RISK TO HUMAN HEALTH RELATED TO THE PRESENCE OF PFAS IN FOOD (EFSA 2020)

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MANDATE & SELECTION OF PFASs

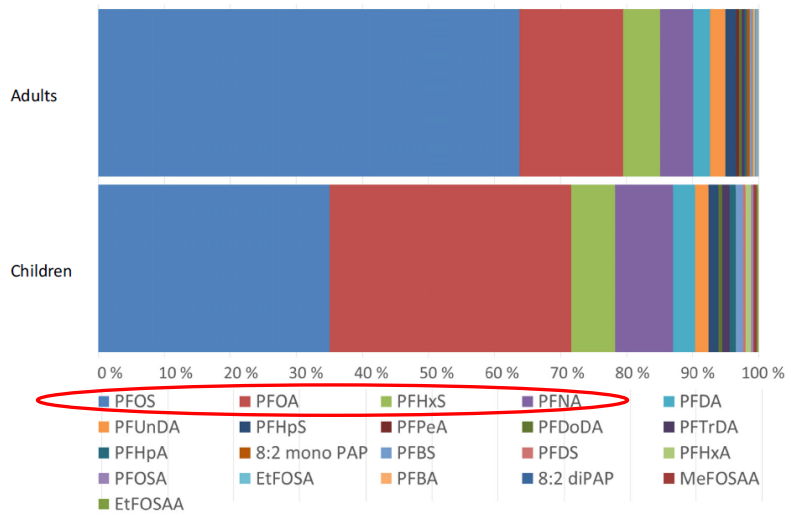
- ✓ September 2015 – EFSA received a request from the European Commission for a scientific opinion “on the risks to human health related to the presence of PFASs in food, considering existing hazard assessments and available occurrence data”.

- ✓ Due of the complexity and the large number of PFAS under evaluation, the mandate has being addressed in **two separate opinions**:
  - 1st opinion on PFOS and PFOA in food (EFSA-Q-2015-00526) – published Dec 2018
  - 2nd opinion on PFAS (incl. PFOS, PFOA) in food (EFSA-Q-2017-00549) – published Sept 2020

- ✓ **Selection of 27 PFAS** based on the 2012 PFAS exposure assessment (EFSA Journal. 2012; 10(6): 2743)
  - **14 PFCA** (PFBA, PFPEA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTeDA, PFPeDA, PFHxDA, PFODA)
  - **5 PFSA** (PFBSm PFHxS, PFHpS, PFOS, PFDS)
  - **8 “other” PFAS** (PFOSI, 8:2 FTOH, 8:2 monoPAP, 8:2 diPAP, FOSA, EtFOSA, EtFOSE, FC-807)

RISK ASSESSMENT APPROACH

- ✓ The CONTAM Panel decided for a pragmatic approach: **mixture approach restricted to 4 most abundant PFASs in human serum** (PFOA, PFNA, PFHxS, PFOS)
- ✓ Similar effects in animals and toxicokinetics
- ✓ **Effects on immune system** considered critical for assessment
- ✓ 4 studies showed inverse associations with antibody response following booster vaccination to tetanus and diphtheria



- ✓ Critical study (Abraham et al., 2020):
  - reverse association between antibody response (HIB, tetanus, diphtheria) in breastfed infants and PFAS
  - **$BMDL_{10}$ of 17.5 ng/mL** (sum of 4 PFASs)*
  - corresponds to serum level of **6.9 ng/mL** in 35 year old **mothers**
  - corresponds to long term maternal exposure of **0.63 ng/kg bw/day**
  - → **Group TWI**: 7 days x 0.63 = **4.4 ng/kg bw per week (for the sum of PFOA, PFNA, PFHxS and PFOS)**

* Data did not allow the derivation of potency factors; the CONTAM Panel assumed by default equal potencies for effects of these four PFASs on immune outcomes

EXPOSURE ASSESSMENT

- ✓ High proportion of occurrence data submitted to EFSA was <LOD/LOQ, left censored (>90%), exposure assessment limited to 17 PFAS
- ✓ Exposure assessments for single PFAS and for the sum of 4 PFAS are highly uncertain
- ✓ Exposure estimates for the Sum of 4 PFAS (PFOA, PFNA, PFHxS and PFOS):

Age group	Range of mean dietary exposure (LB-UB) (ng/kg bw per week)					
	Mean LB dietary exposure			Mean UB dietary exposure		
	Minimum	Median	Maximum	Minimum	Median	Maximum
Infants	*17*	*34*	*85*	*299*	*500*	*802*
Toddlers	10	21	46	428	519	785
Other children	6	11	21	270	373	572
Adolescents	3	6	11	144	185	290
Adults	4	6	9	95	112	154
Elderly	5	6	15	81	105	131
Very elderly	3	6	22	88	108	139
	Range of 95th percentile dietary exposure (LB-UB) (ng/kg bw per week)					
Age group	95th percentile LB dietary exposure			95th percentile UB dietary exposure		
	Minimum	Median	Maximum	Minimum	Median	Maximum
Infants	*32*	*96*	*195*	*649*	*856*	*1574*
Toddlers	23	53	96	705	938	1603
Children	19	29	68	553	763	1157
Adolescents	9	15	37	309	399	626
Adults	9	16	35	184	229	439
Elderly	12	17	39	161	201	327
Very elderly	9	16	70	153	198	294

Large difference UB and LB exposure: less trust in UB

CONCLUSIONS AND RECOMMENDATIONS

Main conclusions

- ✓ The **Group TWI of 4.4 ng/kg bw per week** (for the sum of PFOA, PFNA, PFHxS, PFOS) is protective for the other potential critical endpoints (increase in serum cholesterol, reduced birth weight, and high serum levels of ALT) considered in the previous Opinion on PFOS and PFOA (EFSA, 2018).
- ✓ Available biomonitoring data suggest exceedance of critical serum levels by large part of the population.
- ✓ This is supported by the exposure assessment, showing exceedance of the TWI, also when using LB data.
- ✓ Exceedances of the TWI at LB exposure estimates indicate a health concern.

Recommendations

Among others,

- Approaches for ~~a~~ derivation of potency factors for PFAS highly needed.
- Exposure assessment needs to be updated (whenever better occurrence data are available obtained with more sensitive analytical methods).