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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

Tenth session

Geneva, 17-21 November 2003

Item 4 (e) (i) of the provisional agenda*

**Issues arising out of the fourth session of the
Interim Chemical Review Committee**

MALEIC HYDRAZIDE - STATUS OF IMPLEMENTATION OF DECISION INC-8/3

Note by the secretariat

Introduction

1. At its eighth session, the Intergovernmental Negotiating Committee, in its decision INC-8/3 (in document UNEP/FAO/PIC/INC.8/19, Annex 1) approved the recommendation of the Interim Chemical Review Committee that maleic hydrazide should not become subject to the interim PIC procedure and that a decision guidance document should not be developed.
2. The approval of the recommendation of the Interim Chemical Review Committee was subject to written confirmation to the secretariat from the four identified manufacturers engaged in international trade (Uniroyal Chemical, Drexel Chemical, Fair Products and Otsuka Chemicals) by 1 January 2002 that the level of free hydrazine is not more than 1 part per million and to their commitment to seek to comply with the specifications of the Food and Agriculture Organization of the United Nations for the potassium salt of maleic hydrazide by 1 January 2004.
3. The purpose of the present note is to provide the Intergovernmental Negotiating Committee with a report on the status of implementation of decision INC-8/3 and to seek guidance on possible further action.

* UNEP/FAO/PIC/INC.10/1.

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A. Background

4. At its first session, the Interim Chemical Review Committee addressed the overall policy issues concerning the addition of chemicals to the PIC procedure on the basis of control actions relating to contaminants, rather than to the chemical itself. It made a general recommendation to the Intergovernmental Negotiating Committee on 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 to the Intergovernmental Negotiating Committee for further consideration. It decided also not to address the draft decision guidance document on maleic hydrazide until after the seventh session of the Intergovernmental Negotiating Committee (see document UNEP/FAO/PIC/ICRC.1/6 paras. 32-38, annex I, section E and annex III. See also annex VI, section A).

5. At its seventh session, the Intergovernmental Negotiating Committee, in its decision INC-7/5 (in document Annex I, UNEP/FAO/PIC/INC.7/15), decided that the Interim Chemical Review Committee should, 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 Intergovernmental Negotiating Committee at its eighth session.

6. At its second session, the Interim Chemical Review Committee considered the issue of maleic hydrazide and recommended to the Intergovernmental Negotiating Committee that it should not be included in the interim PIC procedure provided certain conditions were fulfilled by the four identified manufacturers (Ohtsuko Chemicals, Japan; Fair Products, Drexel and Uniroyal, United States of America). The recommendation to the Intergovernmental Negotiating Committee and the reasoning behind it are given in annex IV of the report of the second session (UNEP/FAO/PIC/ICRC.2/11).

7. At the eighth session of the Intergovernmental Negotiating Committee, the Chair of the Interim Chemical Review Committee presented the aforementioned recommendation on maleic hydrazide. He drew attention to the proviso that if the manufacturers of maleic hydrazide failed to provide confirmation that the level of free hydrazine was not more than 1 part per million, the matter should be referred to the Interim Chemical Review Committee, which would then consider what action should be taken (see document UNEP/FAO/PIC/INC.8/19, paras. 39-45 and annex I (decision INC-8/3)).

8. In that connection, it was noted that the Convention did not cover products that did not enter international trade and that the maleic hydrazide produced in China was for domestic use only. As such products were not exported there was no obligation on that country's manufacturers to provide the confirmation of the level of free hydrazine (see document UNEP/FAO/PIC/INC.9/INF/3, paras. 12-13).

9. Decision INC-8/3 of the Intergovernmental Negotiating Committee at its eighth session on maleic hydrazide is reproduced in annex I to the present note.

10. Subsequent to the eighth session of the Intergovernmental Negotiating Committee, the designated national authority of Japan provided further information on the status of maleic hydrazide production in that country to the secretariat. In the case of Ohtsuko Chemicals, it was stated that the product contained less than 1 part per million free hydrazine and was produced solely for domestic use. An additional manufacturer, the Japan Hydrazine Company, was also identified. The Japan Hydrazine Company produces the choline salt of maleic hydrazide. It was noted that the free hydrazine content of its products would increase considerably during storage, with the result that the level would exceed 1 part per million. The Ministry of Agriculture, Forestry and Fisheries (MAFF) of Japan indicated that it was working with the manufacturer on possible options, including voluntary cancellation and improved product quality, to keep the level of free hydrazine below 1 ppm. The Ministry would keep the Interim Chemical Review Committee and the Intergovernmental Negotiating Committee informed of progress. The letter giving this information is reproduced in annex II to the present note.

11. At the ninth session of the Intergovernmental Negotiating Committee the representative of a regional economic integration organization expressed deep concern about the apparent failure of some manufacturers to comply with the condition of paragraph 2 of decision INC-8/3 whereby they should confirm their commitment to seek to comply with FAO specifications by 1 January 2004. He was particularly concerned to learn that one Japanese manufacturer had been identified as producing the choline salt of maleic hydrazide with a free hydrazine content of more than 1 ppm. That raised serious doubts about the continued validity of decision INC-8/3 not to include maleic hydrazide in the interim PIC procedure (see document UNEP/FAO/PSC/INC.9/21, para.61).
12. The representative of Japan replied that the competent authority in his country had reported that it had measured the hydrazine content of the maleic hydrazide produced by the Japan Hydrazine Company and had found it to be below 1 ppm. The authority was currently preparing a report on that survey and the Government of Japan would submit the results in writing to the secretariat (*ibid.*, para. 62).
13. A report submitted to the secretariat by the Government of Japan in December 2002 stated that the choline salt of maleic hydrazide produced by the Japan Hydrazine Company was exported to the Republic of Korea. Analysis of representative batches of the choline salt of maleic hydrazide showed a level of free hydrazine ranging from 0.2 to 0.5 ppm. It was also noted that analysis of material available in retail stores in Japan showed free hydrazine levels of over 2 ppm. The producer had not applied for FAO specification. The report is reproduced in annex II to the present note.
14. The fourth session of the Interim Chemical Review Committee had before it a status report prepared by the Secretariat (UNEP/FAO/PIC/ICRC.4/14). It was noted (see document UNEP/FAO/PIC/ICRC.4/18, paras. 94-97) that, concerning the potassium salt of maleic hydrazide, one of the three producers in the United States had provided sufficient data to justify an FAO specification and the two further producers in the country had submitted relevant information, which would be considered at the FAO/WHO Joint Meeting on Pesticide Specifications in June 2003. One producer identified in China, one in the Republic of Korea and one in Japan had considered that, since their product was for domestic use only, FAO specification was not required. It appeared that the terms of decision INC-8/3 with regard to the potassium salt of maleic hydrazide had been fulfilled.
15. Also the Interim Chemical Review Committee observed that there were two possible courses with respect to the choline salt of maleic hydrazide: to clarify the question of the stability of the choline salt in storage and, if it was found to be stable, to seek an FAO specification; or, if the substance was not stable and represented a chemical with an unavoidable contaminant, to initiate preparation of a decision guidance document for the choline salt of maleic hydrazide. One representative cautioned that the issue of preparation of such a decision guidance document gave rise to other concerns that went beyond the question of levels of free hydrazine.
16. The Committee welcomed the report by the member from Republic of Korea that the country intended to amend its legislation to comply with the recommended specification of the FAO by the end of the year. The Committee also noted that, where possible, the designated national authority of the Republic of Korea would provide information on the levels of free hydrazine in the choline salt of maleic hydrazide available in that country, and observed that such analysis should also take into account the conditions of storage of the technical material and an indication of the period between its production date and the sampling. On that basis, and possibly with other information, it would be possible to confirm whether the product was decomposing and the hydrazine represented an unavoidable contaminant.
17. The second Joint FAO/WHO Joint Meeting on Pesticide Specifications, in June 2003, further considered the proposal for specifications for the potassium salt of maleic hydrazide based on the data submissions from two manufacturers from the United States of America (Fair Products and Drexel). The Meeting had sufficient information to justify the specifications; however, the initial manufacturer (Uniroyal now Crompton Corporation) had failed to provide the analytical method used for the determination of the active ingredient and of the free hydrazine, which are essential requirements for every specification and serve as the reference for subsequent manufacturers. In the absence of that information, the meeting was

unable to give final approval of the specifications for the potassium salt of maleic hydrazide. As soon as the required analytical methodology is available it will be possible to finalize the specifications. It is not anticipated that the required information on the analytical method used will be available before the tenth session of the International Negotiating Committee.

18. As of June 2003, no further information was available from Japan or the Republic of Korea on the continued manufacture of and trade in the choline salt of maleic hydrazide the levels of free hydrazine which it contains or its stability.

B. Possible action by the Interim Chemical Review Committee

19. The Committee may wish to review the current status of the implementation of decision INC-8/3 concerning the potassium salt of maleic hydrazide and consider what further follow-up may be necessary regarding the choline salt of maleic hydrazide.

Annex I

Decision INC-8/3: Maleic hydrazide^a

The Intergovernmental Negotiating Committee

1. Approves the recommendation of the Interim Chemical Review Committee that maleic hydrazide not become subject to the interim PIC procedure and that a decision guidance document not be developed;
2. Makes subject paragraph 1 to written confirmation to the secretariat from the four identified manufacturers engaged in international trade (Uniroyal Chemical, Drexel Chemical, Fair Products and Otsuka Chemicals) 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 specifications of the Food and Agriculture Organization of the United Nations for the potassium salt of maleic hydrazide by 1 January 2004;
3. Decides that the present resolution shall not cause prejudice to or set precedent for any future policy on contaminants;
4. Requests relevant designated national authorities to encourage each identified manufacturer to provide written confirmation to the secretariat by 1 January 2002 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 specifications of the Food and Agriculture Organization of the United Nations for the potassium salt of maleic hydrazide by 1 January 2004;
5. Requests that confirmations by manufacturers of maleic hydrazide that the level of free hydrazine is not more than 1 part per million be submitted through the relevant designated authority to the secretariat;
6. Requests the Interim Chemical Review Committee to review whether confirmations by the four identified manufacturers of maleic hydrazide that the level of hydrazine is not more than 1 part per million are provided to the secretariat by 1 January 2002, to review the statements and to report to the Intergovernmental Negotiating Committee at its ninth session;
7. Requests designated national authorities to identify additional manufacturers of maleic hydrazide engaged in international trade and submit this information to the secretariat for consideration by the Interim Chemical Review Committee;
8. Encourages the Food and Agriculture Organization of the United Nations to give priority to the preparation of specifications for the potassium salt of maleic hydrazide;
9. Requests designated national authorities in future to provide greater specificity about the chemicals subject to their reported regulatory actions, in order to avoid the necessity of the Interim Chemical Review Committee having to interpret the notifications to determine which chemicals are to be considered;
10. Requests the Interim Chemical Review Committee to follow progress made with regard to the preparation of specifications of the Food and Agriculture Organization of the United Nations for the potassium salt of maleic hydrazide and report to the Intergovernmental Negotiating Committee at its ninth session.

^a UNEP/FAO/PIC/INC.8/19, annex I.

Annex II

Letter from the designated national authority in Japan concerning manufacturers of maleic hydrazide in Japan

Report from MAFF Japan (December 5, 2002)

*Ministry of Agriculture, Forestry and Fisheries of Japan
Agricultural Chemicals Administration Office
Agricultural Materials Division
1-2-1, Kasumigaseki, Chiyoda-ku,
100-8950, Tokyo, Japan*

To: Mr. N.A. Van der Graff
Executive Secretary of Rotterdam convention

Re: Maleic Hydrazide

Dear Mr. N.A. Van der Graaff

Regarding the decision at PIC-INC 5 and also letter of 6. Nov. 2001, Japan would like to notify the identified manufacture of Maleic Hydrazide in Japan.

Japan identified a manufacture, Japan Hydrazine Co. Ltd., in addition to Otsuka Chemical. Co. Ltd, which is already identified in ICRC and INC of PIC convention. Identified manufactures are as follows;

u The addresses and attentions

Ohtsuka Chemical Co.Ltd. Attention: Mr.Akihide Andoh
3-2-27 Ote Dori, Chuo-ku, 540-0021
Osaka, Japan

Japan Hydrazine Company, Inc. Attention: Mr. Naoki Uchino
Iino Bidg.)9F, 1-1, Uchisaiwai-cho 2-chome, Chiyoda-ku,
Tokyo 100-0011,Japan

u Overview of Products

Ø Ohtsuka Chemical

Ohtsuka Chemical is manufacturing Maleic Hydrazine potassium salt which contains free hydrazine contents is bellow 1ppm. It is certified that the content of free hydrazine does not increase during storage and the level is kept bellow 1ppm. And the fact that the company's products is not exported to other countries, then distributed only within Japan.

Finally Japan believes that the products should not be any problem within the scope of PIC procedure.

Ø Japan Hydrazine Company, Inc.

Japan also identified additional Manufacture, Japan Hydrazine Company, Inc., which is producing Maleic Hydrazine in Japan. Japan also informs that it is revealed that the company is producing Maleic Hydrazine Choline Salt. Depending upon our investigation and information provided from the manufacture about of their product, we found that free hydrazine content of their products would be increase considerably during storage; consequently the level would exceed 1ppm.

Japanese MAFF recognizes that the fact is serious and is going to setting regal level of maximum constants of free hydrazine in pesticides. Consequently, the sales of the products which exceed the level would be ban within Japan.

The manufacture is considering voluntarily cancel of manufacturing the product, or improve on the product to keep the free hydrazine below 1ppm. Japan MAFF will supervise and consult with that manufacture about possible solution and Japan MAFF will inform the result in ICRC and INC.

UNEP/FAO/PIC/INC.10/11

Regards,

Takehiko Yokoyama
On Behalf of
Mr. Kiyoshi Sawada
Director,
Agricultural Chemicals Administration Office
Ministry of Agriculture Forestry and Fisheries of Japan

14:12:02 18:12 FAX 15

MISSION DU JAPON

001/006

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to
PC-36/3

FAX

TO : Mr. Jim Willis, Executive Secretary
 Mr. Niek Van der Graaff, Executive Secretary
 Mr. Erik Larsson, Coordinator
 Interim Secretariat for the Rotterdam Convention

FAX No : 022-797-3460 (UNEP Chemical)
 +39-06-5705-6347 (FAO, Plant Protection Service)

PLANT PROTECTION	
Re DEC. - 5 2002	
RECEIVED	Initials
Mr. VAN DER GRAAFF	

TEL NO :

DATE : 4 December 2002 **PAGES:** 6 including this cover

RE: JAPAN: Report on Maleic Hydrazide

FROM: Akiho SHIBATA, Advisor
 Permanent Mission of Japan to International Organisations in Geneva

FAX NO : +41-(0)22-788-3811
TEL NO : +41-(0)22-717-3324

Dear Mr. Willis, Mr. Van der Graaff
 CC: Mr. Larsson

Upon instructions from my authorities, I am hereby submitting the report on the hydrazine content of the maleic hydrazide produced by a Japanese manufacturer. This report is in response to the discussion at the PIC INC9 in Bonn (see UNEP/FAO/PIC/INC.9/L.1 para.58.).

I would appreciate if you could confirm your reception of this report by FAX or by e-mail.

Should you have any further inquiries regarding this matter, please do not hesitate to contact me at the Japanese Mission in Geneva.

Best regards,

Akiho Shibata
 Akiho Shibata
 Permanent Mission of Japan in Geneva

4/12/02 18:12 FAX 15

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002/006

Japan MAFF surveyed the situation of maleic hydrazide choline salt in Japan.

Japan MAFF received the information of the maleic hydrazide choline salt from the Japan Hydrazine Company Inc.

Japan Hydrazine Company Inc. is only one manufacture of maleic hydrazide choline salt.

Japan has other producing company, Otsuka chemical corporation, but their product is potassium salt.

In this document, Japan reports the choline salt only.

We prepare this report base on the information of the manufacture.

Their reports said that free hydrazine content in their export product is 0.38 ppm (mean value of five samples) as follows.

REPORT

1. Chemical name
Maleic Hydrazide Choline salt
2. Product manufacturer
Japan Hydrazine Company, Inc.
3. Product name (local)
Eruno (39 % (MH-C); Liquid formulation)
4. Export country
Korea
5. Export product
Maleic Hydrazide Choline salt (Technical grade)
6. Specification
Content of hydrazine: 1.0 ppm max.
See: C-MH specification
7. Result of content
Manufacturer analyzed content of MH-C, MH and free hydrazine in their product

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Table 1 Content of the maleic hydrazide choline salt for export grade products

Lot No.	2C21-21Y	2C22-21Y	2C23-21Y	2C23-22Y	2C25-21Y
MH-C (%)	59.64	59.77	59.65	60.19	60.23
MH (%)	31.06	31.13	31.07	31.35	31.37
Hydrazine (ppm)	0.4	0.3	0.4	0.2	0.5

See: Result of Hydrazine contaminated level in the export product for the Korea

Conclusion

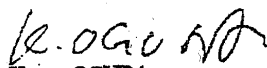
Analytical data of the free hydrazine content in the export grade MH-C product by Japan Hydrazine Company Inc. is 0.38 ppm (mean value of five samples). This level is within their specification.

For the export products, it is technical grade; Japan does not have any stability information on the formulation of import country.

Further more, Japan understands that the import country has regulation of free hydrazine level. Retail pesticide in import country would be sold within their standard.

ACIS analyzed some retail product taking from consumer in Japan; those samples contain over 2 ppm of free hydrazine. The reason for this incident is seem to the effect of inert ingredients.

*ACIS: Agricultural Chemicals Inspection Station, this organization is under the MAFF


Kazuo OGURA

Deputy Director

Agricultural Chemicals Administration Office

Agricultural Production Bureau

Ministry of Agriculture, Forestry and Fisheries

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MISSION DU JAPON

004/006

Oct. 21 2002

Japan Hydrazine Company Inc.
Examination Div. Sakai Laboratory

Result of Hydrazine contaminated level in the export product for the Korea

	2C21-21Y	2C22-21Y
Outlook	light brown water soluble liquid	ditto
Content of MH-choline salt	59.64	59.77
MH (%)	31.06	31.13
Choline (%)	33.59	33.61
Hydrazine ppm	0.4	0.3
PH (at 20°C)	10.3	10.4
	2C23-21Y	2C23-22Y
Outlook	light brown water soluble liquid	ditto
Content of MH-choline salt	59.65	60.19
MH (%)	31.07	31.35
Choline (%)	33.70	33.85
Hydrazine ppm	0.4	0.2
PH (at 20°C)	10.3	10.1
	2C25-21Y	
Outlook	light brown water soluble liquid	
Content of MH-choline salt	60.23	
MH (%)	31.37	
Choline (%)	31.37	
Hydrazine ppm	0.5	
PH (at 20°C)	10.5	

Note List of examination data sheet for the shipment contains the outlook, content of MH-choline salt and free hydrazine.

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JAPAN HYDRAZINE COMPANY, INC.

INO BLDG.,
1-1, UCHISAIWAI-CHO 2CHOME
CHIYODA-KU, TOKYO 100-0011, JAPANTEL: +81-3-3506-3780
FAX: +81-3-3506-3787

October 18, 2002

C-MH specification

Product code : 1340000
Appearance : light yellowish liquid
C-MH content : 59.0-60.4%
MH content : 30.7 - 31.5%
Choline salt : 33.2 - 34.1%
Hydrazine : 1.0 ppm max.
Pfr : 10.0 - 10.7 at 20 deg.C.
Sp.Gr. : 1.14 - 1.16 at 20 deg.C.

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Oct. 21 2002

Japan Hydrazine Company Inc.
Examination Div. Sakai Laboratory

Analytical results for export to Korea

	2C21-21Y	2C22-21Y
Outlook	light brown water soluble liquid	ditto
Content of MH-choline salt	59.64	59.77
MH (%)	31.06	31.13
Choline (%)	33.59	33.61
Hydrazine ppm	0.4	0.3
PH (at 20°C)	10.3	10.4
	2C23-21Y	2C23-22Y
Outlook	light brown water soluble liquid	ditto
Content of MH-choline salt	59.65	60.19
MH (%)	31.07	31.35
Choline (%)	33.70	33.86
Hydrazine ppm	0.4	0.2
PH (at 20°C)	10.3	10.1
	2C25-21Y	
Outlook	light brown water soluble liquid	
Content of MH-choline salt	60.23	
MH (%)	31.37	
Choline (%)	31.37	
Hydrazine ppm	0.5	
PH (at 20°C)	10.5	

Note List of examination data sheet for the shipment contains the outlook, content of
MH-choline salt and free hydrazine.

(3)