Endocrine Activity for Alternatives Assessment

Draft Criterion

Why Endocrine Activity?

- The presence or absence of endocrine activity is of interest to DfE stakeholders.
- Including this endpoint in the alternatives assessment will provide information that could inform decision-making.
- This criterion would evaluate endocrine activity rather than characterize hazard in terms of "endocrine disruption".

Data Resources

- Data that will be considered include:
  - In vitro data (hormone receptor binding assays or ex vivo assays)
  - In vivo data from studies of laboratory animals or wildlife (including aquatic organisms)
  - Ethically conducted human studies
  - Structural similarity to known endocrine active substances using SAR tools such as AIM, QSAR, etc.

Criteria

- Available data for each chemical will be evaluated for evidence of the presence of endocrine activity.
  - If there are no data available to evaluate this endpoint, endocrine activity is unknown, untested and would be marked with a "ND" indicating the absence of information. (No Data)
  - If data are available, then:
    - If data show evidence of endocrine activity then the chemical will be designated as potentially endocrine active, while noting caveats and limitations.
    - If data conclude no evidence of activity (no binding, perturbation, or evidence of endocrine-related adverse effects) then the chemical will be designated as having no evidence of endocrine activity, noting caveats and limitations.

Presentation

- Narrative format
  - Summary statement
  - Data summary
  - Qualitative assessment of the level of evidence supporting designation
    - Presence of equivocal or conflicting data
    - Limitations
    - Level of confidence in the assessment