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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 (d) of the provisional agenda\*

IMPLEMENTATION OF THE INTERIM PRIOR INFORMED CONSENT PROCEDURE

ADOPTION OF DECISION GUIDANCE DOCUMENTS FOR ALREADY IDENTIFIED CHEMICALS

Note by the secretariat

A. Introduction

1. In paragraph 7 of its resolution on interim arrangements,<sup>1</sup> the Conference of Plenipotentiaries decided that all chemicals that had been identified for inclusion in the prior informed consent (PIC) procedure under the original PIC procedure but for which decision guidance documents had not yet been circulated before the date on which the Convention was opened for signature would become subject to the interim PIC procedure as soon as the relevant decision guidance documents had been adopted by the Intergovernmental Negotiating Committee.

2. The Intergovernmental Negotiating Committee, at its sixth and seventh sessions, considered the adoption of decision guidance documents for the six chemicals in question, namely binapacryl, bromacil, ethylene dichloride, ethylene oxide, maleic hydrazide and toxaphene.

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

<sup>1</sup> Contained in the Final Act of the Conference of Plenipotentiaries on the Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (UNEP/FAO/PIC/CONF/5, annex I, resolution 1).

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3. In decisions INC-6/3 and INC-7/2, the Committee adopted decision guidance documents on binapacryl and toxaphene and ethylene dichloride and ethylene oxide respectively, with the effect that these chemicals became subject to the interim PIC procedure as defined in paragraph 2 of the resolution on interim arrangements. With regard to bromacil, the Interim Chemical Review Committee, at its first session, had been of the opinion that the requirements set out in article 5 and annex II to the Convention had not been met and had therefore decided not to recommend the inclusion of bromacil in the interim PIC procedure. The Intergovernmental Negotiating Committee, at its seventh session, endorsed the decision of the Interim Chemical Review Committee on bromacil.

4. With respect to the remaining chemical, maleic hydrazide, the Intergovernmental Negotiating Committee requested the Interim Chemical Review Committee, in paragraph 3 of its decision INC-6/3, to review the chemical, addressing, in particular, the impurity hydrazine and the overall policy issues related to adding chemicals to the PIC procedure on the basis of control actions related to contaminants within the chemical, rather than to the chemical itself and, should it so decide, review and revise, as appropriate, the draft decision guidance document for that chemical for presentation to the Committee at its next session.

B. Consideration by the Interim Chemical Review Committee of the draft decision guidance document on maleic hydrazide forwarded by the Intergovernmental Negotiating Committee

5. At its first session, the Interim Chemical Review Committee addressed the overall policy issues related to adding chemicals to the PIC procedure on the basis of control actions related to contaminants within the chemical, rather than to the chemical itself. It made a general recommendation to the Intergovernmental Negotiating Committee related to the issue of contaminants, but decided to refer the issue of chemicals whose use had been notified as banned or severely restricted on the basis of specified levels of contaminants back to the Intergovernmental Negotiating Committee for further consideration. It also decided not to address the draft decision guidance document on maleic hydrazide until after the seventh session of the Intergovernmental Negotiating Committee.

6. The results of the Intergovernmental Negotiating Committee's deliberations on the issue of contaminants can be found in document UNEP/FAO/PIC/INC.8/7, section A.

7. With respect to maleic hydrazide, the Intergovernmental Negotiating Committee, by decision INC-7/5, requested that the Interim Chemical Review Committee, on a pilot basis, and without prejudice to any future policy on contaminants, apply two approaches to its consideration of maleic hydrazide and its impurity hydrazine and report on the outcome to the eighth session of the Intergovernmental Negotiating Committee.

8. The Interim Chemical Review Committee considered the issue of maleic hydrazide at its second session and made the following recommendation:

“The Interim Chemical Review Committee,

“Noting that maleic hydrazide is not used directly as a pesticide but is formulated as different salts in order to facilitate application/delivery to the target organisms and its uptake by those organisms (for example, the potassium salt of maleic hydrazide is more water-soluble than maleic hydrazide itself and is consequently more readily absorbed/taken up by the target plant),

“Relying on information submitted by industry representatives and a verbal report from the Committee member from China establishing that the only salt of maleic hydrazide moving in trade was the potassium salt,

“Noting also that toxicological reviews by the World Health Organization and the European Union have established that maleic hydrazide containing not more than 1 ppm free hydrazine does not produce adverse effects on health,

“Noting further that the Government of the United States of America has also undertaken a full toxicological review and has supported the re-registration of maleic hydrazide containing up to 15 ppm free hydrazine,

“Considering that the key manufacturer, Uniroyal Chemical, has submitted data in support of a specification by the Food and Agriculture Organization of the United Nations for the potassium salt of maleic hydrazide containing less than 1 ppm free hydrazine for consideration at a meeting of the Organization in June 2001,

“Considering Uniroyal Chemical’s information concerning sampling and analysis of products on the market, which showed that all known commercially available potassium salts of maleic hydrazide have a free hydrazine content of less than 1 ppm,

“Noting that the free hydrazine content in the potassium salt of maleic hydrazide is less than 1 ppm,

“1. Decides to examine the potassium salt and not to pursue consideration of the other forms of maleic hydrazide;

“2. Determines, considering the decision of the Interim Chemical Review Committee above to focus its deliberations on the potassium salt of maleic hydrazide and decision INC-7/4 relating to maleic hydrazide:

“(a) That under scenario 1,<sup>2</sup> there is no evidence of ongoing international trade in the potassium salt of maleic hydrazide in which the concentration of free hydrazine equals or is greater than 1 ppm;

“(b) That under scenario 2,<sup>2</sup> the potassium salt of maleic hydrazide with less than 1 ppm free hydrazine is still moving in trade and the regulatory action did not result in a decrease of the quantity of the chemical used or a decrease in the number of uses;

“3. Recommends:

“(a) That without prejudice or precedent to any future policy on contaminants, maleic hydrazide not become subject to the interim PIC procedure and a decision guidance document not be developed; that this decision be subject to written confirmation to the secretariat from the identified manufacturers by 1 January 2002 that the level of free hydrazine is not more than 1 ppm and to their commitment to seek and comply with the FAO specifications for the potassium salt of maleic hydrazide by 1 January 2004. The relevant designated national authorities should inform the identified manufacturers of this decision;

“(b) That the Intergovernmental Negotiating Committee request the designated national authorities to identify additional manufacturers of maleic hydrazide other than Uniroyal Chemical, Drexel Chemical, Fair Products and Otsuka Chemical;

“(c) That the Food and Agriculture Organization of the United Nations give priority to the preparation of specifications for the potassium salt of maleic hydrazide;

“(d) That designated national authorities in future provide greater specificity about the chemicals subject to their reported regulatory actions to avoid the necessity of the Interim Chemical Review Committee having to interpret the notifications to determine which chemicals are to be considered.”

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<sup>2</sup> See decision INC-7/5 of the Intergovernmental Negotiating Committee.

C. Suggested action by the Intergovernmental Negotiating Committee

9. The Intergovernmental Negotiating Committee may wish to:

(a) Endorse the Interim Chemical Review Committee's recommendation that, without prejudice or precedent to any future policy on contaminants, maleic hydrazide not become subject to the interim PIC procedure and a decision guidance document not be developed, subject to written confirmation to the secretariat from the identified manufacturers by 1 January 2002 that the level of free hydrazine is not more than 1 part per million and to their commitment to seek and comply with the FAO specifications for the potassium salt of maleic hydrazide by 1 January 2004;

(b) Request designated national authorities to identify additional manufacturers of maleic hydrazide other than Uniroyal Chemical, Drexel Chemical, Fair Products and Otsuka Chemical;

(c) Request relevant designated national authorities to encourage each identified manufacturer to provide written confirmation to the secretariat by 1 January 2002,<sup>3</sup> that the level of free hydrazine is not more than 1 part per million and that it is committed to seek and comply with the FAO specifications for the potassium salt of maleic hydrazide by 1 January 2004;

(d) Encourage FAO to give priority to the preparation of specifications for the potassium salt of maleic hydrazide;

(e) Request designated national authorities in future to provide greater specificity about the chemicals subject to their reported regulatory actions to avoid the necessity of the Interim Chemical Review Committee having to interpret the notifications to determine which chemicals are to be considered;

(f) Request the Interim Chemical Review Committee to follow progress made with regard to the preparation of FAO specifications for the potassium salt of maleic hydrazide and report back to the Intergovernmental Negotiating Committee at its ninth session.

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<sup>3</sup> Consideration might be given to adjusting this deadline for any additional manufacturers that may be identified, other than Uniroyal Chemical, Drexel Chemical, Fair Products and Otsuka Chemical, after the eighth session of the Intergovernmental Negotiating Committee.