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CC/06/13

**COMMITTEE ON CARCINOGENICITY OF CHEMICALS IN FOOD,
CONSUMER PRODUCTS AND THE ENVIRONMENT (COC)**

COMPARATIVE RISK ASSESSMENT PROJECT

INITIAL OUTLINE DISCUSSION PAPER

Introduction

1. At the COC 2005 Horizon Scanning meeting, the secretariat proposed that a review on comparative risk assessment (CRA) should be conducted that compared the carcinogenic risk of selected environmental carcinogens with a clearly defined exposure. COC Members ranked this as high priority but did not support the proposal to use smoking cigarettes as a comparator. COC Members suggested that the former Chief Medical Officer's 'risk scale' could be used as a possible alternative approach. COC Members also agreed with the COM's recommendation that both Committees should collaborate together to improve how advice from COC/COM on the potential carcinogenicity and mutagenicity of chemicals is presented to the general public.

Advice from COM

2. A draft discussion paper was considered by the COM at its May 2006 meeting. This is attached as Appendix 1 to this paper. The draft minutes of the wide ranging discussion are appended as Appendix 2 to this paper. The COM noted the difficulties in using the risk scales which had been identified for comparative risk of mutagens/carcinogens and the need to identify appropriate involuntary risks if comparative risk approaches were to be of value. Overall COM members asked for;
 - i) improved use of non-technical summaries for items considered by COM,
 - ii) further consideration of potential use of relative potency and margins of exposure approaches to assist Regulatory Agencies and Government Departments.
 - iii) further advice and possibly a presentation on approaches to comparative risk assessment and improved risk communication.

COC discussion

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3. Members are asked to consider the paper presented to the COM. Questions for consideration by COC on comparative risk assessment are outlined on page 7 of the discussion paper (Appendix 1). Overall questions on comparative risk assessment and risk communication are on page 9 of Appendix 1.

Additional information obtained post COM May 2006 meeting.

4. The DH Toxicology Unit has prepared a list of potential sources of expertise on comparative risk assessment and risk communications which will be tabled at the COC meeting. Members are asked to consider whether the secretariat should approach any particular expert with a view to giving a presentation at the November 2006 COC meeting.
5. The secretariat has been made aware of an internet based comparative risk game used to disseminate understanding of risks associated with environmental radiation. "KU World" formed part of the National Radiological Protection Board's (now the Radiation Protection Division of the Health Protection Agency) contribution to Science Week 2001. A short summary of relevant information and a link to the game are provided at Annex 3 to this cover paper. It is acknowledged that the target audience for this approach is likely to be very wide. Members are asked to comment on the value of such approaches.
6. The FSA has commented that it would find it useful for the COC to consider potential Margin of Exposure (MOE) approaches for genotoxic chemical carcinogens in food. Do members consider this to be a viable approach?

**Secretariat
June 2006**

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[APPENDIX 1 to CC/06/13 = MUT/06/13](#)

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APPENDIX 2 TO CC/06/13

DRAFT COM MINUTES FROM MAY 2006 DISCUSSION ON COMPARATIVE RISK ASSESSMENT.

ITEM 7: COMPARATIVE RISK ASSESSMENT PROJECT INITIAL OUTLINE DISCUSSION PAPER (MUT/06/10)

41. At the COC 2005 Horizon Scanning meeting, the secretariat proposed that a review on comparative risk assessment (CRA) should be conducted that compared the carcinogenic risk of selected environmental carcinogens with clearly defined events. COC Members ranked this as high priority but did not support the proposal to use smoking cigarettes as a comparator. COC Members suggested that the former Chief Medical Officer's 'risk scale' could be used as a possible alternative approach. COC Members also agreed with the COM's recommendation that both Committees should collaborate together to improve how advice on the potential carcinogenicity and mutagenicity of chemicals is presented to the general public.

42. The DH Toxicology unit and secretariat had drafted an initial outline discussion paper which provided an introduction to the current approaches used by the COC/COM to report information on risks the possible approaches to undertaking comparative risk assessment, and how the outcomes of such approaches could be used to provide better communication of risks associated with environmental mutagens/carcinogens. The second part of the review, reported on two references which dealt with strategies for better risk communication.

Comparative risk Assessment.

43. One key objective which arose from the COC discussions was to attempt to compare risks of environmental carcinogenesis with other involuntary risks. Three approaches were identified, namely the Calman risk scale, the Paling Perspective scale, and the Duckworth "riskometer". Members' views on these approaches were sought. Members' views were also requested on the proposal to select potent genotoxic carcinogens and compare their evaluation using these different scales.

Risk communication

44. The usual outcome of COM/COC work is published statements designed to be used by Government Departments and Regulatory Agencies in formulating policy or risk management strategies. In a relatively small number of cases, a decision has been made to produce a non-technical summary which would be aimed at a wider audience.

45. A paper by Leiss et al was summarised and a copy of the recent Royal Society/FSA workshop on risk communications was appended. Also, a short overview of the COT discussions was provided for information.

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46. The COM was asked whether there were any potential approaches outlined, which would be valuable for COC/COM, and whether the committee had any other ideas/areas for discussion on comparative risk assessment or risk communication of committee advice.

COM discussion

47. It was recognised that the committee's main role was communication of specialist scientific advice to government departments and regulatory agencies and that risk communication was mainly a matter for these groups. Members felt that the COM generally advised on hazard i.e. whether a particular chemical was mutagenic or not. It was difficult to convey the concept that a small increase in risk of mutagenicity equated to a small increase in risk of other hazards (such as cancer or effects on reproduction) and even harder to quantify the relationships between chemical induced mutagenicity and other potential end effects. The default assumption of no-threshold was supported by scientific data and had proved valuable for Regulatory Agencies and Government Departments. It was agreed that more work on the use of relative potency and development of Margins of Exposure approaches would be helpful.

48. The committee considered that non-technical summaries of technical statements should be published when possible, but agreed that this was not always appropriate. However, this should be acknowledged in published statements where non-technical statements were not published. Members considered that the discussion of the agenda item on metal hip replacements was an appropriate topic to consider drafting a non-technical summary. The secretariat would liaise with MHRA in this respect. Members felt that the OECD guidance on risk communication could provide a good template for considering non-technical summaries in the future.

49. With regard to a paper by Williams et al., 2004, members considered that of the suggested risk comparison options A and C were the most relevant to the COM. Option A referred to intrachemical comparisons, to show that a particular source of the same exposure was significant/negligible e.g. comparing exposure to mercury fillings with exposure to mercury from eating fish. Option C referred to comparison to background levels of risk e.g. comparing exposure to arsenic from treated wood to exposures from natural environmental sources. There would need to be consideration of such approaches on a case-by case basis

50. Members considered the comparative risk scales reviewed were probably more relevant to COC discussions. Some members felt that a logarithmic scale of comparison similar to the Richter scale for earthquakes might be a useful approach if applied to carcinogenic risk. Generally the committee had concerns over the types of risk comparisons identified in the published literature. It was felt that it was not helpful to express mutagen/carcinogen risks estimates on an annual basis as this might difficult

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for a wider audience to understand. Members considered that comparisons of carcinogenic risk estimates with actuarial risks (where the data existed to determine the actual risk) were not appropriate. Thus it would be difficult to convey the information on the distribution and uncertainty associated with risk estimates associated with carcinogen exposures and then compare to the actuarial risk estimates used in the scales (e.g the risk of death resulting from falling over in the bath). Members also agreed that comparisons of involuntary risks (e.g. to environmental contaminants) with voluntary risks should not be made and hence agreed with COC that smoking was not an appropriate comparator. It was also noted individual perception of the magnitude and acceptability of particular risks varied greatly.

51. Members noted that any adaptations to risk communication procedures used by the COM would need to be judged acceptable by a wider audience than the scientific statements from COM were primarily used. Evaluating the success of any approach would be difficult. This discussion paper would be taken to the COC for further consideration. Members agreed that it would be helpful to have a presentation on comparative risk assessment and improving risk communication. The secretariat agreed to identify appropriate individuals but commented that it was unlikely that there would be sufficient time to arrange a presentation for the July COC meeting.

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APPENDIX 3 TO CC/06/13

NRPB INTERNET BASED GAME FOR COMPARATIVE RISK OF ENVIRONMENTAL RADIATION.

KU World formed part of the National Radiological Protection Board's (now the Radiation Protection Division of the Health Protection Agency) contribution to Science Week 2001.

<http://www.riskit.org.uk/>

How to Play:

1. First you need to judge from the list which activity you think gives the greatest risk. By identifying the highest risk first, you will protect the largest number of people.
2. Assign the risk to the activity you just chose (the first one will be high) and the game will work out the consequences for your population based on the actual risk.
3. Go back to the menu (by clicking on "Finish Activity") and proceed with the next most risky activity.
4. Gradually work your way through the list.
5. If you are unsure how to rank a risk you can click on AIDEM. He will give you some information about the risk but, BEWARE, he gives two opposing views based on newspaper articles. You must decide which is more accurate!

Strategy Tips:

If you need tips on strategy, try clicking on AIDEM!

Remember you need to decide first what is the most risky activity from the list, then go to the next most risky and so on.

Underestimating a risk will mean that people will continue to take the risk, and this will affect the overall health of the group. Equally, if you overestimate a risk it could also be harmful, because it would encourage people to give up doing things that have little risk and engage in more risky activities...