A novel tiered approach to aggregate exposure assessment of chemicals in articles and the environment

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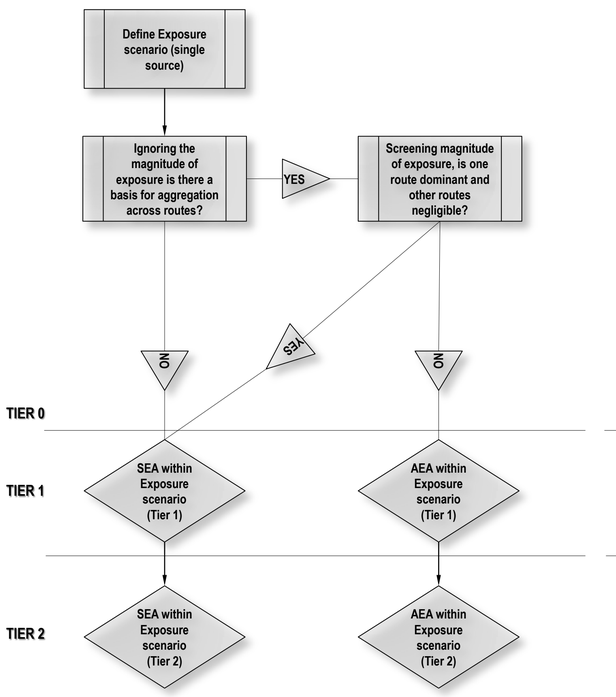
Introduction

TAGS aims at the development of a tiered aggregate exposure assessment methodology for chemical substances in consumer products and the environment.

Methodology

The following series of criteria must be considered when deciding if a simple exposure assessment is sufficient or an aggregate exposure assessment scheme needs to be employed.

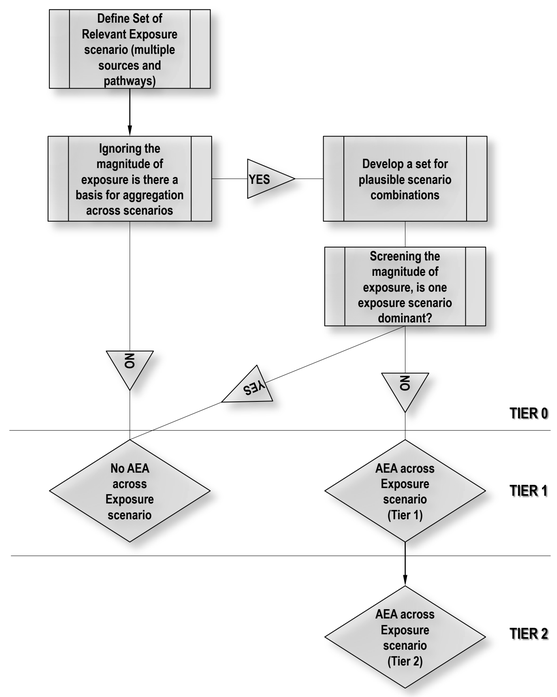


Stage 1 of the Decision Strategy (within Exposure Scenarios)

a) Identify all relevant routes of exposure (inhalation, dermal, ingestion) and the pathways for each exposure route.

b) Identify toxicological and/or health endpoints associated with each route and assess these for commonality.

c) Identify if there is one dominant route and/or pathway of exposure compared to all other routes/pathways combined.

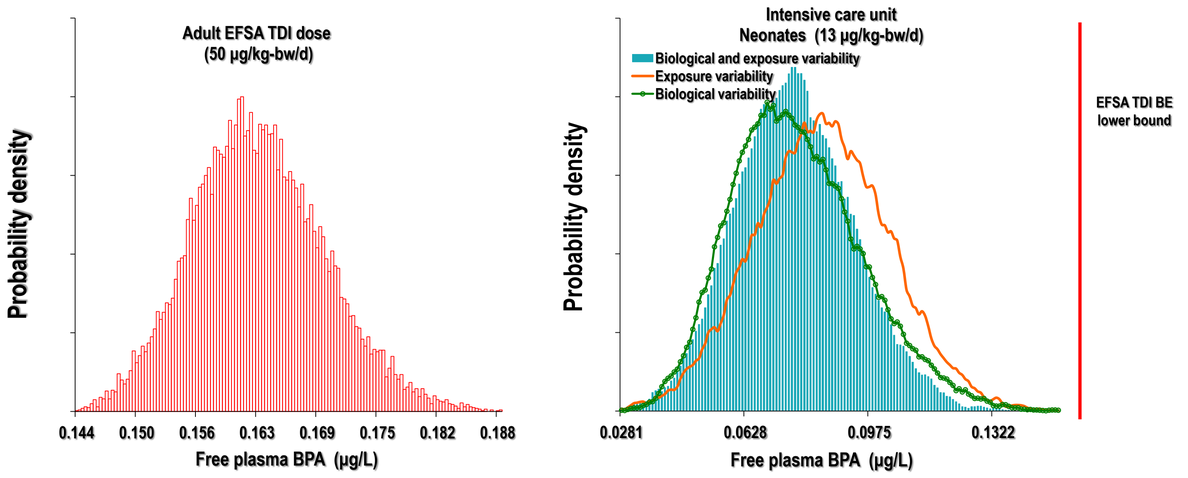


Stage 2 of the Decision Strategy (between Exposure Scenarios)

a) The first step would be to define the population groups of interest (e.g. consumers, workers, susceptible groups, geographical area, socio-economic status).

b) Next, an assessment needs to be made whether the exposure from different scenarios can lead to the same health endpoint or not.

c) For each combination of (sub)population and health end point, develop a set of plausible exposure scenarios. For each set of exposure scenarios, determine if there are any scenarios that completely dominate the exposure from all other scenarios combined.



Regarding premature neonates hosted in intensive care units, it was identified that dose equal to 13 µg/kg_bw/d, corresponds to an internal dose close to the lower part of the corresponding BE value.

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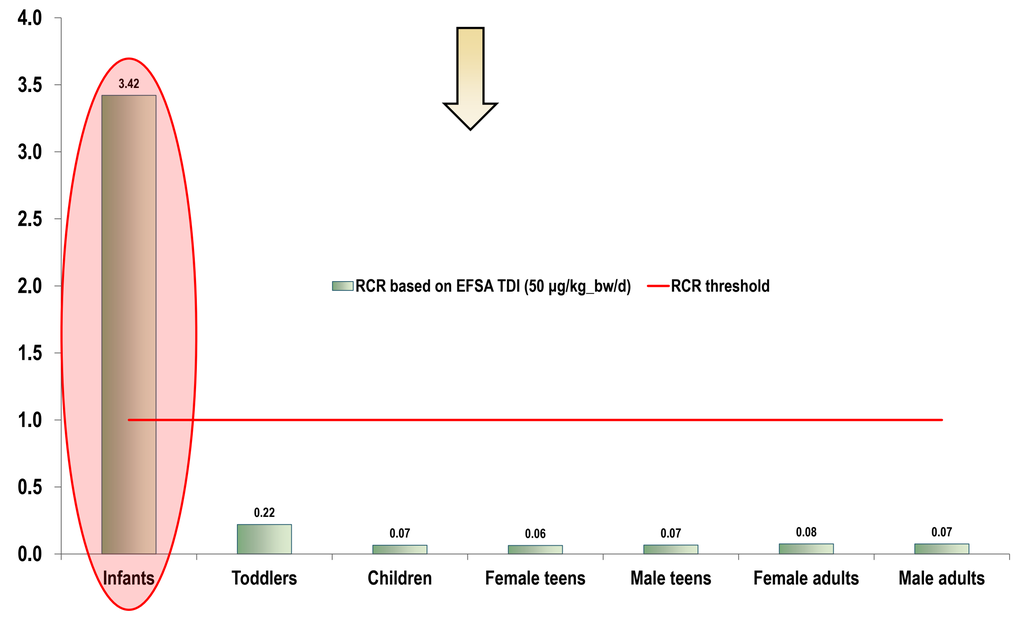
Results

The TAGS methodology was applied in three case studies comprising exposure to (a) BPA); (b) phthalates; and (c) pesticides. Here, we present first results of the application on BPA:
The assessment was initiated by identifying generic data on BPA overall production, toxicological information, preliminary information about biomonitoring data and definition of exposure scenarios (Tier 0).

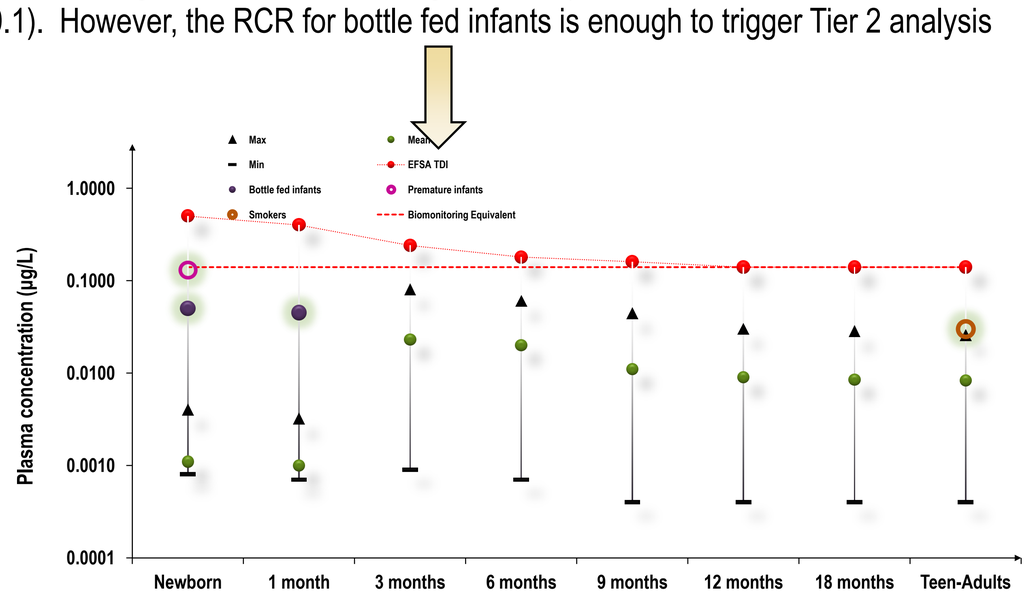
From the analysis, it was found that:

- Significant volumes of BPA are produced
- BPA exhibits toxicological activity at relatively low doses (endocrine disruption)
- BPA was found in biological matrices (urine, blood, umbilical cord)
- Recent findings indicated that humans are exposed to BPA through dermal (thermal paper of cash machines) and inhalation (cigarette filters contain BPA) on top of the conventional exposure through ingestion (tin cans and polycarbonate bottles)

The above reasons trigger a Tier 1 aggregate exposure assessment



Tier 1 assessment indicates that among all plausible exposure scenarios, bottle fed infants run an unacceptable risk due to very high concentrations identified in infant milk formula. Among the rest of age groups, toddler RCR is the highest (0.22), but significantly below 1. Combination of scenarios for adults (canned food, beverage drinks, working as a cashier and being a smoker) resulted once more in low RCR (>0.1). However, the RCR for bottle fed infants is enough to trigger Tier 2 analysis



Tier 2 analysis incorporates probabilistic analysis and pharmacokinetic considerations. RCR is now based on the Biomonitoring Equivalent **(BE)** concept, by estimating plasma concentration of an adult exposed to the EFSA TDI. Although in Tier 2 RCR is below 1 for all possible scenarios (and combinations), exposure scenarios "potentially of concern" include **premature infants hosted in incubators**, and to a smaller extent **bottle fed infants**, and **smoking adults.**