committee are experts designated by the Governments, but appointed by the Intergovernmental Negotiating Committee. Consequently, a number of arrangements, outlined below in a tentative manner, would have to

be made. Thus, when considering designating an expert for appointment by the Intergovernmental Negotiating Committee, Governments would be required to inform the experts that they would have to provide to the interim secretariat a declaration of interests form duly filled in. Such declarations would be submitted by the experts directly to the interim secretariat. Ideally, the submission of this information, including the declaration of interests and its assessment by the interim secretariat, should be done prior to the actual designation of the expert by the Government.

21. Should the interim secretariat believe that a situation of conflict of interest exists or, is likely to arise, it would raise the matter with the prospective or designated expert. The expert could be invited to inform his or her Government that it would not be appropriate for him or her to be designated as an expert or that, once appointed, he or she might not be in a position to participate in some meetings. With the concurrence of the expert, the interim secretariat could provide the Government concerned with relevant information on the matter. Should a disagreement arise between the interim secretariat and the Government regarding a possible conflict of interests, a procedure could be developed whereby the Bureau of the Intergovernmental Negotiating Committee would consider the matter. Thus, should a Government be in disagreement with a proposal by the interim secretariat regarding the unsuitability of a particular expert, one of the following bodies, to be decided by the Intergovernmental Negotiating Committee, would review the matter jointly with the interim secretariat: the Bureau of the Intergovernmental Negotiating Committee, a standing subsidiary body of the Committee set up to review cases of conflict of interest, or a contact group to be established by the Committee on a case-by-case basis. Again, appropriate arrangements would need to be implemented by the interim secretariat with a view to safeguarding the confidentiality of the information provided.

22. A related issue that would need to be considered in detail is how situations of conflict of interest would be monitored and averted during the term of the experts. A possible approach to this might be for the interim secretariat to require experts to submit declarations of interests on a yearly basis. Should the interim secretariat be of the opinion that a situation of conflict of interest has arisen, after discussing the matter with the expert concerned, it could propose to the Interim Chemical Review Committee that participation of the expert in all or some of its activities be suspended, either for a particular meeting, or for the remainder of the term.

23. The procedural aspects involved in dealing with declarations of interests would need to be reflected in an appropriate decision of the Intergovernmental Negotiating Committee.

24. Annex IV to this document contains a draft text for a possible decision by the Intergovernmental Negotiating Committee on further steps in the development of a form for the disclosure of interests by experts and of a possible procedure for the implementation of a process aimed at averting conflicts of interests. The text is a purely tentative proposal, merely intended to provide a basis for further discussion and review of the issues under consideration. The Intergovernmental Negotiating Committee may wish to consider establishing a contact group with the aim of identifying actions that need to be taken and determining whether these shall include the following suggested measures: establishment of a subsidiary body of the Committee to treat cases of conflict of interest in the Interim Chemical Review Committee; development of criteria for the evaluation of information provided by experts through the forms; measures to be taken to ensure confidentiality of the information provided; and steps to be taken to apply approved actions to the members of the Interim Chemical Review Committee previously appointed by the Intergovernmental Negotiating Committee.

25. The Intergovernmental Negotiating Committee is invited to review the above and provide such guidance to the interim secretariat as appropriate.

Annex I

MONTREAL PROTOCOL ON SUBSTANCES THAT DEPLETE THE OZONE LAYER

TERMS OF REFERENCE OF THE TECHNOLOGY AND ECONOMIC ASSESSMENT PANEL

(Extracts)

2. Organization of Technology and Economic Assessment Panel (TEAP), Technical Options Committees (TOCs) and Temporary Subsidiary Bodies (TSBs)

2.2 Nominations

Nominations of members to the TEAP and TOCs may be made by individual Parties to the Secretariat through their relevant government organization. Such a nomination will be forwarded to the TEAP for consideration and, in the case of nominations of the TEAP, for recommendation to the Meeting of the Parties. Any nominations made by the TEAP will be communicated to the relevant Party for consultation before recommendations for appointment are made.

2.3. Appointment of members of TEAP

In keeping with the intent of the Parties for a periodic review of the composition of the assessment panel, the Meeting of the Parties shall appoint the members of the TEAP for a period to be determined by the Parties, subject to re-endorsement by the Parties. In appointing or re-endorsing members of the TEAP, the Parties should ensure continuity as well as a reasonable turnover.

2.6 Termination of appointment

TEAP/TOC Co-Chairs can dismiss a member by a two-thirds majority vote. A dismissed member has the right to request a vote of its relevant Panel, Committee or TSB and will be restored if supported by one-third of the members of that body. A dismissed member of the TEAP has the right to appeal to the next Meeting of the Parties through the Secretariat. A dismissed member of a TOC can appeal to TEAP, which can decide on such issues with a two-thirds majority vote, and can appeal to the next Meeting of the Parties.

2.7 Replacement

If a TOC Co-Chair/Senior Expert relinquishes or is unable to function, the TEAP after consultation with the nominating Party can temporarily appoint a replacement from amongst its bodies for the time up to the next Meeting of the Parties, if necessary to complete its work.

5. Code of conduct by members of the Technology and Economic Assessment Panel

Code of conduct

Members of the TEAP, TOCs and the TSBs have been asked by the Parties to undertake important responsibilities. As such, a high standard of conduct is expected of members in discharging their duties. In order to assist members, the following guidelines have been developed as a code of conduct.

- 1. This code of conduct is intended to protect members of the TEAP, TOCs and TSBs from conflicts of interest in their participation. Compliance with the measures detailed in these guidelines is a condition for serving as a member of the TEAP, the TOCs or the TSBs.
- 2. The Code is to enhance public confidence in the integrity of the process while encouraging experienced and competent persons to accept TEAP, TOC and/or TSB membership by:
 - establishing clear rules of conduct with respect to conflict of interest while and after serving as a member, and
 - by minimizing the possibility of conflicts arising between the private interest and public duties of members, and by providing for the resolution of such conflicts, in the public interest, should they arise.
- 3. In carrying out their duties, members shall:
 - perform their official duties and arrange their private affairs in such a manner that public confidence and trust in the integrity, objectivity and impartiality of the TEAP, TOCs and TSBs are conserved and enhanced;
 - act in a manner that will bear the closest public scrutiny, and obligation that is not fully discharged by simply acting within the law of any country;
 - act in good faith for the best interest of the process;
 - exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances;
 - not give any preferential treatment to anyone or any interest in any official manner related to the TEAP, TOCs or TSBs;
 - not solicit or accept significant gifts, hospitality, or other benefits from persons, groups or organizations having or likely to have dealings with the TEAP, TOCs or TSBs;
 - not accept transfers of economic benefit, other than incidental gifts, customary hospitality, or other benefits of nominal value, unless the transfer is pursuant to an enforceable contract or property right of the member;
 - not step out of their role as a member to assist other entities or persons in their dealings with the TEAP, TOCs or TSBs where this act would result in preferential treatment to any person or group;
 - not knowingly take advantage of, or benefit from, information that is obtained in the course of their duties and responsibilities as a member of the TEAP, TOCs and TSBs, and that is not generally available to the public; and
 - not act, after their term of office as a member of the TEAP, TOCs or TSBs in such a manner as to take improper advantage of their previous office.
- 4. To avoid the possibility or appearance that members of the TEAP, TOCs or TSBs might receive preferential treatment, members shall not seek preferential treatment for themselves or third parties or act as paid intermediaries for third parties in dealings with the TEAP, TOCs or TSBs.

- 5. TEAP, TOC and TSB members shall disclose activities including business or financial interest in production of ozone-depleting substances, their alternatives, and products containing ozone-depleting substances and alternatives which might call into question their ability to discharge their duties and responsibilities objectively. TEAP, TOC and TSB members must annually disclose their activities. They must also disclose any financing from a company engaged in commercial activities, for their participation in the TEAP, TOC and TSB.
- 6. TEAP is responsible for the interpretation and TEAP/TOC/TSB members for the application of this code of conduct.

Annex II



DECLARATION OF INTERESTS

Public health considerations have a primary importance in all FAO work on food safety. Measures need to be taken to ensure that the best possible assessment of scientific evidence is achieved in an independent atmosphere free from either direct or indirect pressures. Thus to assure the scientific integrity and impartiality of FAO's work, it is necessary to avoid situations in which financial or other interests might affect the outcome.

Each expert is therefore asked to declare any interests that could constitute a real, potential or apparent conflict of interest with respect to his/her involvement in a meeting, between (1) commercial entities and the expert personally, and (2) commercial entities and the administrative unit with which the expert has an employment relationship. "Commercial entity" refers to any company, association (e.g. trade association), organization or any other entity of any nature whatsoever, with commercial interests.

What is a conflict of interest?

Conflict of interest means that the expert or his/her partner ("partner" includes a spouse or other persons with whom he or she has a similar close personal relationship), or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others.

Different <u>types of financial or other interests</u>, whether personal or with the administrative unit with which the expert has an employment relationship, can be envisaged and the following list, which is not exhaustive, is provided for your guidance.

For example, the following types of situations should be declared:

- 1. a current proprietary interest in a substance, technology or process (e.g. ownership of a patent) to be considered in, or otherwise related to the subject matter of, the meeting;
- 2. a current financial interest, e.g. shares or bonds, in a commercial entity with an interest in the subject matter of the meeting (except share holdings through general mutual funds or similar arrangements where the expert has no control over the selection of shares);
- 3. an employment, consultancy, directorship, or other position during the past 4 years, whether or not paid, in any commercial entity which has an interest in the subject matter of the meeting, or an ongoing negotiation concerning prospective employment or other association with such commercial entity;
- 4. performance of any paid work or research during the past 4 years commissioned by a commercial entity with interests in the subject matter of the meeting;
- 5. payment or other support covering a period within the last 4 years, or an expectation of support for the future, from a commercial entity with an interest in the subject matter of the meeting, even if it does not convey any benefit to the expert personally but which benefits his/her position or administrative unit, e.g. a grant or fellowship or other payment for the purpose of financing a post or consultancy.

With respect to the above, an interest in a competing substance, technology or process, or an interest in or

association with, work for or support by a commercial entity having a direct competitive interest must similarly be disclosed.

How to complete this Declaration: Please complete this Declaration and submit it to the FAO Secretariat well before the meeting.

Any financial or other interests that could constitute a real, potential or apparent conflict of interest should be declared (1) with respect to yourself or partner, as well as (2) with respect to the administrative unit with which you have an employment relationship. Only the name of the commercial entity and the nature of the interest are required to be disclosed and no amounts need to be specified (though they may be, if you consider this information to be relevant to assessing the interest). With respect to items 1 and 2 in the list above, the interest should only be declared if it is current. With respect to items 3, 4 and 5, any interest during the past 4 years should be declared. If the interest is no longer current, please state the year when it ceased. With respect to item 5, the interest ceases when a financed post or fellowship is no longer occupied, or when support for an activity ceases.

Assessment and outcome: The information submitted by you will be used to assess whether the declared interests constitute a real, potential or apparent conflict of interest, and you will be informed accordingly before the meeting. A conflict of interest may, depending on its nature and extent, result in (i) you being asked not to attend the meeting; (ii) you being asked not to take part in that portion of the discussion affected by the interest; or (iii) you taking part in the meeting but with restrictions on your contribution at the discretion of the Chairperson. For example, you may be invited to take part in the discussion on the item in question but not to participate in any decision-making. Such decisions will be at the discretion of the Chairperson in consultation with the FAO Secretary.

All declared interests will be listed and made available to the meeting as a whole, and following the meeting will be made public, as will any actions taken as a result of the declarations.

Declaration: Have you or your partner any financial or other interest in the subject matter of the meeting in which you will be involved?

Yes:

No:

If yes, please give details in the box below.

Nature of interest, e.g., patent, shares, employment, association, payment (include details on any compound, work) etc.	Name of commercial entity	Belongs to you, partner, or unit?	Current interest? (or year ceased)

Is there anything else that could affect your objectivity or independence in the meeting, or the perception by others of your objectivity and independence?

I hereby declare that the disclosed information is correct and that no other situation of real, potential or

apparent conflict of interest is known to me. I agree to inform you of any change in these circumstances, including if an issue arises in the course of the meeting itself.

Signature:_____

Date:_____

Name:_____

Institution:_____

Note: If more than one page is necessary use copies of this form

December 2000

Annex III



DECLARATION OF INTERESTS FOR WHO EXPERTS

Title of meeting or work to be performed, including description of subject-matter, substance (compounds and organisms), technology or process to be considered:______

Public health considerations have a primary importance in all WHO technical work. Measures need to be taken to ensure that the best possible assessment of scientific evidence is achieved in an independent atmosphere free of either direct or indirect pressures. Thus, to assure the technical integrity and impartiality of WHO's work, it is necessary to avoid situations in which financial or other interests might affect the outcome of that work.

Each expert is therefore asked to declare any interests that could constitute a real, potential or apparent conflict of interest, with respect to his/her involvement in the meeting or work, between (1) commercial entities and the participant personally, and (2) commercial entities and the administrative unit with which the participant has an employment relationship. "Commercial entity" refers to any company, association (e.g., trade association), organization or any other entity of any nature whatsoever, with commercial interests.

In addition, as a result of WHO's strong stance against tobacco use, it is considered relevant for the Organization to know whether experts working with it have, or have had, any relationship with any part of what may be called "the tobacco industry". Nevertheless, declaration of such an interest would not necessarily be considered a reason to disqualify an expert.

What is a conflict of interest?

Conflict of interest means that the expert or his/her partner ("partner" includes a spouse or other person with whom s/he has a similar close personal relationship), or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject-matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others. A potential conflict of interest exists with an interest which any reasonable person could be uncertain whether or not should be reported.

Different <u>types of financial or other interests</u>, whether personal or with the administrative unit with which the expert has an employment relationship, can be envisaged and the following list, which is not exhaustive, is provided for your guidance. For example, the following types of situations should be declared:

- 1. a current proprietary interest in a substance, technology or process (e.g. ownership of a patent), to be considered in or otherwise related to the subject-matter of the meeting or work;
- 2. a current financial interest, e.g. shares or bonds, in a commercial entity with an interest in the subject-matter of the meeting or work (except share holdings through general mutual funds or similar arrangements where the expert has no control over the selection of shares);

- 3. an employment, consultancy, directorship, or other position during the past 4 years, whether or not paid, in any commercial entity which has an interest in the subject-matter of the meeting/work, or an ongoing negotiation concerning prospective employment or other association with such commercial entity;
- 4. performance of any paid work or research during the past 4 years commissioned by a commercial entity with interests in the subject-matter of the meetings or work;
- 5. payment or other support covering a period within the past 4 years, or an expectation of support for the future, from a commercial entity with an interest in the subject-matter of the meetings or work, even if it does not convey any benefit to the expert personally but which benefits his/her position or administrative unit, e.g. a grant or fellowship or other payment, e.g. for the purpose of financing a post or consultancy.

With respect to the above, an interest in a competing substance, technology or process, or an interest in or association with, work for or support by a commercial entity having a direct competitive interest must similarly be disclosed.

How to complete this Declaration: Please complete this Declaration and submit it to the Secretariat. Any financial or other interests that could constitute a real, potential or apparent conflict of interest should be declared (1) with respect to yourself or partner, as well as (2) with respect to the administrative unit with which you have an employment relationship. Only the name of the commercial entity and the nature of the interest is required to be disclosed, no amounts need to be specified (though they may be, if you consider this information to be relevant to assessing the interest). With respect to items 1 and 2 in the list above, the interest should only be declared if it is current. With respect to items 3, 4 and 5, any interest during the past 4 years should be declared. If the interest is no longer current, please state the year when it ceased. With respect to item 5, the interest ceases when a financed post or fellowship is no longer occupied, or when support for an activity ceases.

Assessment and outcome: The information submitted by you will be used to assess whether the declared interests constitute an appreciable real, potential or apparent conflict of interest. Such conflict of interest will, depending on the situation, result in (i) you being asked not to take part in the portion of the discussion or work affecting that interest, (ii) being asked not to take part in the meeting or work altogether, or (iii) if deemed by WHO to be appropriate to the particular circumstances, and with your agreement, you taking part in the meeting or work and your interest being publicly disclosed.

Information disclosed on this Form may be made available to persons outside of WHO only when the objectivity of the meeting or work has been questioned such that the Director-General considers disclosure to be in the best interests of the Organization, and then only after consultation with you.

Declaration:Have you or your partner any financial or other interest in the subject-matter of the meeting orwork in which you will be involved, which may be considered as constituting a real, potential or apparentconflict of interest?Yes:No:If yes, please give details in the box below.

Do you have, or have you had during the past 4 years, an employment or other professional relationship with any entity directly involved in the production, manufacture, distribution or sale of tobacco or any tobacco products, or directly representing the interests of any such entity? Yes: No: If yes, please give details in the box below.

Type of interest, e.g. patent, shares, employment, association, payment (including details on any compound, work, etc.)	Name of commercial entity	Belongs to you, partner or unit?	Current interest? (or year ceased)

Is there anything else that could affect your objectivity or independence in the meeting or work, or the perception by others of your objectivity and independence?

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances, including if an issue arises during the course of the meeting or work itself.

Signature

Date

Name

Institution

Annex IV

Decision INC - .../...: Procedure for preventing and dealing with conflicts of interest relating to the activities of the Interim Chemical Review Committee

The Intergovernmental Negotiating Committee

1. <u>Decides</u> to adopt the declaration of interests form as attached hereto as appendix A for the purposes of designating and appointing experts to the Interim Chemical Review Committee;

2. <u>Decides</u> to adopt the following procedure for the implementation of the declaration of interests form by the interim secretariat:

General provisions

(a) The interim secretariat shall take all necessary measures to ensure the confidentiality of the information provided;

(b) The interim secretariat shall not disclose the information provided by any prospective, designated or appointed expert in the declaration of interests form to any Government or to any other party without the consent of that expert;

(c) The Intergovernmental Negotiating Committee shall considered any issue that is not covered by the present decision. In particular, the Intergovernmental Negotiating Committee shall define the conditions for the disclosure of information provided, when the objectivity of a particular meeting has been called into question. In that case, the Intergovernmental Negotiating Committee shall consult closely with the expert concerned, through the interim secretariat, with a view to determining the conditions for the release of information concerning that expert;

Review process upon initial designation and appointment

(d) When considering designating an expert to the Interim Chemical Review Committee, the Government concerned shall inform the expert that he or she shall be required by the interim secretariat to fill in and submit a declaration of interests form as set out in the appendix to the present decision;

(e) Prior to the designation of an expert by a Government, or concurrently with the process for that designation, the interim secretariat shall require the expert to fill in and submit to it a declaration of interests form;

(f) Should the interim secretariat feel that an actual or potential risk of conflict of interest exists, it shall bring the matter to the attention of the expert and request such further information as necessary. In discussing the matter further with the prospective or designated expert, the interim secretariat may suggest means to bring his or her situation in line with the requirements of the performance of his or her functions on the Interim Chemical Review Committee;

(g) Should the interim secretariat be of the view that, on the basis of the information available, a prospective expert should not be considered for appointment, the interim secretariat may ask the expert to inform his or her Government that he or she should not be designated, or, if such designation has already been made, to request the Government to withdraw its designation for appointment by the Intergovernmental Negotiating Committee;

(h) Should a Government be in disagreement with the view of the interim secretariat, the matter shall be considered by the members of the Bureau of the Intergovernmental Negotiating Committee ² and a representative of that Government;

Review process after designation

(i) The interim secretariat shall request all appointed experts to submit a declaration of interests form on a yearly basis;

(j) Should the interim secretariat be of the opinion that a situation of conflict of interest has arisen, after discussing the matter with the expert concerned, it may propose to the Interim Chemical Review Committee, through its Chairman, that participation of the expert in all or some of its activities, as defined, be suspended.

² Or, the standing subsidiary body for the Committee set up to review cases of conflict of interest or the ad hoc contact group established by the Committee depending on the decision by the Intergovernmental Negotiating Committee.

Appendix A

Intergovernmental Negotiating Committee

Interim Chemical Review Committee

Declaration of interests form

Measures need to be taken to ensure that the best possible assessment of scientific evidence is achieved in an independent atmosphere free of either direct or indirect pressures. Thus, to ensure the technical integrity and impartiality of the Interim Technical Review Committee's work, it is necessary to avoid situations in which financial or other interests in the chemical and pesticide industry might affect the outcome of that work.

Each expert is therefore asked to declare any interests that could constitute a real, potential or apparent conflict of interest, with respect to his/her involvement in the meeting or work, between, on the one hand, commercial entities and the participant personally, and, on the other hand, commercial entities and the administrative unit with which the participant has an employment relationship. "Commercial entity" refers to any company, association (e.g., trade association), organization or any other entity whatsoever, with commercial interests.

What is a conflict of interest?

Conflict of interest means that the expert or his/her spouse, or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject-matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others. A potential conflict of interest exists with an interest which any reasonable person could be uncertain whether or not should be reported.

Different <u>types of financial or other interests</u>, whether personal or with the administrative unit with which the expert has an employment relationship, can be envisaged and the following list, which is not exhaustive, is provided for your guidance. For example, the following types of situations should be declared:

(a) A current proprietary interest in a substance, technology or process (e.g. ownership of a patent), to be considered in - or otherwise related to the subject matter of - the meeting or work;

(b) A current financial interest, e.g., shares or bonds, in a commercial entity with an interest in the subject matter of the meeting or work (except share holdings through general mutual funds or similar arrangements where the expert has no control over the selection of shares);

(c) An employment, consultancy, directorship, or other position during the past four years, whether or not paid, in any commercial entity which has an interest in the subject matter of the meeting or work, or an ongoing negotiation concerning prospective employment or other association with such commercial entity;

(d) Performance of any paid work or research during the past four years commissioned by a commercial entity with interests in the subject matter of the meetings or work;

(e) Payment or other support covering a period within the past four years, or an expectation of support for the future, from a commercial entity with an interest in the subject matter of the meetings or work, even if it does not convey any benefit to the expert personally but which benefits his/her position or administrative unit, e.g., a grant or fellowship or other payment, e.g., for the purpose of financing a post or consultancy.

With respect to the above, an interest in a competing substance, technology or process, or an interest in or association with, work for or support by a commercial entity having a direct competitive interest must similarly be disclosed.

How to complete this declaration

Please complete this declaration form and submit it to the interim secretariat. Any financial or other interests that could constitute a real, potential or apparent conflict of interest should be declared: first, with respect to yourself or partner; and, second, with respect to the administrative unit with which you have an employment relationship. Only the name of the commercial entity and the nature of the interest is required to be disclosed, no amounts need to be specified (though they may be, if you consider this information to be relevant to assessing the interest). With respect to points (a) and (b) in the list above, the interest should only be declared if it is current. With respect to points (c), (d) and (e), any interest during the past four years should be declared. If the interest is no longer current, please state the year when it ceased. With respect to point (e), the interest ceases when a financed post or fellowship is no longer occupied, or when support for an activity ceases.

Assessment and outcome

The information submitted by you will be used to assess whether the declared interests constitute an appreciable real, potential or apparent conflict of interest. Such conflict of interest will, depending on the situation, result in: first, you being asked to inform your Government that you should not be nominated as an expert to the Interim Chemical Review Committee; second, you being asked by the Chair of the Interim Chemical Review Committee or all the activities of the Committee. Your attention is drawn to the procedure set out in decision N.../... of the Intergovernmental Negotiating Committee.

Information disclosed on this form shall not be made available to persons outside the interim secretariat, subject to the decisions of the Intergovernmental Negotiating Committee in cases where the objectivity of a particular meeting has been questioned.

Declaration

Have you or your partner any financial or other interest in the subject matter of the meeting or work in which you will be involved, which may be considered as constituting a real, potential or apparent conflict of interest? Yes: No: If yes, please give details in the box below.

Do you have, or have you had during the past four years, an employment or other professional relationship with any entity directly involved in the production, manufacture, distribution or sale of pesticides or directly representing the interests of any such entity? Yes: No: If yes, please give details in the box below.

Type of interest, e.g. patent, shares, employment, association, payment (including details on any compound, work, etc.)	Name of commercial entity	Belongs to you, partner or unit?	Current interest? (or year ceased)

Is there anything else that could affect your objectivity or independence in the meeting or work, or the perception by others of your objectivity and independence?

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances, including if an issue arises during the meeting or work itself.

Signature

Date

Name

Institution
