

Policy From
Science Project



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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?



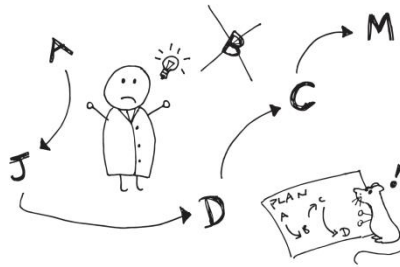
Literature Review Appraisal Toolkit

- 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



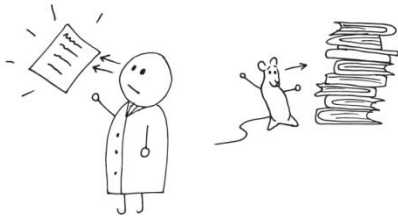
2. Use of protocol



3. Interests & contri



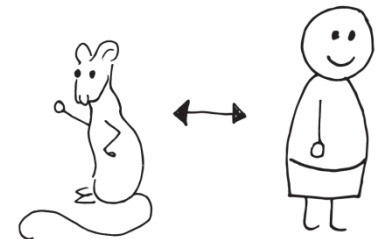
4. Search strategy



5. Selection criteria



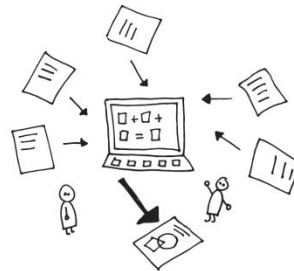
6. Test of relevance



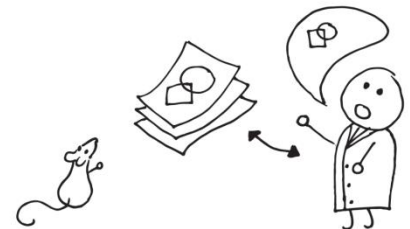
7. Test of reliability



8. Validity of synthesis



9. Clarity of answer

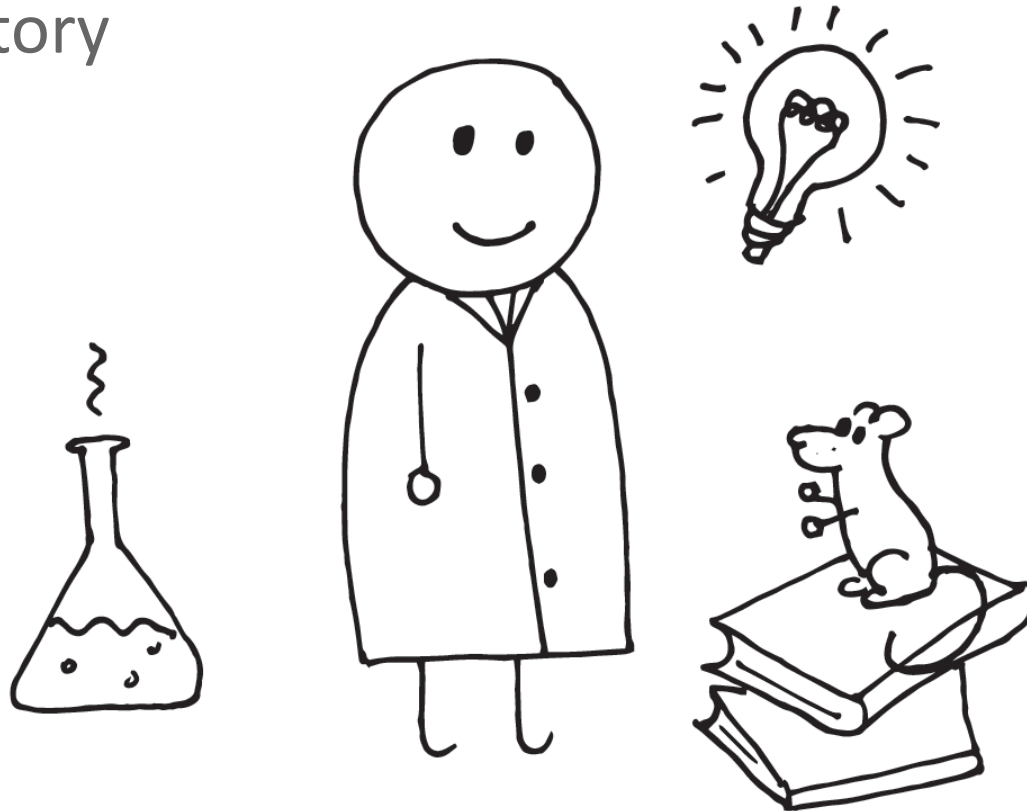


Possible responses

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

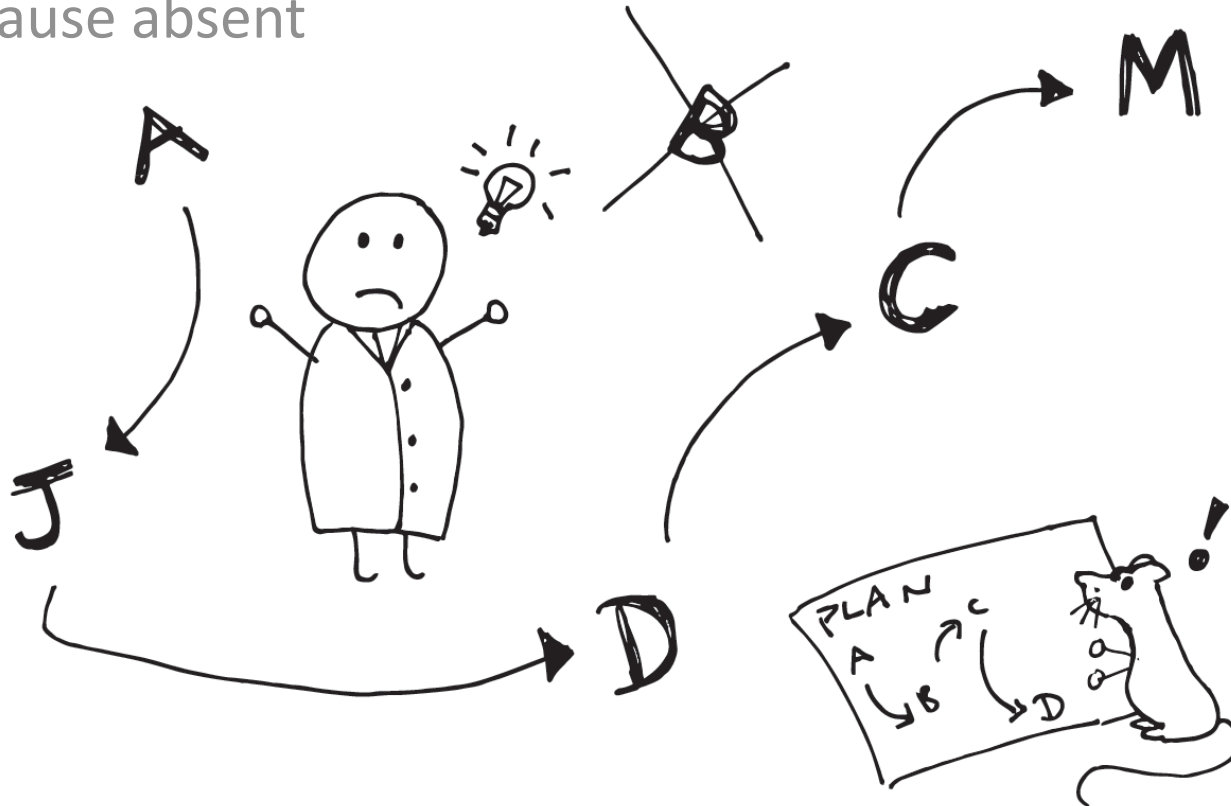
1. Clarity of objective

- Satisfactory



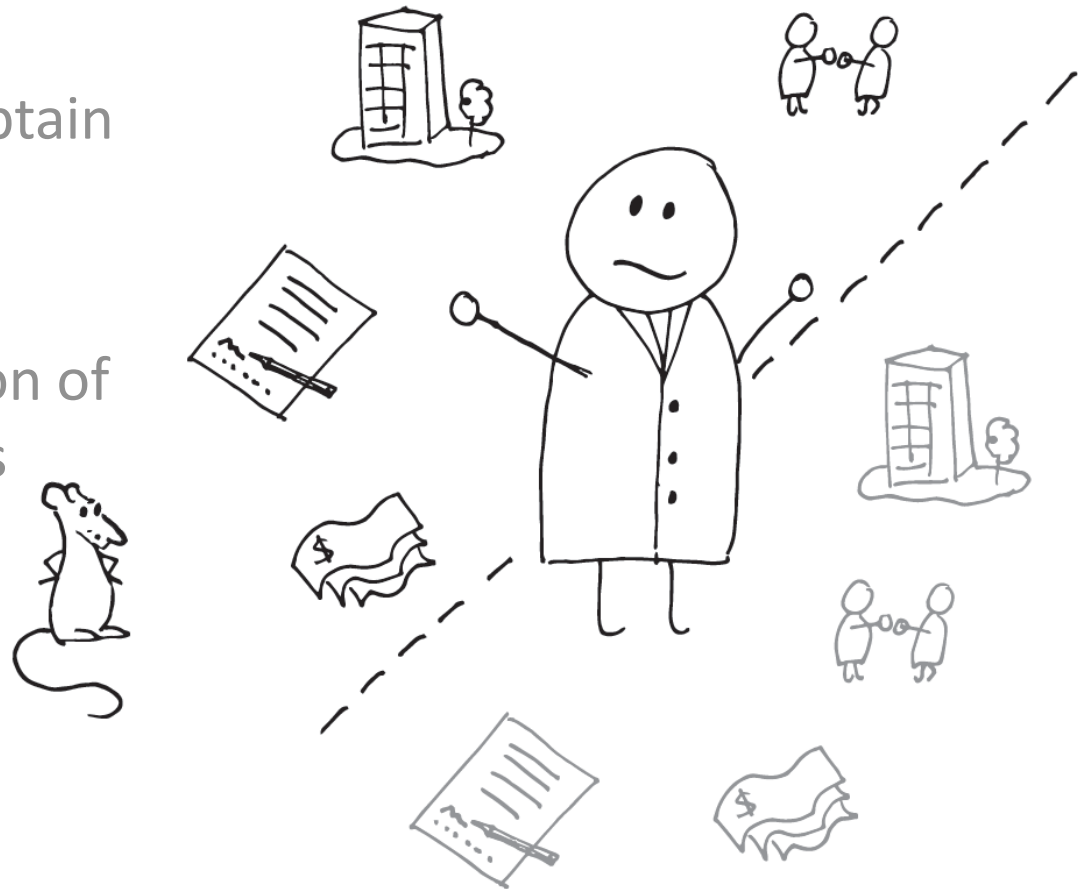
2. Use of protocol

- Unsatisfactory
 - Because absent



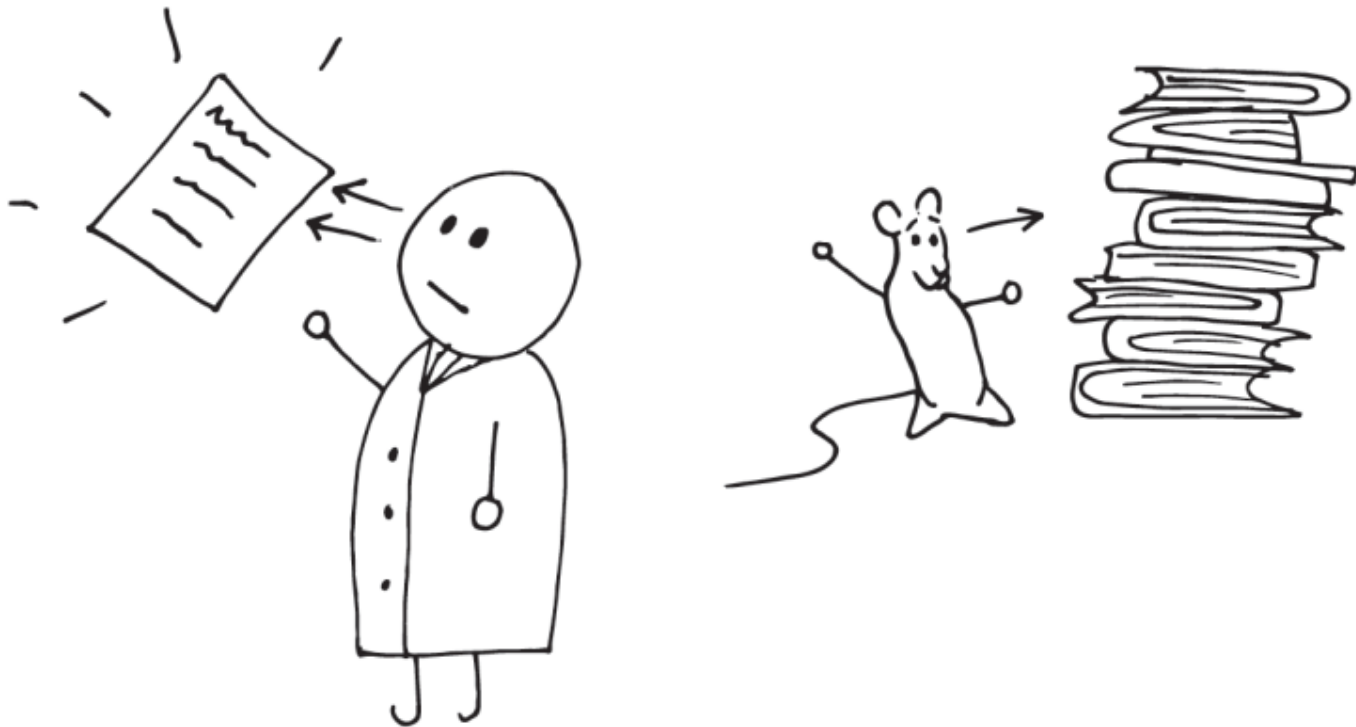
3. Declaration of interests

- Unclear
 - Difficult to obtain
 - Have to be extrapolated
 - No declaration of contributions

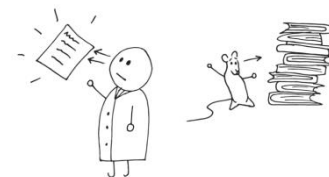


4. Search method

- 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
- Braun et al. 2009. Prenatal bisphenol A exposure and early childhood behavior
- Wolff et al. 2008. Prenatal phenol and phthalate exposures and birth outcomes

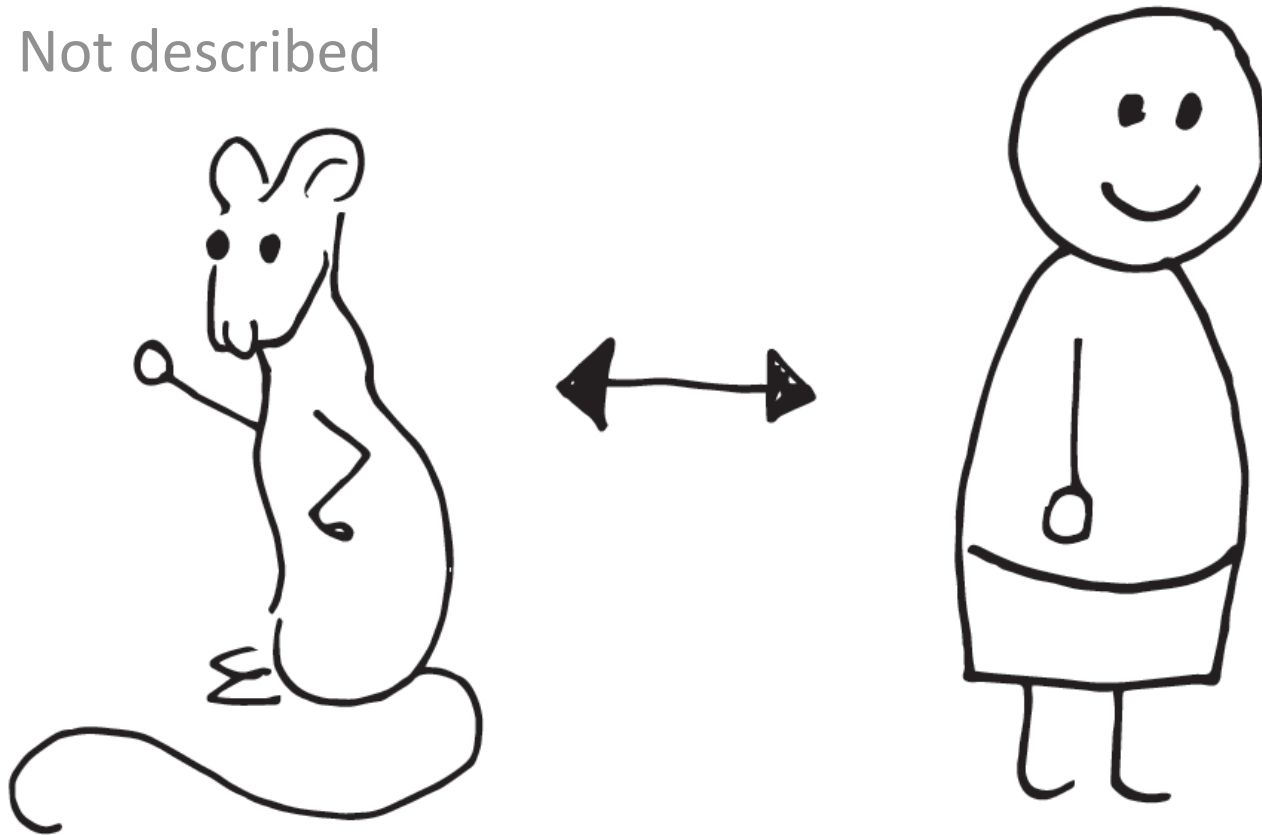
5. Selection criteria

- Unsatisfactory
 - Deliberately selective in using excluded Japanese data



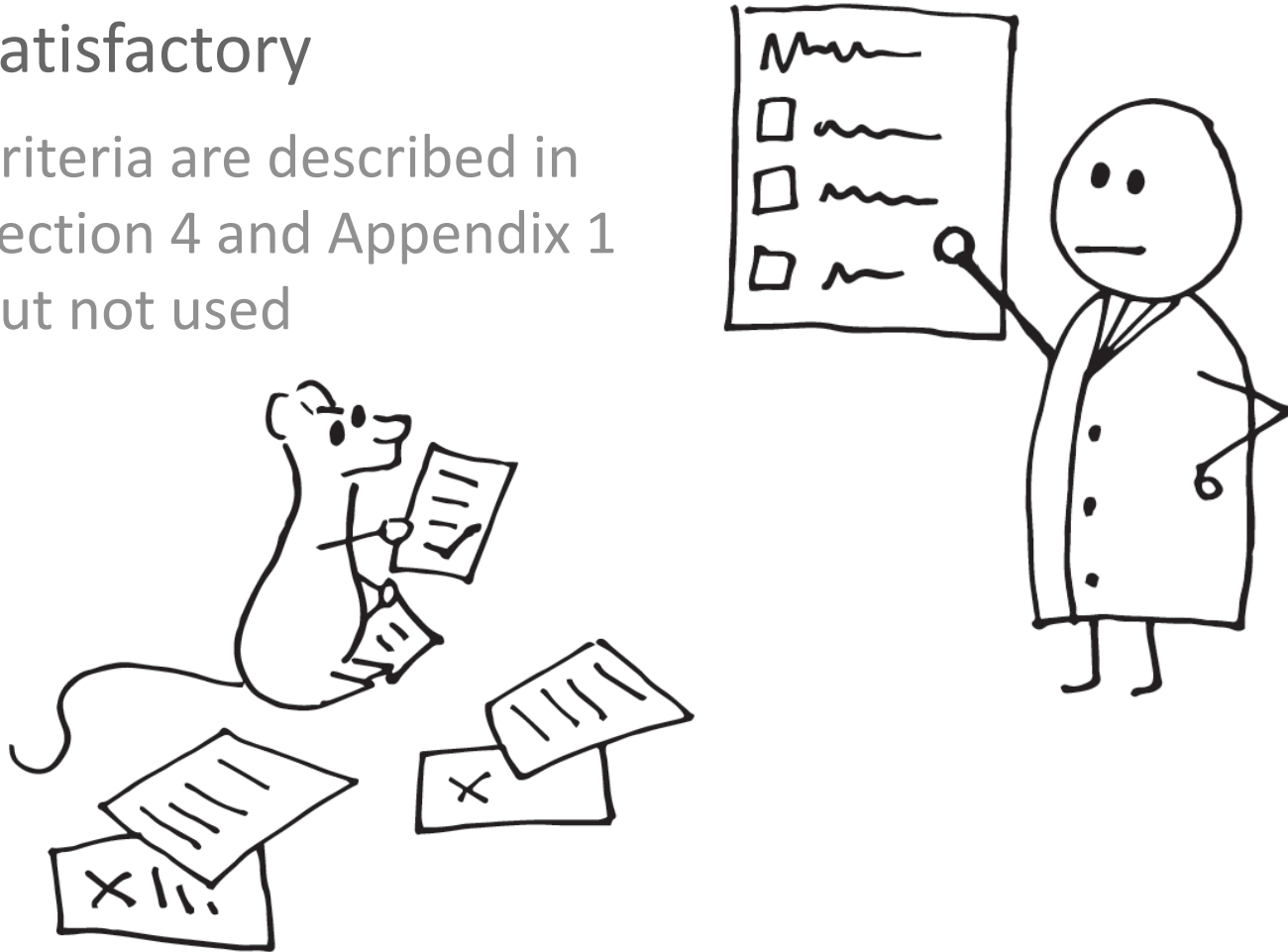
6. Test of relevance

- Unclear
 - Not described



7. Test of reliability

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



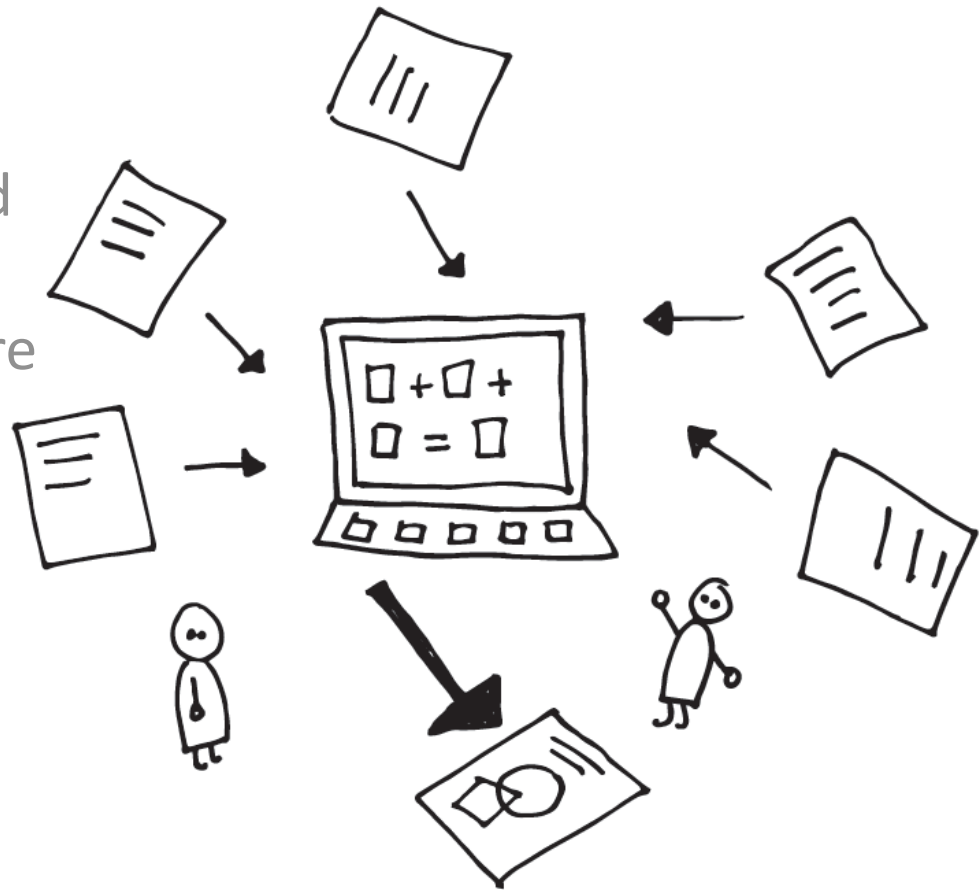
Quality criteria



- 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

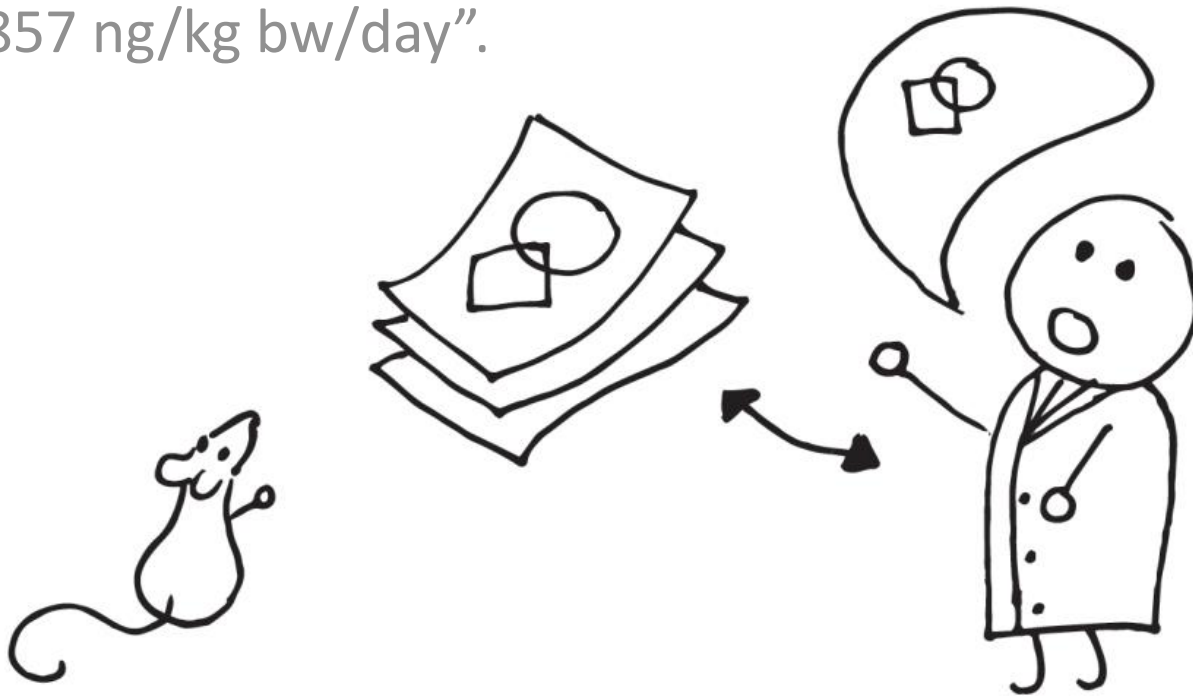
8. Data synthesis

- 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

Criterion	2010 Opinion	2013 Draft Exposure Assessment	2014 Draft Opinion
1. Objective	●	●	●
2. Protocol	●	●	●
3. Interests	●	●	●
4. Search Method	●	●	●
5. Study Selection	●	●	●
6. Relevance Test	●	●	●
7. Reliability Test	●	●	●
8. Synthesis	●	●	●
9. Answer	●	●	●

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