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INTERIM CHEMICAL REVIEW COMMITTEE

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

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

TETRAETHYL LEAD AND TETRAMETHYL LEAD

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 tetraethyl lead and tetramethyl lead 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 tetraethyl lead and tetramethyl lead.
2. The draft decision guidance document for tetraethyl lead and tetramethyl lead is available to the Committee in document UNEP/FAO/PIC/ICRC.5/13.

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\* UNEP/FAO/PIC/ICRC.5/1

### Tabular summary of Comments on the Internal Proposal for Tetraethyl lead and Tetramethyl lead.

| Country                  | Section         | Comment  |  |
|--------------------------|-----------------|--|--|
| Australia                | General Comment | The new format of the DGD combines the TEL and TML parts into a single section and is more reader friendly.<br><br>Please maintain consistent spelling of the word alkyl lead - spellings «alkyl lead» and «alkyllead» are used in DGD).                               | <i>Agreed - Editorial</i>  |
| Australia                | General Comment | It is suggested that the IOMC document used in Section 3.3 “Alternatives General” be made available via the web site rather than in the DGD as a number of the statements in the section requires further elaboration and clarification (See specific comments below). | <i>General section removed. The DGD now simply indicates that the IOMC document also reviews alternatives.</i> |
| Industry                 | Title           | Tetramethyl lead is not longer manufactured and has been completely phased out. We would request all reference to it is deleted from the DGD otherwise it gives the impression that it is still in use and being manufactured.   | <i>Title references notifications provided to the Secretariat and should not be changed.</i>                   |
| USA                      | Introduction    | Introduction refers to Article 10 paragraph 2, should it refer to Article 7 paragraph 3  | <i>Amended introduction now references Article 7 and 10.</i>   |
| Switzerland              | Abbreviations   | ‘inhibition concentration, 50%’ change to ‘Inhibition concentration, 50%’  | <i>Not changed - Lower case seems appropriate.</i>   |
| Australia                | Abbreviations   | Editorial comment: definition of IC <sub>50</sub> , delete «;»   | <i>Editorial</i>   |
| Switzerland<br>Australia | Abbreviations   | Add ‘IOMC Inter-Organization Programme for the Sound Management of Chemicals’  | <i>Editorial</i>   |
| Switzerland              | Abbreviations   | Exchange LOAEL and LDlo (for alphabetic order)   | <i>Editorial</i>   |
| Switzerland              | Abbreviations   | For NOAEL and NOEL, used ‘observable’ rather than ‘observed’   | <i>Not changed - ‘observed’ seems to be the appropriate term.</i>  |
| Switzerland              | Section 1       | Add ‘structural formula’ to the descriptors in the first column  | <i>Agreed - Editorial</i>  |
| USA                      | Section 2.2     | The US Centre for Disease Control currently states that ‘Many studies point to a link between blood lead levels of greater than or equal to 10 mg/dl [in children] and harmful health effects, in particular learning disabilities and behaviour problems              | <i>This update from the US could be posted on the website.</i>   |

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| Australia | Section 2.2 Risk evaluation p 8, 2 <sup>nd</sup> sentence | Consider clarifying the nature of the adverse health effects that occur at 20-30µg/dL, e.g. consider adding the details of these adverse effects to this section or Annex 1.  | <i>Details provided.</i>  |
| Australia | Section 3.2 Other measures to reduce exposure<br>Canada   | Add the first paragraph of the text from Section 3.4 Socio-economic effects Canada, which commences ‘Canada first adopted regulations in 1973.....’ and concludes ‘These requirements were specified in the <i>Gasoline Regulations</i> (SOR/90-247) and subsequent modification’ to <b>Section 3.2 Other measures to reduce exposure Canada</b> as this relates to the history of regulatory controls for lead and is more relevant here than Section 3.4.   | <i>Unchanged - The Working Paper on Preparing Internal Proposals and Decision Guidance Documents indicates that the purpose of Section 3.2 is to provide information about non-regulatory measures.</i> |
| Australia | Section 3.3 Alternatives<br>Canada                        | 1 <sup>st</sup> paragraph «Royal Society» Please clarify if Royal Society refers to « <b>Royal Society of Canada</b> »  | <i>Editorial</i>  |
| Australia | Section 3.3 Alternatives<br>Canada                        | 1 <sup>st</sup> paragraph «an increase in aromatic hydrocarbons»<br>Would be useful to include the value of the increase in the aromatic hydrocarbons.  | <i>Unchanged - Reference documents from Canada do not give that information.</i>  |
| Australia | Section 3.3 Alternatives<br>General                       | Would be useful to qualify some of the IOMC information in this section. For example, the DGD states that «MMT was banned in US in 1979». However, we note that MMT is currently marketed in the United States and is permitted in France, the United Kingdom, Russia and Argentina. New Zealand has limited the Manganese (Mn) content of automotive fuel to no more than 2.0 mg/L Mn - which will be reviewed by 2006. (See <a href="http://www.nicnas.gov.au/publications/CAR/PEC/PEC24/pec24.pdf">http://www.nicnas.gov.au/publications/CAR/PEC/PEC24/pec24.pdf</a> )<br><br>It is unclear from the text the definition of «a significant quantity of benzene» (as well as toluene, xylene, and ethylbenzene ) in all gasoline. Would be useful to include a range of the benzene content. For example, gasoline in Australia contains 3-5% benzene.<br><br>Please include the reference for the Australian Commonwealth Scientific and Industrial Research Organisation study. | <i>Added footnote that provides further information about US situation on MMT. See comment by US on the same issue.</i><br><br><i>Information not available.</i><br><br><i>Reference added.</i>         |

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| Australia    | Section 3.3<br>Alternatives<br><br>General | <p>Some of the IOMC information in this section raises a number of questions that require further substantiation or and clarification.</p> <p>For example, it is unclear from the text:</p> <ul style="list-style-type: none"> <li>• the definition of «a <u>significant</u> quantity of benzene» (as well as toluene, xylene, and ethylbenzene) in all gasoline, and</li> <li>• methods for producing unleaded gasoline that may not produce a significant increase in benzene or other aromatics.</li> </ul> <p>In addition, while the text in this Section states that there are no adverse effects of gasoline oxygenators, it does not state the nature of these oxygenators and appears to contradict Section 3.3 Canada that states there are technical problems to overcome with (the oxygenators) methanol and ethanol.</p> <p>Australia also notes that the oxygenator MTBE has an unpleasant odour and taste which may present a problem if MTBE is unintentionally released into water sources relied upon for drinking. A number of incidents have been reported in the literature regarding the contamination of water with MTBE.</p> <p>Additionally, Australia notes there are concerns about low levels of benzene (See the Australian (NICNAS) risk assessment of benzene at: <a href="http://www.nicnas.gov.au/publications/CAR/PEC/PEC21/PEC21index.htm">http://www.nicnas.gov.au/publications/CAR/PEC/PEC21/PEC21index.htm</a></p> | <i>See related comment above by Australia.</i>     |
| USA          | Section 3.3                                | <p>The last sentence in the last paragraph (MMT was banned in the US in 1978) is likely to mislead readers, and should be deleted. If not deleted, it should be clarified. Although use of MMT as a fuel additive was prohibited in the US in 1978, the prohibition was based on concerns for possible effects on catalytic converters, not toxic effects. A waiver to the prohibition was granted in 1995.</p>   | <i>Added footnote using details by US comment.</i> |
| South Africa | Section 3.3                                | <p>MMT is not banned in the US, as they are currently using it. Please clarify the present status</p>   | <i>See comment above.</i>                          |
| Australia    | Section 3.4 Socio-economic effects         | <p>Consider adding the caveat «<b>Countries should consider the results of this information in the context of their own national conditions</b>»</p>  | <i>Caveat added.</i>                               |

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| Australia | Section 3.4 Socio-economic effects<br>Canada                  | Consider clarifying the dollar values in this section as Canadian dollars, e.g. « <b>in 1983 Canadian dollars</b> »<br><br>Please include the reference(s) relied upon for data presented in this section.  | <i>Clarification added.</i><br><br><i>References provided in Annex 4.</i>   |
| USA       | Section 3.4   | Information on observations after the action had been taken would be interesting. This may be suitable for posting on the website   | <i>No change to the DGD required.</i>   |
| Industry  | Section 4 Hazards and Risks to Human Health                   | Tetraethyl lead is being phased out because it poisons catalytic converters in car exhaust systems and because the inorganic lead combustion products add to the overall lead burden in humans. It is not being phased out because of its toxicological properties and associated risk to the general population.<br>This important distinction should be clearly made, possibly by heading up the section with the hazards and risks for inorganic lead and placing the TEL data in appendices for further information | <i>This is not consistent with the agreed format of a DGD. Furthermore, the distinction between inorganic lead and TEL/TML is already made elsewhere, e.g., section 2.2 and introductory text to Annex 1.</i> |
| Australia | Section 4.1 Hazard Classification                             | Add Directive 67/548/EEC to the list of references.   | <i>Reference added.</i>   |
| USA       | Section 4.2   | Suggest including US CDC blood lead level of 10 µg/dl for children (with reference)   | <i>Information could be posted on the PIC website.</i>  |
| Australia | Annex 1 Section 1 Physico-Chemical properties tetraethyl lead | «died» Replace with: « <b>dyed</b> ».   | <i>Editorial</i>  |
| Australia | Annex Section 1 Physico-Chemical properties tetraethyl lead   | Clarify if the flash point for tetraethyl lead is open cup or closed cup.   | <i>IPCS Safety Card, which is the reference for this information, does not indicate whether it is open cup or closed cup. Information not found elsewhere.</i>  |
| Australia | Annex 1 Section 2.1.2 Absorption                              | 4 <sup>th</sup> paragraph. Include the reference for the statement that the relationship between blood level and the concentration of lead in exposure sources is curvilinear.  | <i>Reference added.</i>   |

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| Australia   | Annex 1 Section 2.1.2 Absorption 2nd para, 1 <sup>st</sup> sentence | Is not the amount of lead absorbed via the gastrointestinal tract dependent upon the bioavailability of the lead; determined predominantly by the amount of Pb dissolved in the stomach?   | <i>This paragraph summarizes the discussion of the Royal Society of Canada. The document does not address the issue of bioavailability. The next paragraph, which summarizes the WHO indicates that bioavailability is a factor to consider.</i> |
| Australia   | Annex 1 Section 2.1.2 Metabolism                                    | 1 <sup>st</sup> paragraph. Amend «transformed in trialkyl derivatives» to «transformed to trialkyl derivatives»  | <i>Correction made.</i>  |
| Switzerland | Annex 1 Section 2.1.2 Metabolism                                    | ..., TEL and TML are not the primary toxic substances but they are converted ('toxic substances' replacing 'toxins'). COMMENT – Toxins are by definition toxic (or poisonous) substances produced by living organisms.   | <i>Correction made.</i>  |
| USA         | Section 2.1.2   | The discussion of distribution could indicate that once in bone lead can remain there for decades (half life in a human skeleton is 20 years), but later in life it can come back out of bone to cause significant exposure. This is particularly problematic during pregnancy, as the fetus can be exposed to lead that had accumulated in the mother many year earlier. (reference provided).  | <i>Additional paragraph with this information included in this section.</i>  |
| Industry    | Annex I, Section 2.2  | From the Canadian data (Fig 1), even at the height of the use of leaded gasoline, total lead in air concentrations (not all came from cars) were less than 0.6 ug/m <sup>3</sup> in 1975. Based on their overall assessment of contribution of lead in air to lead in blood, this would give a contribution from cars of between 1.6 to 3 ug/dl. However, blood leads in Canada were around 15 ug/dl in 1975, so the % contribution was <20% in the worst case.<br>It is, therefore, not correct to state in S.2.2 that the contribution of gasoline to lead in blood is 30 – 35% (adults) and 30 – 40% (children). This is further endorsed on p 24 in the statement from the UK Dept. of Env. That the reduction in the permissible level of lead in gasoline during 1985 appeared to contribute slightly to the decrease of lead in the body burden of children | <i>Additional information provided in Section 2.2 to clarify how Canada arrived at its conclusion.</i>   |
| USA         | Section 2.2.1   | The statement 'There is no evidence to suggest that any association of PbB concentration with blood pressure is of major health importance' would appear to be in conflict with the statement in section 2.2.3 indicating hypertension is seen at doses of less than 7 µg/dl.  | <i>Sentence deleted.</i>   |

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| USA         | Section 2.2.1   | OECD 1993 is cited as evidence of carcinogenicity of lead compounds is inadequate. In the US National Toxicology Program's 11 <sup>th</sup> Report on Carcinogens, lead and lead compound have been nominated for inclusion as a human carcinogen. A final decision has not yet been made. However, the NTP did some meta-analyses on results from human studies. These analyses revealed elevated risks for lung cancer, stomach and intestinal cancer following lead exposure. | <i>Information may be posted on the PIC website.</i>                                |
| USA         | Section 2.2.1   | The discussion of health effects to humans could note that lead is stored in the human skeleton and that this lead can be released from the bone at a later date and serve as a significant endogenous source of exposure.   | <i>This information has been provided in section 2.1.2 as per US comment above.</i> |
| Switzerland | Annex 1 Section 2.2.2   | ...determined to be 0.0077 µmol/l blood (0.16 µg/dl)   | <i>This is the verbatim text from the WHO 1995.</i>                                 |
| Switzerland | Annex 1 Section 2.2.3   | 'Formation of blood cells' – delete 'Formation of', as it is not the formation of the erythrocytes that is affected, but the synthesis of haem and of globin.  | <i>Correction made.</i>   |
| Australia   | Annex 1 Section 2.2.6.1 Inhalation  | May not the described adverse effects of leaded gasoline sniffing be confounded by not only inhalation of lead but also volatile hydrocarbons contained in gasoline? Suggest adding «Lead toxicity secondary to gasoline sniffing can occur»   | <i>Section taken verbatim from IPCS document on organic lead.</i>                   |
| Australia   | Annex 1 Section 2   | Please include «Summary of mammalian toxicity and overall evaluation» section.   | <i>Section added.</i>   |
| Australia   | Annex 1 Section 3.1. Introduction 4 <sup>th</sup> para, 1 <sup>st</sup> sentence. | Suggest clarifying the nature of the lead alkyl combustion product(s).   | <i>Clarification provided.</i>  |
| Australia   | Annex 1 Section 3.1 Introduction 4 <sup>th</sup> para, 2 <sup>nd</sup> sentence   | Suggest clarifying if «70% of the alkyl lead» is inorganic lead particles  | <i>Clarification provided.</i>  |
| Australia   | Annex 1 Section 3.2 General population exposure                                   | Clarify if all the information in this section is sourced from WHO, 1995.  | <i>Clarification provided.</i>  |

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| Australia   | Annex 1 Section 3.3 Food 1 <sup>st</sup> para 3 <sup>rd</sup> sentence | For clarity consider replacing «The WHO (1977) reports that the range.....» with «The WHO (1977) reports that the Pb range.....».  | <i>Clarification provided.</i>  |
| Australia   | Annex 1 Section 3.4 Air  | «In several Member States of the E.C.....» Confirm if this information is sourced from OECD, 1993.   | <i>Clarification provided.</i>  |
| Australia   | Annex 1 Section 3.4 Air  | «Numerous studies document a relationship.....»Clarify the references for these studies.   | <i>Clarification provided.</i>  |
| Australia   | Annex 1 Section 3.4 Air 6 <sup>th</sup> para, 1 <sup>st</sup> sentence | For clarity consider replacing «The average PbB levels for the population.....» with «The average PbB levels for the Canadian population.....»   | <i>Clarification provided.</i>  |
| USA         | Annex 1 Section 4.1.2  | This section states ‘However, the release of lead from organic complexes to the soluble, and thus bioavailable....’ This is a bit unclear, as even lead that is bound is still bioavailable to humans, as noted in section 3.2   | <i>This entire section is taken verbatim from the WHO 1995.</i>   |
| Switzerland | Annex 1 Section 4.3.2  | ....concentrations above 0.1 and >40 mg/l for fresh-water organisms and above 2.5 and >500 mg/l for marine organisms. COMMENT: this does not really make sense, even though this is an exact copy of the WHO (1989) text. Since the higher values most likely are the values for hard water, it would make sense to clarify it here, and not only in the following sentence. | <i>This is the verbatim text from the WHO 1989.</i>   |
| USA         | Annex 3, section 4.1   | In providing updated information, we may wish to note on this point that ‘Many countries and organisations now believe that blood levels of lead below this amount could cause adverse effects’  | <i>This type of comment does not belong in this annex, as it is intended to be a summary of the notifications and original decisions.</i> |
| Switzerland | Annex 4 References Other measures to reduce exposure                   | For ‘Environmental Health Criteria 85: Lead – Environmental Aspects. IPCS/WHO, the year reference should be 1989, not 1995.  | <i>Editorial</i>  |