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Interim Chemical Review Committee

Fourth session

Rome, 3-7 March 2003

Item 6 of the provisional agenda*

STATUS REPORT ON COMPLIANCE WITH DECISION INC-8/3 ON MALEIC HYDRAZIDE

Note by the secretariat

1. The purpose of this note is to provide the Interim Chemical Review Committee with a report on the status of compliance of the identified manufacturers of maleic hydrazide with the decision of the eighth session of the Intergovernmental Negotiating Committee INC8/3, concerning maleic hydrazide (Annex 1, UNEP/FAO/PIC/INC.8/19).

A. Background

2. 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 (UNEP/FAO/PIC/ICRC.2/11).

3. The seventh session of the Intergovernmental Negotiating Committee, in 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 (Annex 1, UNEP/FAO/PIC/INC.7/15).

4. At its second session the Interim Chemical Review Committee considered the issue of maleic hydrazide and recommended to the Intergovernmental Negotiating Committee that it not be included in the interim PIC procedure provided certain conditions were fulfilled by the four identified

* UNEP/FAO/PIC/ICRC.4/1.

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 may be found in Annex IV of the report of ICRC2 (UNEP/FAO/PIC/ICRC.2/11).

5. At the eighth session of the Intergovernmental Negotiating Committee, the Chair of the Interim Chemical Review Committee presented the recommendation on maleic hydrazide. He drew the attention of the meeting 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 back to the Interim Chemical Review Committee, which would then consider what action should be taken. He also reported that there were manufacturers of maleic hydrazide in one more country (China) and that therefore any consideration by the Interim Chemical Review Committee should be applicable not only to the four already identified manufacturers but also to the three manufacturers in that country.

6. 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 are not exported then there was no obligation on that country's manufacturers to provide the confirmation as to the level of free hydrazine.

7. The Chair of the Interim Chemical Review Committee clarified that all that was required was a simple statement that certain manufacturers in a given country were producing maleic hydrazide, to a certain specification, together with clarification of whether the maleic hydrazide was, or was not, in international trade. Such statements would then be considered by the Interim Chemical Review Committee. The Committee noted that such statements should be provided through the designated national authority of the Party where the production occurred. Decision INC-8/3 on maleic hydrazide is contained in Appendix I to the present document.

8. Subsequent to the eighth session of the Intergovernmental Negotiating Committee further information on the status of maleic hydrazide production in Japan was provided to the secretariat in a letter from the designated national authority of that country. 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 their 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 they were working with the manufacturer on possible options including voluntary cancellation and improved product quality and that they would keep the Interim Chemical Review Committee and the Intergovernmental Negotiating Committee informed. A copy of the letter is contained in Appendix II to the present document.

9. At the ninth session of the Intergovernmental Negotiating Committee the representative of a regional economic integration organization was deeply disturbed 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.

10. The representative of Japan said 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 by the end of November 2002.

11. The Intergovernmental Negotiating Committee requested the Interim Chemical Review Committee to report to it at its tenth session on the status of implementation of decision INC-8/3 concerning maleic hydrazide.

B. Current Status

12. Uniroyal Chemical (now Crompton Corporation) provided data in order to obtain an FAO specification for the potassium salt of maleic hydrazide. The data were reviewed at the FAO/WHO Joint Meeting on Pesticide Specifications (JMPS) in June 2001 and additional information requested. The additional information was provided and considered by the JMPS in June 2002. It was agreed that the submitted information was a sufficient basis for an FAO specification for the potassium salt of maleic hydrazide (containing a maximum of 1 mg/kg hydrazine).

13. Drexel and Fair Products Inc., (USA) have submitted information regarding their products to demonstrate their compatibility/equivalence to the Uniroyal/Crompton specification. This information will be considered by the JMPS at its meeting in June 2003. Presuming that the evaluation is favourable the existing Uniroyal/Crompton specification will be extended to include the potassium salt of maleic hydrazide produced by Drexel and Fair Products and be available by the end of 2003.

14. Ohtsuko Chemicals and the Japan Hydrazine Company (Japan) have not sought FAO specifications for their products. In the case of Ohtsuko chemicals, it is their view that as their product (potassium salt of maleic hydrazide) which contains less than 1ppm free hydrazine, is for domestic use only an FAO specification is not required. The Japan Hydrazine Company manufactures the choline salt of maleic hydrazide for export to Korea. In a report submitted to the secretariat by MAFF Japan dated 5 December 2002, it was stated that the results of the analysis of representative batches of technical material indicated a level of free hydrazine ranging from 0.2 to 0.5 parts per million. It was also noted that analysis of technical material available at retail stores in Japan showed free hydrazine levels of over 2 parts per million. A copy of this report is contained in Appendix II to the present document.

C. Possible Action by the Interim Chemical Review Committee

15. In accordance with decision INC8/3 the Committee may wish to review the information submitted by the Government of Japan and consider what further follow-up may be necessary.

APPENDIX I

Decision INC-8/3: Maleic hydrazide¹A. 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.

¹ (Annex 1, UNEP/FAO/PIC/INC.8/19)

APPENDIX 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;

◆ 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

◆ Overview of Products

➤ Ohtsuka Chemical

Ohtsuka Chemical is manufacturing Maleic Hydrazine potassium salt which contains free hydrazine contents is below 1ppm. It is certified that the content of free hydrazine does not increase during storage and the level is kept below 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.

➤ 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 legal 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.

Regards,

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

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)

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.53.).

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
 Permanent Mission of Japan in Geneva

to

PL-36/3

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

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

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

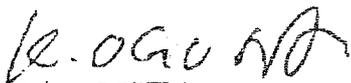
Conclusion

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 Inspector: Station, this organization is under the MAFF


Kazuo OGURA

Deputy Director

Agricultural Chemicals Administration Office

Agricultural Production Bureau

Ministry of Agriculture, Forestry and Fisheries

Oct. 21 2002

Japan Hydrazine Company Inc.

Examination Div. Sakaide 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	31.95
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.

**JAPAN HYDRAZINE COMPANY, INC.**

IINO BLD'G.,
1-1, UCHISAIWAI-CHO 2CHOME
CHIYODA-KU, TOKYO 100-0011, JAPAN

TEL: +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.
Pp : 10.0 - 10.7 at 20 deg.C.
Sp.Gr. : 1.14 - 1.16 at 20 deg.C.

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	33.85
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.

(3)