

Annex 8.10

<u>Methodology</u>	<u>Input data</u>	<u>Advantages</u>	<u>Disadvantages</u>
Worst case calculation single use, using conventional EU food consumption and cube model	(Residual) Content of substance in the FCM. Thickness of article (when deviating from 250µ) density of the polymer	Easy to use to calculate the EDI	Huge overestimation,
Worst case calculation whole life time (FDA approach)	(Residual) content of substance in the FCM. Weight of FCM in contact with food Number of uses over the life time	Easy to use to calculate the EDI, once the different parameters to fill in the equation are known.	Still overestimation, constant release rate of migrants over time, so no difference between first migration and last migration; calculated amounts might still be high in some cases.
Other Exposure assessments - Probabilistics, to consider if necessary			
Matrix approach	Approach based on: 1, (Residual) content of substance in the FCM. 2, Extraction figures 3, Real migration results	LOI = 100µg/dm ² ; meaning that in the analytical test, the migration limit might be set at 100µg/dm ² instead of 1,67 µg/dm ²	Matrix has been developed for packaging, polymers or combination of polymers might be different for repeated use applications; assumption (might be by expert judgement) no CMR substances
FDA approach	Tiered approach, start with 1 and then go down to the next step if needed. 1, (Residual) content of substance in the FCM. 2, Extraction figures	Worst case assumption: 1000g/inch ² (1inch ² =6,452cm ²), worst case calculations, extraction tests with best solvent at highest T for 10 days	Constant release of migrants over the use, so no difference between first migration and last migration Does not address CMR substances
Rubber approach	Appropriate criteria to develop for plastics	Will help to focuss on materials and articles that require to be risk assessed, as function of relevant parameters (to determine)	The approach still need to be developed Does not address CMR substances
Exposure modeling	(Residual) content of substance in the FCM. Repeated use scenario's (used/not used cycles) Number of uses over the life time Partition coefficients Diffusion coefficient	Still overestimation, so still room for refinement with real migration data	Need the right parameters for the modeling Expert knowledg needed to run the modeling tool
Probabilistic Approach	Tiered approach, start with 1 and then go down to the next steps if needed. 1, (Residual) content of substance in the FCM. 2, Extraction figures 3, Real migration results Food intake knowledge (food consumption survey)	Allow to derive more realistic exposure secenario	Appropriate only for articles in contact with specific food Require probabilistic exposure models and expert knowledge to run the modelling tool