CC/2017/03

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

Draft Lay introduction to COC guidance statement series

Enclosed in Annex A is the first draft of the lay introduction to accommodate the COC guidance statement series as was suggested in the July 2016 meeting.

Members are invited to comment on the structure and contents of the draft.

Imperial College Toxicology Unit/Secretariat
March 2017

Lay introduction to COC guidance statement series

The Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC) is an independent UK advisory committee reporting to the Department of Health and the Food Standards Agency (FSA). The terms of reference for the COC include providing general advice to government departments and regulatory agencies on whether chemicals may cause cancer in humans, and similar topics. This includes issues such as ways of testing, undertaking research, and assessing the level of risk posed by chemicals that may cause cancer (risk assessment).

The COC has periodically published guidelines on how to assess whether chemicals have the capacity to cause cancer (carcinogenicity). These included guidance on best practice for testing chemicals to see if they are likely to cause cancer (i.e. whether they are carcinogenic) (COC, 1982; COC, 1991; COC, 2004).

The most recent revision of guidance began in 2010 and is continuing. The key topics that underpin this work are separated into ten distinct but interrelated Guidance Statements, which are being updated as important new information becomes available. These statements give the Committee's views on the general principles and emerging scientific discoveries, experimental methods, and analysis relevant to carcinogenic hazard and risk assessment.

In this context, the term 'hazard' refers to whether or not a substance or activity is thought to be capable of causing cancer (i.e. is it a hazard?), while 'risk' is the likelihood that exposure to the substance or activity will actually lead to the development of a cancer (i.e. what is the chance of harm occurring?). When a substance or activity is identified as being a carcinogenic hazard, the level of cancer risk (carcinogenicity) will depend on how and how much exposure has occurred.

The available Guidance Statements are as follows:

G 01: A strategy for the risk assessment of chemical carcinogens (published 30 June 2012)
This overarching statement presents the Committee's recommended general approach to assessing the carcinogenicity of a chemical.

G 02: Interpretation of Evidence of Carcinogenicity in Humans: Epidemiology and Case Reports (in preparation)
This Statement will provide guidance on how studies of health effects in humans (human epidemiological studies) and related case studies can be used to help to assess the carcinogenicity of a chemical.

G 03: Hazard identification and characterisation: conduct and interpretation of animal carcinogenicity studies (published 2 February 2015)
To date, the potential for substances to cause cancer in humans has been identified in the main through laboratory studies using animals. The most common approach has involved exposing laboratory mice or rats to a test substance for 2 years (known as the '2-year bioassay'). This Guidance Statement discusses the setup of such animal studies and how the data obtained can be used to identify and characterise substances that may cause cancer, including the relevance of this information to the likelihood of carcinogenicity in humans.

G 04: The use of biomarkers in carcinogenic risk assessment (published 1 July 2013)
Substances, structures, or processes that indicate the presence of cancer, and can be measured in the body, are termed 'biomarkers' (biological markers). This Guidance Statement discusses how biomarkers are used in different parts of the carcinogenic hazard and risk assessment process.

G 05: Defining a point of departure and potency estimates in carcinogenic dose response (published 29 September 2014)
In order to estimate how likely it is that a person will develop cancer or how many people in a given population are likely to develop cancer from exposure to a particular substance, it is necessary to investigate the 'dose-response relationship' between that substance and the cancer that it causes – i.e. how the amount and duration of exposure to the substance (the dose) affects the nature and extent of cancer seen in those exposed (the response). Guidance Statement G 05 gives advice on how to derive and use the various methods that are needed to assess this.

G 06: Risk characterisation methods (published 30 June 2012)
Studies of chemicals in laboratory animals (as discussed in G 03) usually employ higher doses of substances than humans would normally be exposed to. This means there are uncertainties in estimating the effects in humans (i.e. characterising the risk) from the animal data. Guidance Statement G 06 gives the views of the Committee on how to estimate the level of risk to humans from exposure to low levels of different types of carcinogens.

G 07: Alternatives to the 2-year bioassay (parts a, b published 2 February 2016; parts c, d in preparation)
Steps are being taken to replace, where possible, the 2-year rodent bioassay (see Guidance Statement, G 03) with alternatives that limit the use of laboratory animals, that are cheaper and more practical to carry out, and that produce information about substances that cause cancer in humans. This Guidance Statement, in four parts, provides an overview of approaches that have been proposed as alternatives, including some of the different types of animal and non-animal tests that may be

used, and how these have been suggested to be incorporated into an overall testing strategy.

G 08: Statement on the risk assessment of the effects of combined exposures to chemical carcinogens (published 1 July 2010)
It is not possible for the risk assessment process to account for the combined action of all the potential exposures to mixtures of carcinogens that theoretically could occur. However, the Committee has identified some general principles that may be considered when assessing the risk of cancer from a combination of different substances, and this is discussed in Guidance Statement G 08.

G 09: Assessing the risks of less than lifetime exposure to carcinogens (in preparation)
People do not always experience lifetime exposure to a cancer causing substance or activity and exposure may occur for limited periods of time. This Guidance Statement will discuss approaches to assess how the risk of cancer would be expected to vary when a person is exposed for a period of time that is less than a complete lifetime.

G 10: Joint statement on nanomaterial technology (published 1 December 2005)
Guidance Statement G 10 is a position statement from the three advisory Committees, the Committee on Toxicology (COT), the Committee on Mutagenicity (COM) and the COC on nanomaterials, to which humans and the environment are increasingly likely to be exposed. Nanomaterials can be defined as having at least one dimension with a size of less than 100 nm. The Joint Statement considers risk assessment and a suggested initial strategy for toxicology testing.

COC
Month tbc 2017

References:
COC (1982) Guidelines for the Testing of Chemicals for Carcinogenicity. Report on Health and Social Subjects no. 25. London.

COC (1991) Guidelines for the evaluation of chemicals for carcinogenicity. Report on Health and Social Subjects no. 42. Department of Health, London.

COC (2004) Guidance on a strategy for the risk assessment of chemical carcinogens. Department of Health, London, UK.