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INTERIM CHEMICAL REVIEW COMMITTEE

Fourth session

Rome, 3 – 7 March 2003

Item 5 (b) (ii) of the provisional agenda\*

INCLUSION OF CHEMICALS IN THE INTERIMPRIOR INFORMED CONSENT PROCEDURE  
CONSIDERATION OF DRAFT DECISION GUIDANCE DOCUMENTS:

DNOC

Note by the Secretariat

1. In line with the process for the development of decision guidance documents set out in decision INC-7/6, the internal proposal for the DNOC was circulated to the Interim Chemical Review Committee and its observers for information and comment. Annexed to the present note is a tabular summary of the comments received on the internal proposal and how they were addressed in preparing the draft decision guidance on DNOC.

2. The draft decision guidance document for DNOC is available to the Committee in document UNEP/FAO/PIC/ICRC.4/12.

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





### Tabular summary of Comments on the Internal Proposal for DNOC

| POINT                             | AUTHOR                  | COMMENT   | RESPONSE   |   |
|-----------------------------------|-------------------------|---|--|---|
| <b>Abbreviations</b>              |                         |   |  |   |
|                                   | Ecuador and Australia   | In "Abbreviations which may be used in this document, it does not be enclosed "DT50". | This abbreviation added (page II) since it appears 4 times in the DGD (point 1.8, point 4.1.1, point 4.1.2 (x 2), and point 4.1.5 (x 3).   |   |
|                                   | Australia               | E.C.: European Community<br><br>K→k, Kg→Kg, POEM (Prediction → Predictive)<br>L→ 1    | No addition made since no abbreviation used in DGD. The only use was on page 10, now changed to European Community.<br><br>Agreed.<br><br>Agreed and consistency applied throughout DGD. |   |
| <b>Decision Guidance Document</b> |                         |   |  |   |
| 1                                 | Identification and uses | Ecuador   | On the common name it would be better to write "DNOC and all its salts"  | Amended to reflect the guidance provided by INC.9   |
|                                   |                         | Australia   | Has the Working Group been provided with sufficient evidence by the E.C. and Peru that the notifications cover other salts in addition to the ammonium salt?                             | Yes.  |
|                                   |                         | Ecuador   | On CAS - No.(s), are the potassium and ammonium salt and what about CAS number (2312-76-7)(The Pesticide Manual, A World Compendium. Twelfth Edition. 2000) for sodium salts ?           | Agreed (page 1).  |
|                                   |                         | Australia   | Harmonised System Customs Code- Identical codes?   | Text amended (page 1).  |
|                                   |                         | Chile   | CAS numbers of the salts should be indicated in Annex III  | Noted: it will be listed in Annex III as INC 9 advised.   |
|                                   |                         | Ecuador   | In use(s) in regulated category after "ovicide", should said as well as "fungicide.  | Agreed. (This was not an "intended use" in the E.C. regulation, but it is indicated in the EC documentation (page 6 of the monograph, point 1.4.1.1) that DNOC has a fungicide action). |

| POINT                            |                                       | AUTHOR      | COMMENT   | RESPONSE   |
|----------------------------------|---------------------------------------|-------------|---|--|
| 2.1                              | Final regulatory action               | Ecuador     | In 2.1, Final regulatory action, about Peru, the first paragraph, last line, should said "valid for all types of formulations ...."   | Language reflects that in Peruvian regulatory action. No change made pending confirmation from Peru (page 2).  |
| 2.3                              | Risk evaluation                       | Australia   | 2.3 → 2.2, plus other typographical corrections.  | Agreed (page 2).   |
|                                  |                                       | Germany     | add under point "2.3 Risk evaluation, European Community, Environmental Impact" after the first sentence, that "DNOC is highly toxic to honey bees (LD 50 oral: 2 µg/bee)". | Agreed, subject to reformulation (page 3).<br>Amended and further revised to reflect information contained in the EU monograph that under field condition no significant risks were identified (see point 4.2.3 in the Annex 1). This has also been reflected in point 5.3 of Annex 1. |
|                                  |                                       | Switzerland | Note, last line: ... to cover all salts of DNOC.  | Agreed (page 3).   |
| 3.1                              | Regulatory measure to reduce exposure | Ecuador     | In 3.1, Regulatory measures to reduce exposure, about Peru, in the last line, instead of are prohibited, should said "were prohibited"                                      | Agreed (page 3).   |
| 3.3                              | Alternatives                          | Ecuador     | On page 4, in the second paragraph should said "The European Community and Peru did not provide any specific information on..."   | Agreed (page 4).   |
| 4                                | Hazards and risks to human health ... | Italy       | A correct EU classification is given in the par. 4 of the draft. However in the 28 <sup>th</sup> ATP the R40 phrase is replaced with R68.                                   | Agreed. R 40: possible risks of irreversible effects was renumbered as R 68 after the EC had submitted its notification. Text amended accordingly (page 4).  |
| 4.2                              | Packaging and labelling               | Switzerland | - Hazard Class: Cancel UN Subsidiary Risks: 8 (See UN Recommendations on the transport of dangerous goods, Model Regulations 2001)  | Agreed (page 5).   |
|                                  |                                       |             | - International Maritime dangerous Goods (IMDG) Code: .....(amendment: IMDG, .... .... The Maritime Safety Committee, 30-00, 2000)  | Agreed (page 5).   |
| <b>Introduction to the annex</b> |                                       |             |   |  |

| POINT  |  | AUTHOR    | COMMENT  | RESPONSE  |
|--|--|-----------|--|---|
|  |  | Australia | Was this document referenced in either of the notifications from E.C. or Peru? If not, should not be included as this Annex only includes very limited data from sources not referenced by the notifications in support of their final regulatory actions eg WHO first aid information | <p>Noted: The working paper on preparing internal proposals and DGDs states on page 5 in relation to Annex 1 that ‘The results of international reviews such as those of WHO/IPCS/JPMR should also be included in this section where available and considered relevant.’</p> <p>In line with the approach taken for monocrotophos a brief comparative summary of the EHC evaluation has been prepared and inserted in Section 2.2.7. The specific references in individual sections of Annex I have been removed and the remaining text checked against the information contained in the monograph on DNOC submitted by the European Commission to ICRC3.</p> |
| <b>Annex 1: Further information on the substance</b> |  |           |  |   |
| <b>2</b>   | <b>Toxicological properties</b>                    |           |  |   |
| 2.1.3  | Absorption, distribution, excretion and metabolism | Australia | Editorial changes  | Agreed (page 9-10).   |
| 2.2.1  | Acute Toxicity                                     | Australia | Editorial changes (dermal)   | Agreed (page 10).   |
| 2.2.2  | Short-term toxicity                                | Australia | <p>In section ‘oral’, first sentence: add Charles River before ‘rats’</p> <p>In the same section, delete:<br/>The NOEL was set at 2.89 mg/kg bw/day.</p> <p>In the same section, add: IPCS, 2000 (ref. ?)</p>  | <p>No change made. The strain was not indicated for other species throughout the DGD (page 11). However, we have added F-344 rats in point 2.2.4 and Sprague-Dawley rats in point 2.2.5 because the choice of the strain is important in carcinogenicity and toxicity for reproduction.</p> <p>No change made. Information from EC supporting documentation ( page 18 of the EC monograph).</p> <p>No change made. Summary of principal conclusion of EHC is in section 2.2.7.</p>  |
|  |  |           | Introduce separate sections on dermal and inhalation   | Agreed (page 11).   |
| 2.2.3  | Genotoxicity                                       | Australia | Typo   | Agreed (page 11).   |

| <b>POINT</b> |  | <b>AUTHOR</b> | <b>COMMENT</b>  | <b>RESPONSE</b>   |
|--------------|--|---------------|---|---|
| 2.2.4        | Long-term toxicity and carcinogenicity | Australia     | Editorial   | Agreed (page 12).   |
|              |  | Italy         | In par. 2.2.4 is stated "The NOELs for long-term toxicity were set at 0.59 mg/kg bw/day in males on the basis of increased food consumption....". Furthermore in par. 2.2.7 is stated "The calculation of the ADI was carried out from the NOEL in the most sensitive species. From the two-year study in rats, it was established as 0.1 mg/kg bw/day". Please explain this discrepancy. | Inconsistency in text has been corrected  |
|              |  | Australia     | Add (ICPS, 2000)  | No change made. This study is noted in the EC supporting documentation (section 2.2.7). |
| 2.2.5        | Reproduction                           | Australia     | Editorial   | Agreed (page 12).   |
| 2.2.7        | Summary and Overall evaluation         | Switzerland   | 2.2.7 Note ... to cover all salts of DNOC.  | Agreed (page 12-13).  |
| <b>3</b>     | <b>Toxicological properties</b>        |               |   |   |
| 3.4          | Operator Exp.                          | Australia     | Minor editorial and formatting changes  | Agreed (page 14).   |
| 3.5          | Medical data                           | Australia     | Minor editorial   | Agreed, subject to further correction (page 16).  |
| 4.1.1        | Environmental fate and effects/soil    | Australia     | Minor editorial   | Agreed (page 16).   |
| 4.1.5        | Persistence                            | Australia     | Editorial   | Agreed (page 17).   |

| POINT   |  | AUTHOR    | COMMENT   | RESPONSE  |
|---|--|-----------|---|---|
| <b>4.2</b>  | <b>Ecotoxicity – Effects on non target organisms</b> |           |   |   |
| 4.2.1   | Terrestrial vertebrates                              | Italy     | In par. 4.2.1 and 5.1 of the Annex 1 an oral rat LD50 of 26 mg/kg bw is used as reference values for mammals risk evaluation. However in par. 2.2.1 the lower limits for the LD50 values are 20 and 16 mg/kg bw for rats and mice respectively. Please explain in the text the reason for that choice even there are not implications in the final risk evaluation. | <p>Point 2.2.1 gives a range of pooled values (20-85 mg/kg) that originate from both notifying countries.</p> <p>During the EC review of the substance, the industry provided several values included in various peer-reviewed handbooks. The reviewing committee asked for primary publications. Among the available original papers, the value of 26 mg/kg was retained as the most reliable to serve as a basis of the EC risk evaluation.</p> <p>Small change made to point 4.2.1 to make it clear that the indicated LD50 value was that retained in the EC risk evaluation.</p> <p>No changes needed to points 2.2.1 and 5.1.</p> |
|   |  | Australia | Editorial, plus query over LD <sub>0</sub> .  | <p>Editorial agreed (page 18).</p> <p>LD50 and LD<sub>0</sub> have been included for pheasants and partridges from the supporting documentation..</p>   |
| 4.2.3   | Honey Bees & Other arthropods                        | Australia | Editorial. Use <i>Brassica napus</i> instead of 'rape's   | Agreed (page 18). Wording at the end of the paragraph has also been modified to take account of change to point 2.3 of DGD.   |
|   | Summary  | Australia | Typographical correction  | Agreed (page 20). Wording also modified to take account of change to point 2.3 of DGD.  |
| <b>Annex 3 – Addresses of designated national authorities</b> |  |           |   |   |
|   | EC   | Australia | should there be a C entry as well   | Changed to "CP" (page 23).  |
|   | General  | Italy     | A general lack of references is observed in the DGD and the Annex 1 drafts. References should be given for tox, eco-tox and phys-chem properties.   | No changes made. All the data originate from the supporting documentation of the 2 notifying countries (references included) or from international sources such as EHC 220 (references cited). The drafting of the DGD was performed in line with the guidance document, following the same basic approach as the DGD on monocrotophos.   |