

Document 6



Ms. Sandra Gallina
Director General
DG SANTE
European Commission
Rue de la Loi 200
1049 Brussels
Belgium

Brussels, 10 November 2020

Re: Comments on the European Food Safety Authority (EFSA) lowering tolerable weekly intake (TWI) for certain PFAS substances

Dear Ms. Gallina,

We are writing to you to share 3M's serious concern about (1) the EFSA opinion on the "risks to human health related to the presence of perfluoroalkyl substances in food", as adopted on 9 July and published in September 2020, and (2) the possibly very damaging consequences that such an opinion may have on a variety of key European activities and products, if risk management measures are adopted solely on the basis of this opinion, as described below.

We therefore urge the European Commission to consider the EFSA opinion as provisional to prevent the adoption of unwarranted and disproportionate risk management measures at the European or national level as a result of this opinion.

(1) The TWI established by EFSA is highly questionable and should only be considered, at best, as provisional

In its opinion, EFSA has established a new TWI of 4.4 nanograms (ng) per kilogram (kg) body weight for four PFAS (PFOA, PFOS, PFHxS, and PFNA). This TWI was solely based on observations from a small cross-sectional epidemiological study by Abraham et al. (Archives of Toxicology 2020) based on 101 health infants (< 1 yr of age) showing a statistical association of PFOA with reduced antibody levels to three vaccine antigens. No significant reductions in these antibody levels were observed for the individual analyses of PFOS, PFNA, and PFHxS. There was no increased risk of infections reported in these infants. In their analyses EFSA combined the four perfluoroalkyls in this study to arrive at their overall association with reduced antibody levels. This is problematic since this type of studies can only report statistical associations and cannot establish a cause-and-effect relationship due to their inherent design. Reference values derived from them are therefore highly questionable.



The new TWI is also highly questionable considering that available laboratory animal data on the PFOS and PFOA immunotoxicity studies cited by EFSA have not demonstrated concordance, and the immune-related data for PFHxS and PFNA are even more limited. In addition, the collective epidemiologic data cited by EFSA do not suggest an increased propensity for infection with exposure to PFOS or PFOA in humans. Given that EFSA has acknowledged that "a clear mode of action of immunotoxicity by PFOS and PFOA has not been established", it remains uncertain how these data points can serve as a foundation for a new TWI.

We also note that, in 2018, EFSA had established a TWI in a preliminary opinion on PFOA and PFOS mainly based on an increase in serum total cholesterol also observed in cross-sectional epidemiological studies. This preliminary opinion was noticeably questioned by the German federal Institute for Risk Assessment (BfR) and the Dutch national Institute for Public Health and the Environment (RIVM).^{1 2} In its new 2020 opinion, EFSA has considered the uncertainty between cholesterol and PFOS and PFOA levels to be much larger than originally thought in 2018, and thus EFSA abandoned that endpoint, which shows the need for caution in basing a TWI on such epidemiological studies.

In view of the above, the TWI proposed by EFSA should only be considered, at best, as provisional.

(2) The new TWI established by EFSA is not suitable to justify new risk management measures

3M is also seriously concerned that the European Commission or authorities in the Member States at the federal, national, regional or local level may take premature and damaging risk management measures on the basis of this new EFSA opinion.

This EFSA opinion responds to a request from the European Commission "for a scientific evaluation on the risks to human health related to the presence of perfluoroalkyl substances (PFASs) in food".

However, the assessment was made on the sum of only four PFASs: PFOA, PFNA, PFHxS and PFOS and therefore one cannot extrapolate this EFSA opinion for other PFAS. This should be clarified by the European Commission to avoid misinterpretations.

¹ BfR, August 2019, Neue gesundheitsbezogene Richtwerte für die Industriechemikalien PFOS und PFOA. Available on: <https://www.bfr.bund.de/cm/343/neue-gesundheitsbezogene-richtwerte-fuer-die-industrie-chemikalien-pfos-und-pfoa.pdf>
² EFSA CONTAM Panel, December 2018, Minutes of the expert meeting on perfluorooctane sulfonic acid and perfluorooctanoic acid in food assessment. Available on: https://www.efsa.europa.eu/sites/default/files/efsa_contam_2018.pdf



Also, with a TWI of 4.4 nanograms (ng) per kilogram (kg) body weight, guidance values derived from such TWI would be so low, in particular if applicable to the four substances, that there are no analytical methods available to measure such low levels in drinking water, foodstuffs, or food contact materials. This means that if this TWI is used as a basis to elaborate mandatory limits in drinking water or in foodstuffs, companies and other actors in the food and drinking water supply chain will not be able to ensure or demonstrate compliance with such limits.

Therefore, the supply of any food or water within the countries or regions where such limits would be established would become illegal under EU law and these products could no longer be placed on the EU market. Such limits would also dramatically and disproportionately impact soil remediation efforts and water quality and emission standards.

In view of the above, 3M urges the European Commission to put the EFSA opinion into perspective to prevent the adoption of unwarranted and disproportionate risk management measure at the European or national level from being taken.

3M shares the objective of the European Commission to protect human health and the environment. At the same time, risk management measures must remain proportionate to the risks involved and must be based on an appropriate assessment of all facts and circumstances, particularly in cases where there remain significant uncertainties. This is critical for ensuring that stakeholders are fully able to comply with EU law.

We thank you for your attention to this important matter and would welcome the possibility to discuss with you and your team the above and contribute our scientific expertise on PFAS to help meet the Commission's objectives. In this respect, we would appreciate you direct us towards the members of your team who are leading on this matter.

Yours sincerely,

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