

PVP / Risk Assessment Update

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PVP / Risk Assessment Update

Meeting of CSAP-Risk APs and MOE – July 7th, 2014

- MOE core review overhaul – MOE elaborate in afternoon panel
- Update of CSR standards involves all MOE risk assessors – new standards expected over the next 16 months and finalized by Spring 2016 (Stage 10 Amendments) - **opportunity for CSAP Risk APs to assist? (resources TBD)**
- 17 documents are in preparation (14 in phase 1 and 3 in phase 2); CSAP provided comment on all 14 in September 2014

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- **Technical Bulletin 3** in final stages – provides rapid “rejection criteria” for risk assessments.
 - RA needs to be stand-alone document
 - Confirms DSI shows delineation and stable/decreasing concentrations
 - Confirms assessment is sufficiently comprehensive and recent
 - Confirms risk assessment organized under the standard TOC components
 - Follows appropriate protocols, guidance and policy
 - Contains professional statement of QP
 - Lists common errors or omissions
 - Need to sum HQs for commonly acting substances

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- **Technical Guidance 7 – CSAP Review of New Draft**
- HHRA – requirement for addition of risks via multiple pathways, and for chemicals sharing a similar mechanism of toxicity or target organ has been added to TG7. Request for clarification by CSAP.
- ERA – changes to TRVs to ensure that TRVs are not provided only as intakes; prefer use of ECx values rather than NOAELs; preferred sources of TRVs and screening levels; sum total dose and risks from multiple media for particular COPC

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Technical Guidance 7 – Items Requiring Resolution (V.3 and Draft)

- HHRA – existing note on addressing classes of carcinogens (PAHs, PCDDs/PCDFs, Coplanar PCBs) in conflict with CSR Section 1 definition of “carcinogenic substances” defined by IARC, USEPA classifications. Update to CSR needed?
- ERA – existing requirement that “Toxicity Profiles” *must* be provided in conflict with Protocol 20, Appendix 1 DERA Checklist Item 4.10, which indicates toxicity profiles are “optional”

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- **Draft AG14** – Clarifies Usage of PVP and will simplify Protocol 12
 - Added reference to PVPs for site profile releases
 - Clarifies roles/responsibilities (QPs vs. APs; risk APs vs. standards APs)
 - Under AG6, PVPs could be required for site profile release scenarios 4 and 5 under EMA 54(3)(d) – this is new and in effect now
 - Removed 10-fold multiplier for Type 1b and 2 risk controls (Table 1)
 - Added AP signature block for PVP – **will need to be signed by the AP and is a concern for CSAP due to potential increased AP liability**
- CSAP provided comment September 15

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- **Status of PVP Submissions:**

- Initially informal inclusion until August 1st 2014 - adjustment period
- **New Procedure 12** revision **not complete** and **AG14 not yet official** – therefore legally **Procedure 12** (V. 1.0 – effective date April 1, 2013) **prevails and requires submission of PVP.**
- **Message #1:** Officially submit a PVP as part of CofC Package – informal adjustment period is over
- **Message #2:** Until Procedure 12 and AG14 are re-issued, the CSAP/MOE performance audit will flag deficiency but **not** be punitive

Questions