INTERIM CHEMICAL REVIEW COMMITTEE
Third session
Geneva, 18 – 22 February 2002
Item 6 (b) on the provisional agenda *

INCLUSION OF CHEMICALS IN THE INTERIM PRIOR INFORMED CONSENT PROCEDURE
- REVIEW OF PROPOSALS FOR SEVERELY HAZARDOUS PESTICIDE FORMULATIONS

GRANOX TBC and SPINOX T

Note by the Secretariat

1. Further to the information provided by the Secretariat in document UNEP/FAO/PIC/ICRC.3/17.Add.1, the Secretariat would like to provide for your kind information those comments and information that have been received between 7 and 14 January 2002.
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ANNEX I– Countries where the designated national authority responded to the request for information on the formulations Granox T.B.C. and Spinox T

As of 14 January 2002, the designated national authorities in the following countries had replied to the request for information of 25 October 2001 (in bold: countries whose reply has been received between 7 January and 14 January 2002).

<table>
<thead>
<tr>
<th>Country/Organisation</th>
<th>Date received</th>
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<tbody>
<tr>
<td>Bhutan</td>
<td>18 December 2001</td>
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<tr>
<td>Canada</td>
<td>9 January 2002</td>
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<tr>
<td>Chile</td>
<td>10 January 2002</td>
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<tr>
<td>People’s Republic of China</td>
<td>19 December 2001</td>
</tr>
<tr>
<td>Colombia</td>
<td>26 November 2001 and 11 December 2001</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>3 December 2001</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>17 December 2001</td>
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<tr>
<td>Estonia</td>
<td>26 November 2001</td>
</tr>
<tr>
<td>Finland</td>
<td>6 December 2001</td>
</tr>
<tr>
<td>Israel</td>
<td>27 December 2001</td>
</tr>
<tr>
<td>RDA Republic of Korea</td>
<td>17 December 2001</td>
</tr>
<tr>
<td>Latvia</td>
<td>25 November 2001</td>
</tr>
<tr>
<td>Lesotho</td>
<td>18 December 2001</td>
</tr>
<tr>
<td>Malaysia</td>
<td>9 January 2002</td>
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<tr>
<td>Mexico</td>
<td>20 December 2001</td>
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<tr>
<td>New Zealand</td>
<td>11 December 2001</td>
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<td>Tanzania</td>
<td>10 January 2002</td>
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<td>Turkey</td>
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<td>Vietnam</td>
<td>9 January 2002</td>
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<tr>
<td>Zimbabwe</td>
<td>8 December 2001</td>
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<tr>
<td>European Union</td>
<td>18 December 2001</td>
</tr>
</tbody>
</table>

A copy of the correspondence and attachments submitted to the Secretariat has been sent to the chair of the inter-sessional task group on these two formulations and is available from the Secretariat on request. A complete set of this correspondence will be available at the third session of the Committee in February 2002.
January 9, 2002

Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Service
FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Gentlemen;

Subject: Senegal Notification for Granox TBC and Spinox T

On behalf of CropLife International I am pleased to provide the Interim Secretariat with the industry response to a request for information relating to the Senegal notification on a severely hazardous pesticide formulation and in accordance with Annex III Part 2 of the Rotterdam Convention. CropLife International and its member organizations support the Rotterdam Convention. We believe that sound regulation of pesticides should be science-based, balanced and fair and serve the intended purpose of informing countries of hazards in other countries that are relevant to their own situations. We are providing comments, herewith, in that spirit as the ICRC embarks on the consideration of the first notification for a severely hazardous pesticide formulation.

The comments were generated by a task group of four basic manufacturers of the three active ingredients contained in the subject formulations: Dupont for benomyl, FMC Corp. for carbofuran, and Uniroyal/Crompton Corp. and UCB Group for thiram. Some of the information presented was gleaned from personal communications with Senchim and S.P.I.A., the local distributors of the subject three-way mixture.

None of the basic manufacturers in the task group formulate or sell the subject three-way formulation anywhere in the world and are unaware of sales of the subject formulation or any formulation variants outside of Senegal. The ICRC may wish to take the absence of international trade into consideration, even though evidence of international trade is not a criterion for listing a severely hazardous pesticide formulation.

Given that the task group did not have firsthand knowledge of the incidences, it decided to undertake an indirect approach to understanding the relationship between the twenty-two reported incidents that were available and the subject formulation. It conducted an evaluation of the incident report forms from a scientific standpoint to understand how well the reported incidents matched the known modes of action and toxicological properties of the individual active ingredients. We encourage the ICRC to include this information in its deliberations.

It is clear from the incident reports that fatalities and intoxications occurred in men involved in the equivalent of a short-term occupational use. The conditions of use would be expected to result in an acute exposure and a rapid onset of symptoms. Based on animal testing and the experience of years of use in the field, symptoms of poisoning associated with the three individual active ingredients are known to occur within minutes or hours of exposure. However, only one reported incident occurred in this timeframe. More than 90 % of the symptoms occurred after 2 months. Therefore, the observed symptoms did not correlate with the exposures. Furthermore, all three active ingredients are rapidly excreted from the body so a cumulative effect of exposure cannot explain the delay in onset of symptoms. We note that the Rotterdam Convention defines a severely hazardous pesticide formulation as a “severe health effect…observable within a short period of time.” Because adverse health effects were not observed shortly after exposure we encourage the ICRC to consider whether the reported incidences qualify under this definition.

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According to the incident reports the most prevalent symptoms of alleged exposure to the subject formulation were chest pain (91%), dyspnea (82%) and oedema (73%). Based on a review of symptoms described in Material Safety Data Sheets, one would not expect to observe this combination of symptoms from exposure to the subject three-way mixture. All other reported symptoms occurred in less than 36% of the affected individuals and in most instances less than 10% of the cases. Because the conditions of use and duration of exposure were so similar among the subjects, this suggests the absence of a correlation between symptoms and exposure to a common toxicant.

The three active ingredients of the subject formulation share a carbamate moiety, but belong to different pesticide classes and have different mechanisms of toxicity. Benomyl interferes with cell division, carbofuran interacts with acetyl cholinesterase, and thiram interferes with cellular energy transfer. Therefore, one would not expect exposure to all three active ingredients to be additive in their acute effects.

The Senegal notification makes clear that the product was misused and identifies the inability to read the product label as the underlying cause. There was also disregard for the pictogram of the skull and crossbones, the universal symbol for a dangerous product. Under the circumstances the proposed educational measures and monitoring by Senegal are appropriate and laudable and recognize that product can be used safely according to label. We would also recommend the use of pictograms on the label in accordance with the FAO Code of Conduct.

CropLife International is grateful for the opportunity to provide its views on the Senegal notification and is prepared to assist the ICRC with additional information as may be available.

Sincerely,

Michael A. Morelli, Ph.D.
Chair, PIC Project Team
CropLife International

cc: C. Verschueren - CropLife International
M Laget – UCB Group
P Pritchard – Uniroyal/Crompton Corp
L Hershberger – Dupont Crop Protection
J Becker – FMC Corp
C Barnes – US EPA
ANNEX III

Rapport de l'Investigation de l'Epidemie d'une Maladie d'Etiologie Inconnue a Kolda
December 2000

Dr. Eugenia Gomes do Espirito Santo, SNGE; Dr. Laurence Marrama, IPD; Dr. Kader Ndiaye IPD;
Dr. Malan Coly, OMS; Dr. Dior Diagne, ISED; Dr. Pape Ndour, ISED; Dr Ousseynou Ba.

SNGE - Service Nataional des Grandes Endemies
IPD - Institut Pasteur de Dakar
OMS - Organisation Mondiale de la Sante
ISED - Institut de Sante et de Developpement
Region Medicale de Kolda, Service Regional des Grandes Endemies

Note by the Secretariat

The document is only available as a hard copy in French. However in view of the importance of his
information to the work of the intersessional Task Group headed by M. Ammati we have made it
available to the intersessional Task Group in its present form in order that it might be reflected in their
presentation to the full Committee during the third session of the ICRC.

We are in the process of having the document translated and will have an English version posted on
the Rotterdam Convention site and available to all members of the Committee by the meeting in
February. If in the meantime you wish to see a copy of the document in French please let us know and
we will send one to you, or you can download it from the Internet at www.pic.int at the page
containing the documents relevant to ICRC3.