

Proposed NTP CERHR Small Dataset Process

Chemicals nominated for evaluation by the CERHR are reviewed quarterly by the CERHR Core Committee, which is made up of NTP agency representatives. Highest priority chemicals are identified based on production volume, extent of scientific literature on reproductive or developmental toxicity testing, human exposure, and public concern. The Center staff prepares a dossier on the candidate chemical, which highlights exposure studies and human and experimental animal reproductive toxicity studies. The CERHR Core Committee meets quarterly and reviews the dossiers and recommends chemicals to the Associate Director, NTP, for expert panel evaluation. The Core Committee may reach one of three decisions on the nominated chemical: selected for expert panel evaluation, not selected, or deferred. In some cases, chemicals with limited reproductive or developmental toxicity data may be deferred for later consideration, in spite of high production volume, likelihood of human exposure, or considerable public concern. Small databases may contain important information about reproductive and developmental risks, toxicokinetic considerations, and needed research studies – information which would be helpful to the public and regulatory agencies. To address these needs, the proposed Small Datasets Process would evaluate chemicals with a high degree of public concern but a toxicology database too small to merit a full expert panel evaluation and public meeting.

CERHR chemical evaluations by the Small Dataset Process would follow the same NTP CERHR guidelines as the full expert panel evaluations and have several opportunities for public comment. However, the expert reviewers would not convene in a public meeting. Key features of the chemical evaluation by the Small Datasets Process are outlined below.

- The CERHR Core Committee will recommend a chemical for evaluation by the Small Datasets Process to the Associate Director, NTP.
- The NTP CERHR expert panel guidelines will be followed to ensure a uniform evaluation format and transparency of the process by which conclusions are reached.
- Publicly available sources of data will be used in the evaluation, consistent with the full expert panel evaluation.
- Individuals with specific expertise relevant to the available data will be chosen as evaluators (expert reviewers) from the NTP CERHR expert registry.
- NTP CERHR will write sections 1–5 of the draft report. Expert reviewers will suggest modifications and approve the report.
- Opportunities for public comment on chemical selection, the draft report, and the final report will be the same as for a full expert panel evaluation. However, there

will be no public meeting. Unlike the expert panel process where the draft report contains sections 1–4 and section 5, Summaries, Conclusions, and Critical Data Needs, is drafted at the public meeting, the draft Small Dataset Report will contain sections 1–5.

- NTP CERHR staff and expert reviewers will review public comments on the draft Small Dataset Report. CERHR staff will revise the draft report; prepare final conclusions and an executive summary. The final report will be reviewed and approved by the expert reviewers, NTP staff, and the NTP CERHR Core Committee and made available for public comment. The final Small Dataset Report and the public comments on that report will be publicly available through NTP-CERHR and posted on the CERHR web site.