COC input to other work

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Presentation by Dr John Doe “Revised strategy for the assessment of Chemical Carcinogenicity”

3.33 In March 2024, Dr John Doe joined the COC meeting to present on a paper he was preparing on a revised strategy for assessment of chemical carcinogenicity.

3.34 The presentation outlined the caveats with the current approach with respect to the adequacy of the animal studies conducted and the need to move to a graded rather than a binary outcome to carcinogenicity assessment. A framework for evidence evaluation was presented, and a matrix of potential outcomes suggested. Examples were provided indicating that removing data from the two-year bioassay and also human epidemiological data on cancer still provided sufficient information to support decision making on the potential for cancer.

3.35 Members welcomed the presentation of this strategy alongside case examples of chemicals to demonstrate how a different approach could be utilised in practise. Suggestions were made with respect to possible further improvements which could include consideration of how a margin of exposure approach would look without two-year rodent bioassay data. It was noted that there was a benefit in the approach with respect to drawing in mechanistic, in vitro, in silico and toxicokinetic data into the assessment approach.

3.36 Dr Doe was thanked for his presentation.

EFSA Consultation on draft “Scoping paper on the revision of the opinion on the Margin of Exposure for chemicals which are both genotoxic and carcinogenic”

3.37 COC provided comments in response to the EFSA consultation on the draft

“Scoping paper on the revision of the opinion on the Margin of Exposure for chemicals which are both genotoxic and carcinogenic”.

3.38 The COC welcomed EFSA’s proposed review of the opinion on the margin of exposure for chemicals which are genotoxic and carcinogenic. The COC agreed with the anticipation that there will be a decrease in carcinogenicity studies conducted in the future, and therefore it will be important to develop an approach that utilises data from other studies.

3.39 The COC recognised the intention in this scoping document to make useful steps in the move away from using animal test data for risk assessment and communication.

3.40 The COC was uncomfortable with the continued assumption that chemicals can be categorised as carcinogenic or not carcinogenic, suggesting instead that the outcome should be an expression of risk if increasing the possibility of cancer occurring modification of cancer risk by chemicals | Toxicology Research | Oxford Academic (Harrison, D.J. and Doe, J.E., 2021. The modification of cancer risk by chemicals. Toxicology Research, 10(4), pp.800-809).

3.41 The COC noted the use of BMDLs and T25 as the reference point as a basis for an MOE approach in the 2005 opinion, however often insufficient information was available to derive a BMDL so e.g. a NOAEL has to be used. COC welcomed development of advice on a range of options for reference points that can be used with an MOE approach.

3.42 The COC recognised EFSA’s ambition to develop an approach which does not necessarily require animal carcinogenicity studies. COC noted that EFSA may wish to consider how much data would be adequate for an assessment and using an MOE approach, e.g. for some compounds a single dose 90-day study may be all that is available to form the basis of a risk assessment.

3.43 The COC agreed that it would be helpful for EFSA to consider any further guidance or clearer definitions on MOEs which are less than 10,000 as can be the case for natural contaminants. Similarly, it would be helpful to strengthen the scientific rationale and explanation for use of an MOE of 10,000 with a BMDL10 from an animal carcinogenicity study to support risk managers.

3.44 The COC noted that it would be helpful to supplement the planned considerations on the toxicology evidence, with further consideration of the uncertainties in occurrence data to support the exposure assessment aspect of an MOE approach. This could also include guidance for less than lifetime exposures.

EFSA Consultation on draft “Request for scientific review of the methodologies available to assess the long-term toxicity and carcinogenicity of plant protection products and mixtures”

3.45 COC provided a number of comments to EFSA on the consultation on the draft “Request for scientific review of the methodologies available to assess the long-term toxicity and carcinogenicity of plant protection products and mixtures”.

3.46 The COC suggested clarity on the focus of the document which was predominantly relating to mixture effects and recommended obtaining additional support from expert in metabolism and/or toxicokinetics. Some specific comments were also provided on the different sections of the document.

OECD submissions related to carcinogenicity

3.47 UKHSA leads for the UK on human health discussions at the OECD meetings of the Working Group of National Coordinators of the Test Guidelines Programme (WNT). A number of submissions were made in 2024 on assays of relevance to carcinogenicity and UKHSA requested COC comments on these submissions. COC provided a number of comments on the various assays which supported the UK response.