PFS Project Appraisal of EFSA 2013 Draft Exposure Assessment of BPA

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Summary

• **Main findings**: Draft Exposure Assessment either not conducted according to a scientifically robust methodology, or insufficiently documented to be able to determine one way or another

• **Recommendations**: publish protocols before conducting Opinions; develop tools for valid and consistent appraisal of the relevance and methodological quality of research.
About the PFS Project

• Started around November 2012 from a kernel of an idea at Centre for Sustainable Healthcare in 2010
• Taking systematic review methods for synthesising data in medical science and adapting them to chemical risk assessment (Whaley 2013)
• Paul Whaley (Lancaster), Yannick Vicaire (Réseau Environnement Santé), Crispin Halsall (Lancaster)
BPA: Who to believe?
Literature Review Appraisal Toolkit

- Identified 9 main components to literature reviews conducted for chemical risk assessment
- Derived from literature review appraisal tools and guideline documents used in medicine
1. Clarity of objective
2. Use of protocol
3. Interests & contribs
4. Search strategy
5. Selection criteria
6. Test of relevance
7. Test of reliability
8. Validity of synthesis
9. Clarity of answer
Possible responses

• **Satisfactory.** Clear, valid and consistent procedure.
• **Unclear.** Insufficient documentation to evaluate.
• **Unsatisfactory.** Positive evidence of inconsistent or invalid procedure.
1. Clarity of objective

- Satisfactory
2. Use of protocol

- Unsatisfactory
  - Because absent
3. Declaration of interests

- Unclear
  - Difficult to obtain
  - Have to be extrapolated
  - No declaration of contributions
4. Search method

- Unsatisfactory
  - Relevant studies were missing from review
Missing studies

- Stahlhut et al., 2009. Bisphenol A data in NHANES suggest longer than expected half-life, substantial nonfood exposure, or both.
- Fénichel et al. 2012. Unconjugated bisphenol A cord blood levels in boys with descended or undescended testes
- Spanier et al. 2012. Prenatal exposure to bisphenol A and child wheeze from birth to 3 years of age
- Perera et al. 2012. Prenatal bisphenol a exposure and child behavior in an inner-city cohort
- Wolff et al. 2008. Prenatal phenol and phhalate exposures and birth outcomes
5. Selection criteria

- Unsatisfactory
  - Deliberately selective in using excluded Japanese data
6. Test of relevance

- Unclear
  - Not described
7. Test of reliability

- Unsatisfactory
  - Criteria are described in Section 4 and Appendix 1 but not used
Quality criteria

• Criteria are described but there is no explanation of how they inform judgements of study quality

• Included studies seem to be treated as if they are equally valid, regardless of method
  • Migration data from PlasticsEurope (line 986)

• Single studies are interpreted as offering the best estimates of BPA exposure regardless of weaknesses
  • Juberg et al. 2001 for BPA exposure from pacifiers
8. Data synthesis

- Unclear
  - Inconsistencies and apparent errors in calculating exposure
9. Clarity of answer

• Unsatisfactory
  • Uncertainty charts show BPA ranging up to 1100 ng/kgbw/d; abstract only presents result as “up to 857 ng/kg bw/day”.
## Analysis of EFSA Opinions

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Recommendations

• Publish protocols before conducting Opinions
• Declare relevant interests and contributions in the body of each Opinion
• Use valid tools for appraising the relevance and methodological quality of research
• Transparently document all significant decisions made in the review process
• Present all results (e.g. search, selection) relevant to appraising methodological quality of Opinions