COM Horizon Scanning 2021

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Forward look from the Chair

2.50 The Chair suggested two main areas of potential interest to the COM, which were genomics and next generation sequencing, and the use of genotoxicity markers in human biomonitoring. It was anticipated that in the next few years genomics and sequencing would be seen more in genotoxicity, including Duplex sequencing. There was a potential for this to support or even replace genotoxicity testing, particularly testing for gene mutation or point mutation. Developments in these areas may also provide an opportunity to gain more information from biomonitoring, occupational exposure or environmental exposure.

Presentation by Health and Safety Executive

2.51 Dr Lata Koshy gave a presentation on the work of the Health and Safety Executive (HSE) post the UK exit from the EU. HSE are involved in a number of activities within UK REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), which includes identifying hazards, such as mutagenicity, and identifying substances of Very High Concern (SVHC). Most of the HSE work on Classification, Labelling and Packaging regulation relates to hazard identification for industrial chemicals. The HSE is also involved in the regulation of biocides and pesticides. Additionally, the HSE produces summaries for ministers and HSE opinions on the mandatory classification of substances and whether to align with EU opinion. The future work programme of the HSE is still being worked out post EU Exit and will be limited by resource and recruitment. HSE anticipated that it would complete the evaluation of two to three active substances per year. Evaluation of mutagenicity is a key part in determining whether an active substance will be given approval. Mutagenicity is also a key factor in the UK review of new and existing substances and import tolerance for pesticides. Due to the short timeline, it may be difficult consulting with COM, which has three meetings per year.

2.52 Some key differences for HSE since the UK exit from the EU is that the HSE has to act in isolation from EFSA and ECHA and from that peer review process. Its independence meant that it had to improve its own individual peer review process and has set up various expert groups and developed links with various other expert advisory groups. HSE may consult the COM in the future in relation to complex genotoxicity data sets and for advice in reviewing GHS for germ cell mutation category 1 and 2. The COM guidance documents, and expert advice will be useful to the HSE and its advice on specific areas, for example, on mode of action/threshold mode of genotoxic action and the use of QSARs.

Government assessors

2.53 Assessors from other Government Departments and agencies were asked for any horizon scanning topics they wished to highlight. VMD had an interest in biopharmaceutical molecules and their potential for mutagenicity. VMD were not aware of any guidance on how to assess the mutagenic potential, for example, of modified stem cells or monoclonal antibodies, particularly those sourced from different species (e.g. xenogeneic stem cells). VMD may seek the view of the COM of this area in the future. BEIS noted that it had set up its own expert scientific advisory groups following UK exit from the EU and that it would be seeking to develop links with secretariats for other expert advisory groups, such as the COM.

2.54 Members of the COM were asked to send in any thoughts on horizon scanning topics to the COM secretariat.

OECD

2.55 The COM was sent a consultation on a new draft Test Guideline on the mammalian erythrocyte Pig-a gene mutation assay. Members were requested to send any comments to the secretariat so that these could be collated and sent to the OECD.

OECD Draft Detailed Review Paper on the Miniaturised Versions of the Bacterial Reverse Gene Mutation Test

2.56 Members were requested to provide comments on an OECD Draft Detailed Review Paper (DRP) on the miniaturised Ames test (bacterial reverse gene mutation test) for collation by the National Coordinator at UK HSA. Assessors were requested to also send any comments which would be submitted separately.

2.57 It was noted that the DRP will not lead to a revision of the TG (TG471), but the aim of the review was to provide recommendations on the use of each of the mini-Ames tests proposed. From a UK perspective it was considered important to highlight and record any controversial points that were not in line with UK practice.

2.58 There was general agreement with the recommendations of the DRP. It was felt that until a robust validation process of the mini-Ames assays had been carried out, no further progress could be made in implementing the assays for regulatory testing. Further justification was requested, including better definition of what the assay is for, e.g., increasing output and reducing costs, incorporation of information relating to how laboratories were chosen to take part and whether there is a clear benefit of using mini-Ames assays above TG471. It was intended that a short written summary of the text submitted to OECD would be provided to COM members at the meeting in March 2022.