Application of the TAGS tiered approach for aggregate exposure assessment to the flame retardant BDE-209

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Within the CEFIC LRI funded TAGS project, a tiered approach to aggregate exposure assessment was developed. Three tiers are distinguished: a qualitative Tier 0 guiding the user through a series of questions to set the scope of the aggregate assessment, a conservative Tier 1 based on screening-level models, and a Tier 2 providing detailed source to (internal) exposure assessment tools. An optional pre-Tier 1 was introduced to enable use of available biomonitoring data in early steps of the risk assessment process. The framework for tiered aggregate exposure assessment is associated with guidance for uncertainty assessment and verification of exposure assessments. The methodology has been applied to three case studies, of which the case study on BDE-209 – a brominated flame retardant – is presented.

Tier 0

BDE-209 is a brominated flame retardant used in textile (mainly upholstery), in construction and in transportation. Its use in electric and electronic equipment is prohibited in the EU since 2008 (RoHs regulation). BDE-209 is a chronic toxicant with neurotoxicity (young children) as critical health effect. As the health effect is systemic and absorption is possible via all routes (although low via the dermal route), aggregation of exposure across routes is required. Subscenarios should account for higher use of flame-retarded textile in UK, actual situation and time trend due to RoHS regulation). BDE-209 is transformed in the abiotic and biotic environment to lower brominated congeners that are potentially more toxic.

Pre-Tier 1

Approach

Human biomonitoring data for BDE-209 (serum) were collected. Two one-compartmental steady-state toxicokinetic models were used to convert US-EPA RfD and EFSA BMDL to equivalent serum levels.

Results

Most serum levels were below LOD or LOQ, some extremes were found. Using the RfD, the equivalent serum level ranged between 60 - 2500 ng/g lipid, the lower value was only exceeded for the upper range of three studies (Figure 1) and in cord blood data for France.

Conclusion

The results indicate little reason for concern. However, data for (UK) children are lacking, the assessment did not take into account cumulative exposure to lower brominated congeners that could have resulted from BDE-209 degradation. There is uncertainty in the toxicokinetic model, which is also not applicable to children.

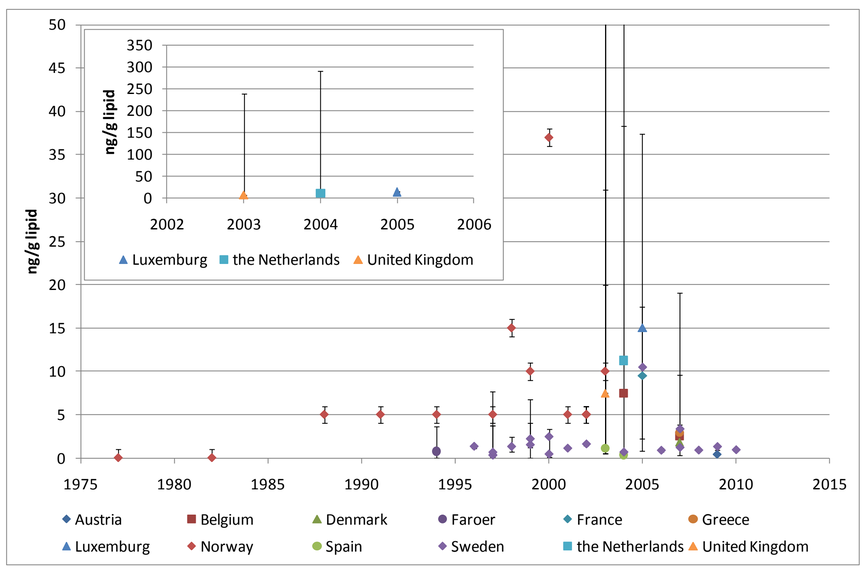

Figure 1: Serum levels (average and ranges) of BDE-209 in EU populations

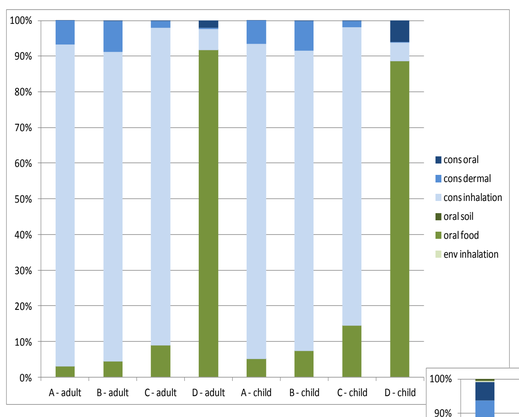

Figure 2: Contribution of routes and pathways using ECETOC TRA (Tier 1)

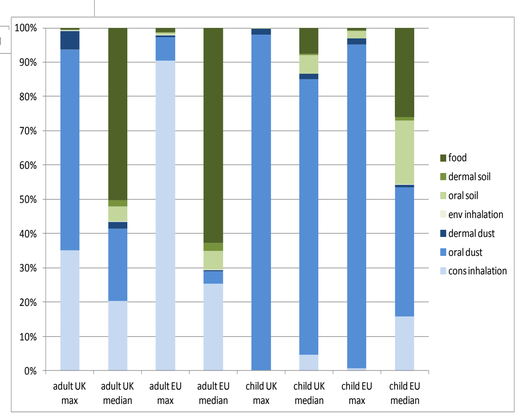

Figure 3: Contribution of routes and pathways using measured levels Tier 1

Tier 1

Approach

ECETOC TRA v2 was used for environmental and consumer exposure. Data were extracted and post-processed for aggregation within and across scenarios. Exposure of children was added, as well as oral and dermal exposure to soil.

As an approach to verify the ECETOC TRA predictions, measured concentrations were used to calculate exposure while keeping the same exposure factors. Dietary intake was also modelled according to EFSA's Comprehensive Food Consumption Guidance and Database (L1 level).

Results

ECETOC TRA v2 was overly conservative when compared to measured levels and indicated significant risk for all meta-scenarios. The assessment based on measured levels only gave an RCR >1 for the high exposure UK child scenario. Contribution of routes and pathways differed between the ECETOC TRA and measured data based assessments (Figure 2 and 3). The dietary assessment using EFSA's methodology resulted in higher intakes.

Conclusion

The assessment based on measured levels indicated a risk for one subpopulation. However, direct contact with consumer articles could not be accounted for when using measurements. The generation of lower brominated congeners was also not accounted for at Tier 1.

Tier 2

Approach

Default emission estimates were replaced by more realistic values derived from available sources (VECAP, OECD, …). The EUSES-TGD model was used in sequence to model degradation of BDE-209 and generation of lower brominated congeners. PECs were compared with measured levels. Measured concentrations (P50 and P95) were used in a probablistic exposure assessment for environmental, consumer and dietary pathways. Results were compared with biomonitoring data.

Results

The approach to degradation/formation of congeners worked well, but verification was hampered by lack of data and contribution of other sources to lower brominated congeners. A risk was only indicated for the highly exposed UK child (Figure 4), where consumer exposure was dominant. Comparison of adult exposure with available biomonitoring data indicates plausible results.

Conclusions

Complexity and lack of data hampered source-to-dose consumer modelling. Further refinement should look at subpopulations with potential high exposure. Further information on the contribution of BDE-209 degradation to levels of lower brominated congeners is needed.

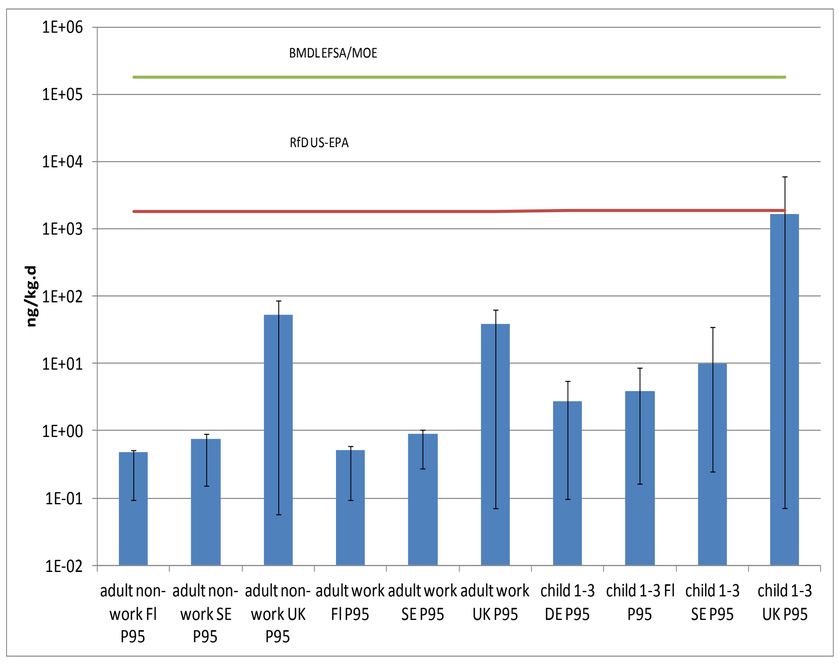

Figure 4: Average aggregate exposure to BDE-209 at P95 concentrations (excluding dietary exposure) (error bars indicate P5 and P95 exposures)

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