

Background to the request

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2008 - EFSA CONTAM PANEL Opinion on PFOS & PFOA

- In 2008, the EFSA Panel on Contaminants in the Food chain (CONTAM) published a risk assessment on PFOS, PFOA and their salts.
- Tolerable Daily Intake (TDI) established, based on experimental animal data:
 - for PFOS - 150 ng/kg bw per day
 - for PFOA - 1.5 µg/kg bw per day
- Only a limited exposure assessment was possible due to a lack of occurrence data in food
- **The CONTAM Panel concluded that it is unlikely that adverse effects of PFOS or PFOA are occurring in the general population.**
- The CONTAM Panel recommended, however, further monitoring of PFASs in food.

2010 - Commission Recommendation 2010/161/EC

- Following the 2008 CONTAM Panel opinion, in 2010 the European Commission adopted Commission Recommendation 2010/161/EC on the monitoring of PFASs in food.
- Limit of quantification (LOQ) of 1 µg/kg for the monitoring of PFAS in food was recommended.
- Monitoring data following this recommendation are being collected by EFSA.



2012 - EFSA Scientific Report on PFASs in food – Occurrence & Dietary Exposure

- The occurrence data generated by the monitoring under Commission Recommendation 2010/161/EC, have been used in the EFSA Scientific Report on PFASs in food - occurrence and dietary exposure, published in 2012.
- Report included data on 27 PFASs from 13 European countries during the period 2006-2012.
- Dietary exposure estimates:
 - For PFOS <3.5 % of the TDI for average consumers and <6.7% of the TDI in high consumers.
 - For PFOA <0.3 % of the TDI for average consumers and <0.5% of the TDI in high consumers.
 - Exposure in toddlers was 2 -3 times higher compared to adults.
 - In the low ng/kg body weight (bw) range for the other PFASs.

2012 report confirmed that dietary exposure to PFOS & PFOA is highly unlikely to exceed the health-based guidance values established by EFSA.

- 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*”.
- A CONTAM Panel Working Group (WG) was established to develop the draft opinion. The WG initiated its activities in March 2016.
- Due of the complexity and the large number of PFASs under evaluation, the mandate is being addressed in two separate opinions:
 - 1st opinion on perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) in food (EFSA-Q-2015-00526) – [published in 2018](#)
 - 2nd opinion on perfluoroalkyl substances (PFASs) in food (EFSA-Q-2017-00549) – [Draft opinion under public consultation \(24 March -20 April 2020\)](#)

Health based guidance values (HBGV) derivation based on human epidemiological data

- PFOS - critical effects
 - Increase of serum total cholesterol
 - Decrease in antibody response at vaccination (children)
- PFOA - critical effect
 - Increase in serum total cholesterol
- Benchmark dose modelling of serum levels of PFOS and PFOA and estimations of the corresponding daily intakes (using PBPK modelling) were performed.
- The CONTAM Panel established tolerable weekly intakes (TWIs) for both PFOS and PFOA within the low ng/kg bw per week range
 - **13** ng/kg bw per week for PFOS (*corresponding serum levels of 21 – 26 ng/mL*)
 - **6** ng/kg bw per week for PFOA (*corresponding serum levels of 9.2 – 9.4 ng/mL*)

Explanatory note:

*"Due to the nature of the **scientific uncertainties** described in this opinion and in the minutes of the expert meeting of 24 September 2018 (EFSA/CONTAM/3503) and **the possible application of the forthcoming Scientific Committee guidance on combined exposure to multiple chemicals**, the conclusions of this assessment will be reviewed in parallel with the finalisation of the EFSA scientific opinion on "The risks to human health related to the presence in food of PFASs other than PFOS and PFOA" (EFSA-Q-2017-00549). The indicative timeline for this is December 2019. Until such time, the conclusions and derived tolerable weekly intakes shall be considered provisional."*

The details from this 2nd assessment, which considers the **27 PFASs** previously covered in the EFSA 2012 Scientific Report, including PFOS and PFOA, will be given in the four presentations that follow.

27 PFASs considered in this opinion:

- Perfluoroalkyl carboxylic acids (PFCAs)

PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnDA, PFDoDA, PFTTrDA, PFTTeDA, PFPeDA, PFHxDA, PFODA

- Perfluoroalkyl sulfonic acids (PFSAs)

PFBS, PFHxS, PFHpS, PFOS, PFDS

- Other PFASs

PFOSI, 8:2 FTOH, 8:2 monoPAP, 8:2 diPAP, FOSA, EtFOSA, EtFOSE, FC-807



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