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DIRECTION DE L'ENVIRONNEMENT
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Division Environnement, santé et sécurité
Environment, Health and Safety Division

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To: Task Force on Endocrine Disrupter Testing and Assessment (EDTA)

SUBJECT: PEER REVIEW PANEL REPORT OF THE UTEROTROPHIC ASSAY VALIDATION

Dear Colleagues,

I am writing to you today to provide you with a copy of the report of the Peer Review Panel for the uterotrophic bioassay and to seek your comments and views on the next steps necessary for the use of this assay as the basis for an OECD Test Guideline.

As you will recall, the issue of the uterotrophic bioassay was discussed at the EDTA8 meeting in January 2005 and at the WNT17 meeting in April 2005. At that time, the EDTA and WNT were advised that the circulation of the first draft of the Peer Review Panel (PRP) in 2004 had revealed that there was a lack of consensus amongst the PRP members as to the validation status of the uterotrophic assay. The WNT17 meeting asked that the PRP report be finalised and then be referred back to the EDTA for further consideration, and that the EDTA advise the WNT on how best to progress this project after consideration of the final PRP report.

The PRP report was revised by the Secretariat during 2005, in line with the PRP responses to a series of charge questions posed to the Panel between October 2003 and February 2004 during teleconference meetings. The Panel based their responses on the data and other information provided in validation reports developed during the OECD validation process, as well as on their experience with the assay and validation processes. The individual responses from Panel members to those charge questions have been attached for the information of the EDTA, but the identity of the individual members have been removed from the document.

EDTA members are asked to consider the attached PRP report and the summary of responses to the questions posed during the peer review process. In summary, the PRP report identifies that, in general, the Panel agreed that the uterotrophic assay was valid for use for the detection of particular endocrine-disrupting endpoints as part of an overall testing strategy, but that there were a number of areas (such as the number of negative compounds and the usefulness of the assay for detecting weak agonists and androgens) that require further validation (possibly retrospectively, using existing data) before the assay would be considered to be validated for other purposes. This is obviously my simple summary of a complex validation exercise, and the EDTA members are asked to consider the attached report and supporting information carefully, especially given the lack of consensus amongst the PRP members on some of these issues.

The Secretariat is seeking comments from the EDTA on the way forward for the development of this assay into an OECD Test Guideline. As you may be aware, the development of an OECD Test Guideline is already an agreed project on the 2003-05 rolling workplan for the Test Guidelines programme and the

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development of the Test Guideline may be possible in parallel with the further validation activities, if necessary. Input is sought from the EDTA members on a number of issues, such as whether further (retrospective or prospective) validation is necessary to further refine the assay, and if so which member country would take the lead for such an activity, and what would be the timeline for such work? The EDTA members are encouraged to consult widely within your countries to gauge your position on the validation status of the uterotrophic assay, in light of the Peer Review Report, and to indicate if there are regulatory applications for a Test Guideline based on the assay, either immediately or with further assay development.

It is envisaged that the VMG-mammalian and the EDTA will meet in March and April, respectively, in 2006. These dates will be decided over the coming weeks. The issue of the uterotrophic assay is likely to be on the agenda for those meetings, and so it is important for EDTA members to provide their comments and views on the status of the uterotrophic assay, and the next steps in this validation activity, to the Secretariat by 13 January 2006.

If you have any queries regarding this correspondence, and/or wish to pose further questions, please do not hesitate to contact me.

Yours Sincerely,

Drew Wagner
Principal Administrator
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