

Migration of APFO from PTFE

It was decided to develop a new method of extraction of APFO from PTFE samples (extraction during 8 h at reflux with 95 % ethanol at pH = 10 on finely ground material) as well as a new method of detection of APFO using capillary gas chromatography. This method allows the detection down to 1 µg, which corresponds to a detection limit of 10 ppb in the polymeric sample.

The methods of extraction and titration are described in detail in attachments I and II.

It was then decided to determine the residual APFO in five samples produced by the four manufacturers of the common interest group. The samples were chosen in such a way that the worst case situation is covered (maximum initial content of APFO, softest post treatment in terms of temperature, time, washing etc., ensuring the potentially highest residue).

The five samples were tested by three different companies to make sure that the developed methods are sufficiently robust. The results are summarised in the attached table I.

The table shows clearly that the highest residual amount found was 30 ppb.

Using the convention of 6 dm² in contact with 1 kg of food and considering a maximum wall thickness of 6 mm, the amount of PTFE in contact with 1 kg of food becomes

$$60 \text{ cm} \times 10 \text{ cm} \times 0,6 \text{ cm} \times 2,16 \text{ g/cm}^3 = 777,6 \text{ g}$$

The residue of APFO in this material is

$$30 \text{ ppb or } 30 \cdot 10^{-9} \times 777,6 = 23328 \cdot 10^{-9} \text{ g or } 23328 \cdot 10^{-6} \text{ mg or } 0,023328 \text{ mg}$$

Assuming a 100 % migration, which is probably a large overestimation for a 6 mm thick sample, we see that the migration would be around 0,025 mg/kg food or 25 ppb.

In other words, the maximum potential migration in food simulant is 0,025 mg/kg, which is twice below the limit set for a reduced technical dossier.

Table 1

Samples	APFO residues in ppb as determined by company		
	A	B	C
1	15 - 30	10 - 20	< 10
2	23	10 - 19	< 10
3	29	11 - 12	< 10
4	31	16 - 20	< 10
5	31	9 - 14	< 10