Overview of the comments received during the public consultation on the draft BPA assessment protocol

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Workshop on BPA hazard assessment protocol
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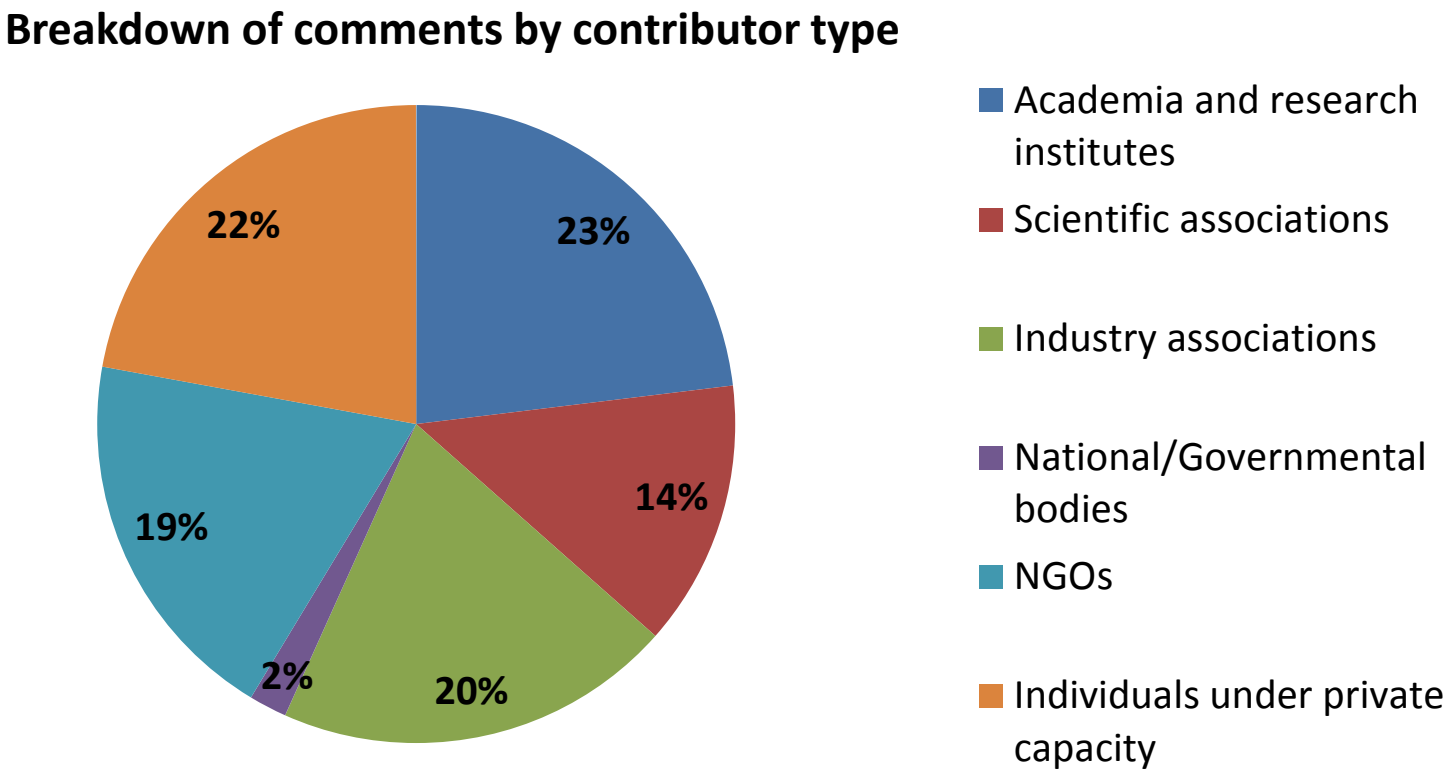
efsa
European Food Safety Authority

Comment statistics

104 comments received overall



Comments affiliations

	Parties	Number of comments
Academia and research institutes		
1	Technical University of Denmark	5
2	University of Melbourne	7
3	Lancaster Environment Centre	8
4	University of Sussex	4
Scientific associations		
1	Endocrine Society	10
2	Evidence-Based Toxicology Collaboration (EBTC)	4
Industry associations		
1	Metal Packaging Europe	15
2	PlasticsEurope	6
National/Governmental bodies		
1	National Institute of Public Health and Environment (RIVM)	1
2	European Commission	1
NGOs		
1	The Endocrine Disruption Exchange	19
2	Breast Cancer UK	1
Individuals under private capacity		
1	Fera	11
2	R.I.S.K. Consultancy	10
3	Food safety systems GmbH	2

Summary of comments

- **Welcome to a pre-planned BPA assessment protocol**: improved transparency and validity of findings

- **Study inclusion / exclusion criteria**
  - Cut-off date: 2013-2017 (NTP/FDA Report public.), papers published in 2013-2017 already appraised by EFSA in previous opinions using different criteria, all evidence for critical endpoints, re-evaluation of critical studies (e.g. Tyl et al 2008)
  - Letters to the Editors, reviews, book chapters, etc.
  - Non-English studies (through call for data?)
  - Cross-sectional and single-dose studies, spot urine samples
  - Animal inhalation studies, non mammalian studies
  - Immunotoxicity studies already appraised in 2016
  - Co-exposure with endogenous hormones in MoA studies

- **Systematic vs narrative approach**
  - narrative methods applied to certain areas (TK, genotox, in vitro) may undermine the systematic review approach

Summary of comments

- **Internal validity**
  - Unclear difference between **risk of bias** (RoB) and **quality**: partly overlapping features & double counting?
  - Unnecessarily complex process, quality not validated
  - Need more explanations, e.g. choice of key questions, what is sufficient number of animals, historic controls, etc)
  - Expert selection for WG experts/reviewers
  - Authors will NOT be contacted for clarifications or missing info
  - Studies' financial conflicts of interest

- **WoE approach**
  - Methodology not sufficiently clear and transparent;
  - Use of GRADE pre-defined methodology to downgrade or upgrade evidence
  - Meta-analysis vs graphic representation of studies
  - How are tiers 1, 2 3 studies used? Negative studies?

Summary of comments

- **Relevance and adversity**
  - Relevance evaluation in 2 steps (relevance of the endpoint to the hazard sub-question and human relevance of the effect in animals) is unclear
  - Human relevance and adversity section: unnecessary, not transparent, relying too much on expert judgement

- **Method for performing hazard characterisation**
  - Inclusion of ALAN studies in the hazard characterisation

- **Method for performing uncertainty analysis**

Next steps

Thank you for your constructive comments!!

End of 2017

Technical report on the protocol public consultation

Revised Hazard assessment protocol endorsed by the CEF Panel

2018

Start of BPA re-evaluation

US FDA/NTP report on 2 year study in rats