**Question Reference:** PQ 48711/21

**For Answer:** 6 October 2021

**Question Received From:** Damien Ward, DAFM

**Question Submitted By:** Matt Carthy TD

**Question:** "To ask the Minister for Agriculture; Food and the Marine if he has considered a ban on polyfluorinated alkyl substances in food packaging; and if he will make a statement on the matter"

**FSAI Response:**

**FSAI:**

Background

Perfluoroalkylated substances (PFAS) is the collective name for a very large group of fluorinated compounds with high thermal, chemical and biological inertness. PFAS have been widely used in industrial and consumer applications including oil- and water-resistant coatings, grease proof treatments for paper, fire-fighting foams, mining and oil well surfactants, floor polishes, and insecticide formulations.

Legislation

Restrictions on the use of PFAS are being considered across a number of pieces of legislation in the EU. In Ireland, multiple agencies and departments are involved in EU discussions on these measures, including the Department of Enterprise, Trade and Employment, the Health and Safety Authority, the Food Safety Authority of Ireland, and the Environmental Protection Agency. The EU is formulating a plan to phase out the use of PFAS by 2030 as part of its [Sustainable Chemicals Strategy](https://www.consilium.europa.eu/media/48827/st06941-en21.pdf) of the Union, though it has not yet been adopted as a binding measure. The objective of the European Commission under the [Chemicals Strategy for Sustainability](https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf) is to ban all PFAS, unless the EU deems their use essential. Since 2009, perfluorooctane sulfonic acid and its derivatives (PFOS) have been included in the international [Stockholm Convention](http://www.pops.int/TheConvention/ThePOPs/AllPOPs/tabid/2509/Default.aspx) to eliminate their use. In addition, the Stockholm Convention regulates the global elimination of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds. PFOA has been banned under the Regulation on persistent organic pollutants (POPs) since 4 July 2020. Perfluorohexane sulfonic acid (PFHxS), its salts and related compounds as well as perfluorinated carboxylic acids (C9-14 PFASs) are being considered for inclusion in the Stockholm Convention and consequent global elimination. Perfluorinated carboxylic acids (C9-14 PFASs), their salts and precursors will be restricted in the EU/EEA from February 2023 onwards following a decision taken by the European Commission on the REACH Regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals). Discussions are ongoing at EU level with regards to monitoring and restrictions on PFAS in food and food contact materials (FCMs) and the FSAI plays an active role in these discussions. In the meeting of the EU Working Group on FCMs held in June 2021, Denmark indicated that under [REACH](https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas), the Netherlands and Germany, with support from Norway, Denmark and Sweden are preparing a restriction proposal to cover a wide range of PFAS uses, in support of the statements made in the [Environment Council](https://data.consilium.europa.eu/doc/document/ST-15039-2019-INIT/en/pdf) in December 2019. It is anticipated that this proposal will be submitted to ECHA in July 2022 and will necessitate a review and amendment to the FCM legislation. These five countries currently employ a group definition of PFAS that would encompass approximately 4,700 substances.

In the EU, [Regulation (EC) No 1935/2004](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004R1935-20210327) as amended lays down general requirements for all materials and articles intended for contact with food. Article 3 of Regulation (EC) No 1935/2004 requires that materials and articles, including active and intelligent materials and articles, are manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: (a) endanger human health, or (b) bring about an unacceptable change in the composition of the food, or (c) bring about a deterioration in the organoleptic characteristics thereof.

Regulation [10/2011](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0010-20200923) as amended, on plastic materials and articles intended to come into contact with food contains a list of substances permitted for use in plastic FCMs, which includes several PFAS. Before substances are authorised for use in plastic FCMs, all substances require a risk assessment by the European Food Safety Authority (EFSA) to determine their safety, restrictions of use and other matters related to their safety, which manufacturers using them must comply with.

In Ireland, all EU legislation on FCMs is given effect by the [European Union (Plastics and other materials) (Contact with food) Regulations 2017](http://www.irishstatutebook.ie/eli/2017/si/49/made/en/pdf) (S.I. No. 49 of 2017) which was amended in [2018](http://www.irishstatutebook.ie/eli/2018/si/257/made/en/pdf) and [2019](http://www.irishstatutebook.ie/eli/2019/si/278/made/en/pdf).

Risk

In 2020, the European Food Safety Authority (EFSA) published its [Scientific Opinion](https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6223) which considered the risk from 27 PFAS in food. The assessment focussed on 4 PFASs (PFOA, PFOS, PFHxS and perfluorononanoic acid (PFNA)) as a group because they were found to have similar toxicological properties and contributed most to exposure. The EFSA considered decreased response of the immune system to vaccination to be the most critical human health effect. The EFSA noted that the health based guidance value (Tolerable Weekly Intake) established for this critical effect would also be protective for other adverse effects, including increased serum cholesterol, reduced birth weight and high serum levels of the liver enzyme alanine transaminase (ALT).

Concerning the risk from the migration of PFAS from FCMs into food and potential human exposure, as outlined in EFSA’s assessment, in the majority of cases high dietary contributors are foodstuffs of animal origin and commodities which would not typically be packaged in grease- or water- repellent FCMs. For the combined exposure to PFOA, PFNA, PFHxS and PFOS, the main contributing food categories were ‘Fish meat’, ‘Fruit and fruit products’ and ‘Eggs and egg products’, observed for all population groups. The EFSA did note that the use of PFAS-containing FCMs is likely to contribute to human exposure to PFAS, but that this may not be reported in the data. They explained that diet is the major source of PFAS exposure for most of the population, but on an individual basis, other routes such as dust ingestion and indoor air inhalation may also contribute substantially. The EFSA identified the transfer of PFAS from FCMs as an uncertainty and subsequently recommended that more studies focus on this area. The EFSA concluded that the assessment identified exceedances of the health based guidance value which indicates a concern for human health.

**Additional Information:**

Insert any additional information here (including links / references to follow on questions)