

## COMMITTEE ON CARCINOGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

### COC Guidance Statements

1. The Committee is nearing completion of its guidance statement series on risk assessment of chemical carcinogens with further papers being discussed at this meeting. This paper provides an overview of the whole guidance statement series in [Table 1](#), and attached at [Annex 1](#) are all the available published statements, which are on the COC website.
2. The only statement which has not yet been started is “Interpretation of Evidence of Carcinogenicity in Humans: Epidemiology and Case Reports” (G02). Work on this document will begin when the report of the joint COT-COC Synthesising Epidemiological Evidence Subgroup is available.
3. The guidance statements have been designed as independent documents so they can be updated in a flexible manner and as necessary to reflect developments in approaches or scientific consensus.
4. It is likely once all the statements have been published that some changes will be necessary in cross-referencing between statements including the overarching statement to ensure consistency

### Questions for the Committee

5. Members are asked to consider the overview table and published statements and highlight whether there are any gaps that the Committee should address, or particular aspects that need to be updated, other than those on the agenda for discussion at this meeting.

**COC Secretariat**

**July 2016**

Table 1: Overview of COC guidance statements

	Year	Version
<p>G 01 <b>A Strategy for the Risk Assessment of Chemical Carcinogens</b></p> <p>An overarching statement which presents the Committee's recommended general approach to assessing the carcinogenicity of a chemical.</p>	2012	4
<p>G 02 <b>Interpretation of Evidence of Carcinogenicity in Humans: Epidemiology and Case Reports</b></p> <p>Advice on how epidemiological studies and case reports can be used to inform carcinogen risk assessment</p>		1
<p>G 03 <b>Hazard identification and characterisation: Conduct and Interpretation of Animal Carcinogenicity Studies</b></p> <p>Advice on guidelines for the conduct of studies, validity of design, and the interpretation of results including the significance of findings in humans</p>	2015	1
<p>G 04 <b>The use of Biomarkers in Carcinogenic Risk Assessment</b></p> <p>A discussion of biomarkers of exposure, effect and susceptibility and their uses</p>	2013	1
<p>G 05 <b>Points of Departure and Potency Estimates</b></p> <p>Advice on appropriate use of various methods for identifying a level of (no) effect or a point of departure, including: NOAEL, T25, TD<sub>50</sub> and BMDL<sub>10</sub>. Also discussion of the Threshold of Toxicological Concern</p>	2014	1
<p>G 06 <b>Risk Characterisation Methods</b></p> <p>Committee advice on the derivation of the margin of exposure, ADIs and TDIs, also discussion of low dose extrapolation of cancer risk</p>	2012	1

<p>G 07 <b>Alternatives to the 2-Year Bioassay</b></p> <p>The Committee's views on proposed alternatives, split into 4 parts:</p> <ul style="list-style-type: none"> <li>a) In vivo assays</li> <li>b) Cell transformation assays</li> <li>c) Developing methodologies</li> <li>d) Alternative testing strategies incorporating results from short-term tests</li> </ul>	<p>Parts a &amp; b 2016</p> <p>d – in prep</p>	<p>1</p>
<p>G 08 <b>Risk Assessment of Mixtures of Chemical Carcinogens</b></p> <p>A statement risk assessment of chemical mixtures and the concepts of additivity and interaction, whether synergy or antagonism</p>	<p>2010</p>	<p>1</p>
<p>G 09 <b>Assessing the Risks of Less than Lifetime Exposure to Carcinogens</b></p> <p>Discussion of approaches to assess risk of cancer from less than lifetime exposures to carcinogens</p>	<p>In prep</p>	<p>1</p>
<p>G 10 <b>Nanomaterial Toxicology</b></p> <p>A position statement from COT, COC and COM with a suggested initial strategy for toxicology testing of nanomaterials.</p>	<p>2005</p>	<p>1</p>

CC/2016/06 – Annex 1

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### COC Guidance Statements

This annex contains the published COC Guidance statements:

- A strategy for the risk assessment of chemical carcinogens (G01)
- Hazard identification and characterisation: conduct and interpretation of animal carcinogenicity studies (G03)
- The use of biomarkers in carcinogenic risk assessment (G04)
- Defining a point of departure and potency estimates in carcinogenic dose response (G05)
- Risk characterisation methods (G06)
- Alternatives to the 2-year bioassay (G07) – part a) *In vivo* assays, and part b) Cell transformation assays.
- Statement on the risk assessment of the effects of combined exposures to chemical carcinogens (G08)
- COT, COM and COC Joint statement on nanomaterial toxicology (G10)

These documents are available here:

<https://www.gov.uk/government/collections/coc-guidance-statements>

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**July 2016**