



**United Nations
Environment Programme**

**Food and Agriculture Organization
of the United Nations**

Distr.
GENERAL

UNEP/FAO/PIC/ICRC.3/INF2
11 January 2002

ENGLISH ONLY

INTERIM CHEMICAL REVIEW COMMITTEE

Third session

Geneva, 17-21 February 2002

Item 7(a) 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 four 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 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

* UNEP/FAO/PIC/ICRC.3/1.

identified manufacturers (Osuko 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) than had been originally thought 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.
8. Decision INC-8/3 on maleic hydrazide is contained in Appendix I to the present document.

b) Current Status

9. The report of the second session of the Interim Chemical Review Committee was circulated to all designated national authorities on 12 June 2001 along with a request that they identify additional manufacturers of maleic hydrazide. As of 11 January 2002, in addition to the three manufacturers in China, a further manufacturer of maleic hydrazide was identified in Japan (Japan Hydrazine Company Inc.).
10. On June 11 2001 a letter was sent to the designated national authorities in those countries where the four identified manufacturers of maleic hydrazide were located (United States and Japan) drawing their attention to the recommendation of the Interim Chemical Review Committee. This letter was accompanied by a copy of the recommendation from the Committee, the name and address of the relevant manufacturers, as well as, brief guidance on the procedures that the manufacturers should follow regarding FAO specifications.
11. A reminder was sent to the designated national authorities in Japan and the United States on 6 December 2001.
12. Responses were been received from the manufacturers in the United States (Fair Products, Drexel, Uniroyal) through the designated national authority in which they indicated that their products do not contain hydrazine in concentrations above 1 part per million and their intention to pursue FAO specifications.
13. The response from the designated national authority in Japan noted that in addition to Osuko Chemicals, the Japan Hydrazine Company was also making maleic hydrazide. In the case of Osuko Chemicals it was stated that the product contained less than 1 part per million free

hydrazine and was produced solely for domestic use. The Japan Hydrazine Company produces the choline salt of maleic hydrazide and it was noted that the free hydrazine content of their products would increase considerably during storage with the result that the level would exceed 1part per million. It was stated that the Ministry of Agriculture, Forestry and Fisheries (MAFF) of Japan was 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.

14. The responses submitted to the secretariat may be found in Appendix II to this document.

c) Possible Action by the Interim Chemical Review Committee

15. In accordance with decision INC8/3 the Committee may wish to review the letters provided by the five manufacturers and consider what further follow-up may be necessary.

The results of these deliberations will form the basis for a report to the ninth session of the Intergovernmental Negotiating Committee on the level of compliance with decision INC8/3.

Appendix I

Decision INC-8/3: Maleic hydrazide¹

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

Letters from manufacturers in the United States forwarded by the designated national authority

Drexel
Fair Products
Uniroyal Chemicals

Letter from the designated national authority in Japan

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

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

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Iino Bidg.)9F, 1-1, Uchisaiwai-cho 2-chome, Chiyoda-ku,
Tokyo 100-0011,Japan

◆ Overview of Products

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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.

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Regards,

Takehiko Yokoyama

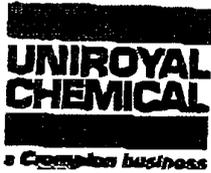
On Behalf of

Mr. Kiyoshi Sawada

Director,

Agricultural Chemicals Administration Office

Ministry of Agriculture Forestry and Fisheries of Japan



PL 32/14

December 21, 2001

Office of Pesticide Programs
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Attention: Cathleen M. Barnes
Government & International Services Branch (7506C)

Subject: Maleic hydrazide: PIC Procedure, FAO Specification

Dear Ms. Barnes:

Reference is made to the your e-mail message dated 12/11/01.

This letter confirms that Uniroyal Chemical has started the process necessary to develop an FAO Specification for maleic hydrazide. The initial paperwork was filed with FAO/Rome in March 2001, and was subsequently assigned the case number PL32/14.

If you have any questions on this matter, please feel free to contact me.

Sincerely,

UNIROYAL CHEMICAL COMPANY, INC.

Allen R. Blem
Registration Section
Crop Protection R&D

arb/cath1221.doc

Uniroyal Chemical

74 Amity Road, Bethany, CT 06524-3402 (203) 393-2163 (203) 393-2290 fax



Drexel Chemical Company

December 7, 2001

Fed Ex # 7926 8885 5893

Ms. Cathleen M. Barnes 7506C
International Programs Manager
Office of Pesticide Programs
USEPA Headquarters
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Ref: Your letter dated October 17, 2001, regarding FAO Specification for Free Hydrazine in Maleic Hydrazine

Dear Ms. Barnes:

Thank you for alerting us to the requirement that manufacturers of maleic hydrazide commit to seeking and complying with an FAO specification for free hydrazine in maleic hydrazide. The purpose of this letter is to inform you that Drexel Chemical Company's maleic hydrazide meets the free hydrazine limits in all countries where sold and Drexel hereby commits to seek and comply with the FAO specifications for free hydrazine for the potassium salt of maleic hydrazide by January 1, 2004.

Sincerely,

Roy W. Olson
Business Development Manager

RO/mp

cc: RDS/LS/BJ



fair products, inc.

Ms. Cathleen Barnes, International Programs Manager
Office of Pesticide Programs (7504-C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

December 10, 2001

Subject: Fair Products, Inc.'s response to the EPA letters of October 5th and 17th 2001 regarding voluntary Certification of Hydrazine levels in End-Use Pesticide products and requests that we pursue a full FAO/PIC Specification for our MH products.

Dear Ms Barnes:

Fair Products hereby Certifies that the End-Use products produced and sold both Domestically and Internationally by our company do not and will not contain hydrazine concentrations that exceed 1 ppm. In fact, a review of our manufacturing specifications from recent production batches indicates that hydrazine levels rarely exceed 0.1 PPM. As many have already indicated, this has been the case for about the last 20 years since the MH industry discontinued the production and use of the diethanolamine salt forms of MH (DEA-MH) in favor of the potassium salt MH form (KMH).

In regards to the request that we pursue a full FAO Specification for MH, we further agree to pursue such a specification so long as undue economic hardships as a result of excessive data assemblage and production do not occur. Fair Products' position is largely that we have recently completed a successful re-registration of all MH products for the US EPA. This effort included the production and assemblage of all pertinent Physical and Chemical data, Manufacturing processes, and Environmental and Toxicological data for our Technical Grade Active Ingredients, Manufacturing Products and our respective End-Use Products at considerable expense to Fair Products. These recently completed data, Fair Products believes should be sufficient to support the FAO specification in full. Any additional data requests by the FAO would have to be evaluated in terms of costs and benefits before we could commit to supply such data.

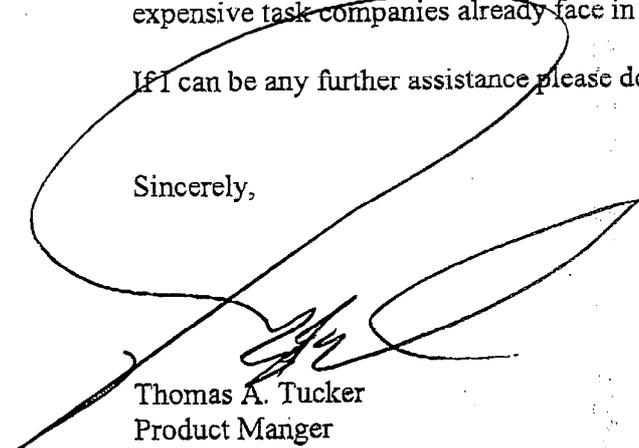
Fair Products, Inc. Agri-Specialties Division Post Office Box 386, Cary, North Carolina 27512-0386
Telephone: (919) 467-8352
FAX: (919) 467-9142

It appears obvious that the main concern and the reasons MH has been linked to any scrutiny by FAO/PIC are hydrazine contamination. Certainly any other environmental and toxicological concerns have been thoroughly evaluated and eliminated during the long history of MH use in the US and abroad and by the recent re-registration of MH by EPA. Since hydrazine is the point of attention, it seems practical that the FAO/PIC interest in MH could be served best by certification of production runs and the resulting products by the various MH producers. This could be accomplished simply and without the dollars, time and effort which would be required to produce a complete FAO Specification for MH. Since the introduction of KMH, hydrazine contamination has become an almost non-issue (this company is not aware of any existing DEA-MH registrations inside the US) and it seems that everyone would benefit from a more streamlined approach.

Finally, Fair Products, Inc. fully appreciates the well-founded intent of the FAO/PIC initiative and would like to cooperate in any way reasonably possible. However we would like to express concerns that the creation of any additional regulatory entities and the resulting duplications and eccentricities can only add to the already difficult and expensive task companies already face in maintaining compliance among these entities.

If I can be any further assistance please do not hesitate to contact me.

Sincerely,



Thomas A. Tucker
Product Manger
Agri-Specialties Division
Fair products, Inc. USA