



FoodDrinkEurope feedback

30 July 2021

We would like to share with you a few, general comments on the current drafts under discussion regarding perfluorinated substances (PFAS) in food:

- 1) Draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards maximum levels of perfluoroalkylated substances in certain foodstuffs;
Annex of the Commission Regulation draft amending Regulation (EC) No 1881/2006 as regards maximum levels of perfluoroalkylated substances in certain foodstuffs.
- 2) Commission recommendation on the monitoring of perfluoroalkylated substances in food and feed

We hope that the fact of providing feedback at this stage is acceptable to you and that our contribution could be considered. We remain at your disposal should you need additional information or clarification.

1) Draft Commission Regulation on maximum levels (MLs) of PFAS in certain foodstuffs

Overall comments

Foremost, we fully agree that consumers should be protected from unsafe levels of chemical compounds such as PFAS. To achieve both a proportionate and a workable regulatory proposal for PFAS, we would like to question the following:

- The need to set MLs for PFAS in all mentioned foodstuffs (eggs, all kind of fish, crustaceans, bivalve molluscs, all kind of meat, offal and milk) given that “higher” PFAS levels in food are mainly resulting from specific “hot spots” and that the analytical results for many samples are “left-censored”
- The need to extrapolate data from one commodity to others of the same group where there is a wide variation within (e.g., group of livestock animals; group of game animals; group of vegetables) and between crustaceans and molluscs. We think that MLs should only be set for those products from those commodities where enough analytical data are available, and the results show higher levels of PFAS, instead of setting MLs for the whole group.
- The need to set MLs for the 4 single PFAS. If the sum of 4 PFAS represents the stricter ML, it is not necessary to also set MLs for the 4 single PFAS. In the draft under discussion the sum of these 4 PFAS is often lower than the sum of the MLs of the single PFAS.

Moving forward, we think that for certain commodities where there are clear gaps, more knowledge needs to be generated through data collection and refining of the analytical methods before setting MLs .

In addition, the commodities for which MLs are proposed are not only consumed as such, but are also processed and are ingredients for composite products. Some of those end-products have long shelf lives, e.g., canned fish or soups up to 3 years. The draft text of the Regulation foresees a transitional period of 1 year after the entry into force of the Regulation. In consideration of preserved products with longer shelf lives, we believe that foodstuffs lawfully placed on the market prior to the entry into force of the Regulation should remain on the market after that date until their date of minimum durability or use-by date. Appropriate transitional periods contribute to sustainable food systems and reduce food waste, one of the ambitions of the Farm to Fork Strategy.

Comments on specific categories

Fish and crustaceans

The ML proposal should be restricted to freshwater fish in first place. The ML proposed for crustaceans should not be extrapolated to bivalve molluscs, given the low levels of PFAS in bivalve molluscs.

Meat

The ML proposal for bovine meat should not be extrapolated to meat from other livestock animals given the low levels of PFAS in pig meat and poultry meat. We think that the setting a ML for pig meat and poultry meat is not justified based on the occurrence data. Similarly, the ML proposal for meat from game animals should be restricted to boar.

More analytical data for a given product from a given animal are necessary to have a more representative picture before setting MLs. Thus, we believe that these products should be taken up in the new/updated monitoring recommendation instead.

Milk

Milk is listed as one of the foodstuffs where MLs would be established, and a level of 0.15 µg/kg for the sum of PFOS, PFOA, PFNA and PFHxS is being proposed. Given the low levels of PFAS which are found in liquid milk, we think that a ML should not be set. Although more time is needed to analyse in detail the implications of the newly proposed ML for milk, we would like to raise to the Commission's attention several concerns:

- Sensitivity of analytical methods is a bottleneck (as also mentioned in recital (6) of the draft Regulation)

- In the EFSA opinion of September 2020¹ milk was not identified as a product that contributes significantly to exposure to PFAS. We therefore wonder why 'milk' is put forward as a foodstuff where MLs are set.
- The Federal Institute for Risk Assessment (BfR)² has recently issued the "Opinion PFAS in Food: BfR confirms critical exposure to industrial chemicals" and emphasised that milk and dairy products contribute only slightly to the exposure to PFAs.
- Incidentally and regionally elevated levels of PFAS in the environment may reflect in the products at farm level. Despite some regional variations, average levels in liquid milk (and with that long term exposure for the consumer) are way below the proposed ML. Dairy products are considered safe based on the tolerable weekly intake of PFAS set by EFSA and thus a ML may not be justified.
- The influence of a farmer's production on PFAS levels in his products is very limited. Taking away the source of PFAS in the environment is the only way to prevent the consumer on the long term for safety risks.
- Hence, a ML for foods including liquid milk can only be applied when levels are adequately controlled in the environment.

Detailed comments on the analytical issues for milk:

- The tests for PFAS are difficult, cost-intensive and cannot be implemented in practice on the basis of the required analytical feasibility.
- The state of Lower Saxony (LAVES; the Lower Saxony State Office for Consumer Protection and Food Safety) examined 219 raw milk samples from the National Residue Control Plan (from all over Lower Saxony) in 2019, in addition to some raw milk samples from a risk area. Please find attached the report „Ergebnisbericht – Monitoring auf PFAS in Niedersachsen und Bremen“ (<https://www.laves.niedersachsen.de/download/154493>). On page 9 table 4.2.1 of the report the results of the 219 raw milk samples are shown.
- The PFOS measurement results from the areas without a corresponding risk background were between 0.01 and 0.044 µg/kg milk, with an average value of 0.022 µg/kg milk and thus above the EU proposal of 0.020 µg/kg milk. The 90th percentile was 0.019 µg/kg, i.e. 10% of the samples are above the planned limit of 0.020 µg/kg. This contradicts the EU approach of deriving the limit value on the basis of the 95th percentile.
- When looking at the measured PFOA concentrations compared to the ML proposed in the draft Commission Regulation, the discrepancy becomes even greater: The median (upper bound) is 0.010 µg/kg milk, i.e. 50% of the samples are above the planned limit value of 0.010 µg/kg.
- Furthermore, we would like to point out that levels in the food must also be safely determined and controlled by the manufacturers. The feedback from practice, however, shows that the commercial laboratories have a limit of detection of only 0.5 µg/kg product. This is above the

¹ Risk to human health related to the presence of perfluoroalkyl substances in food:
<https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6223>

² Opinion PFAS in Food: BfR confirms critical exposure to industrial chemicals
https://www.bfr.bund.de/en/press_information/2021/28/pfas_industrial_chemicals__some_population_groups_sometimes_exceed_the_health_based_guidance_value-277959.html

future ML of 0.020 µg/kg for PFOS and 0.010 µg/kg for PFOA. Thus, manufacturers are not in a position to test the milk for compliance against the proposed MLs.

- When looking at the required LOQs in the draft Commission recommendation on the monitoring of PFAs we see that for PFOA the LOQ is at the ML proposed. This approach does not allow the correct measurement. It is mentioned that LOQ should **be below or at...** So what is the target LOQ then if the LOQ should be **“below or at...”**?

LOQ milk	Proposed ML for milk
0.010 µg/kg for PFOA	0,010 µg/kg for PFOA

- The investment in the complex analysis amounts to approx. 500,000 € for such a special device (HPLC with high-resolution mass spectrometer). Only large research/investigation institutions could afford this. The investment is likely to be passed on through increased examination costs, with the result that the costs of currently about 200 € per analysis will increase even further.
- As part of the Lower Saxony raw milk monitoring, about 20 staple tank samples are examined for PFOS, PFOA, PFHxS and PFNA every six months. All samples were below the limit of determination of 0.5 µg/kg.
- PFOS are ubiquitous (including in plastics installed in the analytical instruments) and laboratories already have problems with the blank value. We also ask you to take these analysis difficulties into account when defining boundary and analytical requirements.
- LAVES also summarizes: "In the vast majority of the milk test results, the measured parameters were below the determination limit for the respective compound. Model calculations were carried out for a health assessment. Accordingly, the milk examined has no harmful exposure to perfluorinated alkyl substances (PFAS)."
- This also raises the question for us if a ML for milk, which must be controlled and evaluated, results into a benefit for safety or health.

Eggs

We would also like to question if a number of less than 300 egg samples is representative for the EU and already allows the setting of a legally binding ML.

2) Commission recommendation on the monitoring of PFAS in food and feed

We support a revision of the monitoring recommendation on PFAS. We would like, however, to raise concerns on working with target LOQs.

- Firstly, sufficient sensitive analytical methods must be developed and established before a monitoring can be started. Difficulties in the implementation will be encountered if only an EU-RL or some official laboratories are able to reach the target LOQs. For food business operators to

participate in the monitoring, sufficient laboratory capacity must also be available in private laboratories.

- In regard to the target LOQs, we would like to question the setting of indicative levels (ILs) and the respective time point. ILs are often considered by some parties as MLs, and therefore the widespread control of indicative values needs to be achievable in routine analysis. When ILs are exceeded, food business operators must take corrective measures, namely, to identify and to mitigate the contamination if possible.
- Given that very low levels have been proposed as ILs (see below), we believe that they might represent more a background contamination. In the case of environmental contaminants like for PFAS, it is often not possible for food business operators to reduce background contamination.
- Thus, we would strongly recommend not to set ILs at this early stage of the monitoring recommendation, but to wait to gather sufficient analytical results for those commodities first.

Indicative levels

The proposed ILs for 4 PFAS (PFOS, PFOA, PFNA and PFHxS) are too low and not feasible today by any reference laboratory from 0.001 to < 0.500 µg/kg. We therefore question the reason for such low ILs proposed, but particularly the fact that ILs shall be set at this stage.

The aim of a monitoring recommendation would be to collect data to get enough data to derive measures afterwards if necessary. ILs are such measures that can be introduced once the data monitoring exercise has collected enough information to derive additional measures.

Analytical methods

The Commission needs to facilitate that an analytical protocol is shared with industry and private labs and that interlaboratory comparison tests are organized including different stakeholders

- No internationally recognized methods for food analysis do exist today (ISO, CEN, Codex, AOAC)
- Only one for water analysis exists, and limited to 2 PFAS at LOQs 0.002 and 0.010 µg/L (ISO 25101)

The recommended instrumental approach is currently neither realistic nor achievable. As stated by the EFSA Opinion in 2018³, *"Methods with best sensitivity and quality control involve stable isotope dilution mass spectrometry (LC-MS/MS)"*. Thus, expensive instrumentation and skilled operators are required, making such analysis not affordable by all operators. As indicated earlier, PFAS are ubiquitous and known to cross contaminate the laboratory environment as well (reagents, solvents, parts of instrumentation) leading to additional constraints and costs for the analysis.

- The difference between the IL for PFHxS compared to the required LOQ has to be checked:
- **IL:** 0.007 µg/kg for PFOS, 0.006 µg/kg for PFOA, 0.002 µg/kg for PFNA and 0.0014 µg/kg for PFHxS in fruits, vegetables, starchy roots and tubers, food for infants and young children sold as ready to eat.

³ Risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food (EFSA 13 December 2018): <https://www.efsa.europa.eu/en/efsajournal/pub/5194>

- **LOQ:** 0.002 µg/kg for PFOS, 0.001 µg/kg for PFOA, 0.001 µg/kg for PFNA and 0.004 µg/kg for PFHxS in fruits, vegetables, starchy roots and tubers and food for infants and young children

For infant products, it is not clear from the text whether the target LOQs are for the dry product (as sold) or as consumed (ready-to-eat).

Summary:

From the draft proposals being put forward, we question the setting of MLs for certain commodities for which more data needs to be collected and the gaps in analytical methods are acknowledged.

We see that one of the key issues is absence of standardised analytical methods. Therefore we would highlight the inherent analytical uncertainties in the draft proposals (no standardized method to meet low LOQs, MLs and the premature ILs proposed).

Considering that PFAS are environmental contaminants, it is often not possible for food business operators to reduce background contamination. Thus, we would strongly recommend not to set ILs at this early stage of the monitoring recommendation, but to wait to gather sufficient analytical results for those commodities first.

FoodDrinkEurope and its members looks forward to continuing contributing with the Commission and Member States to find proportionate regulatory measures for the diverse food categories.