



Notification of draft Order prohibiting the import and sale to consumers of clothing, footwear and waterproofing agents containing PFAS

Purpose

The draft *Order prohibiting the import and sale to consumers of clothing, footwear and waterproofing agents containing PFAS* (hereinafter the draft Order) is hereby notified with a view to limiting the pollution caused by the use of PFAS in clothing, footwear and waterproofing agents for consumers. The purpose of the Order is thus to promote the protection of the environment.

The desire to regulate PFAS nationally arose in particular following leakage from a fire-fighting school in Korsør, Denmark, where members of a cattle grazing association were exposed to high levels of PFOS by eating meat from cattle that had grazed on areas adjacent to a fire-fighting training area. Contaminants with high concentrations of PFOS have also been found at a number of other fire-fighting training areas.

For this reason, as of January 2024, Denmark introduced a prohibition on importing fire-fighting foam concentrate containing total PFAS in a concentration of more than 1 ppm (mg/kg) and intended for use at fire-fighting training areas. At the same time, it was prohibited to use fire-fighting foam concentrate containing total PFAS in a concentration of more than 1 ppm (mg/kg) at a fire-fighting training area. The Danish Ministry of Environment and Gender Equality has previously notified the European Commission of the Danish national provisions on fire-fighting foam concentrate. See TRIS Notification 2023/0390/DK or follow the link to TRIS: <https://technical-regulation-information-system.ec.europa.eu/en/notification/23962>. See also the attachment.

PFAS remains an issue of concern to the Danish government and the Danish population. The Danish government's platform from 2022 states that the government 'will work to ban PFAS substances at the EU level and take initiatives to limit their use in Denmark, just as the government will ensure reduced use of hazardous chemicals, including in consumer goods'.

On 13 January 2023, Denmark, the Netherlands, Germany, Sweden and Norway submitted to the European Chemicals Agency a draft (referred to below as the general PFAS restriction draft) for a comprehensive restriction on the use of PFAS¹. The purpose

¹ <https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49>

of the general PFAS restriction draft is to significantly reduce emissions of PFAS into the environment. Due to PFAS' high persistence, continued emissions and lack of appropriate remediation options, concentrations of PFAS are constantly and irreversibly increasing in the environment and will inevitably lead to adverse effects on human health and the environment. The general PFAS restriction draft is currently being assessed by ECHA's Scientific Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC).

In February 2024, the Ministry of Environment at that time published a mass flow analysis, *Substance flow analysis of PFASs in Denmark*². In the analysis, the consulting firm COWI examined the current import and use of PFAS in Denmark. Based on current knowledge, the analysis provides an overview of the largest sources of PFAS emissions and shows how PFAS is released into the environment in Denmark, including from its use in textiles.

In May 2024, the government published a PFAS action plan, which all parties in the Danish Parliament supported. The draft Order, which is now being notified, is an initiative under this action plan.

The draft Order introduces national provisions on restricting PFAS in clothing, footwear, and waterproofing agents for clothing and footwear for consumers, which fall within the scope of the general PFAS restriction draft, and the national provisions are repealed when the expected EU rules apply.

Content and purpose of the Order

The draft Order envisages restricting the import and sale to consumers of clothing, footwear and waterproofing agents containing PFAS. The ban on the import and sale to consumers of clothing, footwear, and waterproofing agents containing PFAS above a certain concentration is proposed in order to reduce the pollution released into the environment as a result of the use of PFAS.

It is considered that an environmental benefit can be achieved by a national ban, since approximately 40 per cent of all PFAS used and marketed are contained in textiles and waterproofing agents³. Clothing and footwear for consumers account for over 80 per cent of the textiles placed on the market⁴. On the basis of this information, the Ministry of Environment and Gender Equality has estimated that a temporary national ban on PFAS in clothing, footwear and waterproofing agents for consumers will limit emissions of PFAS to the environment in Denmark in the range of 200-300 tonnes per year, which corresponds to approximately 35-50 per cent of the estimated total emissions from the production and marketing of products.

The mass flow analysis⁵ finds that the largest contribution to PFAS emissions in Denmark from textiles comes from the use of polymers with PFAS side chains. The use

² <https://mim.dk/media/ae3o5ayj/substance-flow-analysis-of-pfas-20-feb.pdf>

³ Annex XV Restriction Report for Per- and polyfluoroalkyl substances (PFASs) (<https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49>)

⁴ MST, 2018, Mapping of the textile flow in Denmark (<https://www2.mst.dk/Udgiv/publikationer/2018/06/978-87-93710-32-0.pdf>)

⁵ <https://mim.dk/media/ae3o5ayj/substance-flow-analysis-of-pfas-20-feb.pdf>

of clothing and shoes is responsible for a discharge of 2.3 tonnes of PFAS per year, while waste treatment of clothing and shoes results in a discharge of approximately 380 tonnes of PFAS per year, of which approximately half is exported, whereby the discharge takes place outside Denmark

The Order is expected to enter into force on 1 July 2025. The ban on the import and sale itself will apply from 1 July 2026. If the covered goods are imported before 1 July 2026, the goods may continue to be sold until 1 January 2027.

The Order is issued on the basis of § 30(1) of the Chemicals Act (see BASIC). When deemed necessary to ensure that substances or mixtures do not endanger health or cause damage to the environment, the Minister may make a provision or lay down rules restricting or prohibiting the sale, import and use of certain substances or mixtures. Under the same conditions, the Minister may make a provision or lay down rules restricting or prohibiting the sale, import or use of substances or mixtures with specified properties. This may include requirements as to the purity of the substances and the concentration of the substances contained in a mixture.

The substances regulated by the draft Order are PFAS, which is a collective name for a large group of more than 10 000 synthetically produced fluorinated substances (per- and polyfluoroalkyl compounds). The use of the substances began in the 1950s. PFAS is used in many contexts, including goods such for consumers as clothing, footwear, and waterproofing agents. The substances are stable, poorly degradable and repellent to water and fat. In addition, most PFAS can accumulate in the food chain and/or are mobile in water, and both properties can lead to exposure of both humans and the environment.

Among other things, the PFAS that have been best studied are suspected of being carcinogenic and of having harmful effects on organs and the immune system. The substances can be measured at low blood concentrations on people all over the world and are found worldwide in the environment and in food.

Generally, reference is made to the assessment in the general PFAS restriction draft⁶, which concludes that the combination of identified hazard properties, possible hazard properties and poor degradability contributes to the overall concern. In addition, some PFAS can accumulate in the food chain, and some PFAS can be extremely mobile depending on the molecular structure. Overall, this gives rise to a concern similar to that of the so-called PBT/vPvB substances.

The definition provisions of the draft Order are formulated to correspond to the general PFAS restriction draft and existing EU chemicals legislation.

PFAS is defined as any substance containing at least one fully fluorinated methyl (CF₃) or methylene (CF₂) carbon atom, without any hydrogen, chlorine, bromine or iodine atoms attached to it.

The definition in the general PFAS restriction draft originates from OECD (2021), *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances*:

⁶ <https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49>

Recommendations and Practical Guidance, OECD Series on Risk Management, No 61, published by the OECD, Paris. See the link: <https://www.oecd-ilibrary.org/docserver/e458e796-en.pdf?expires=1723707315&id=id&accname=guest&checksum=54500D1DDD535C521159BDB53ABE653C>.

The definition of PFAS in the Order corresponds to the definition in the general PFAS restriction draft. As in the general PFAS restriction draft, specific molecular structures are exempted in the draft Order. These structures are found in pesticides and medicinal products and are therefore not relevant to the PFAS Order on clothing, footwear and waterproofing agents.

As in the general PFAS restriction draft, the term Article is defined by reference to Article 3(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended.

As in the general PFAS restriction draft, medical devices are defined by reference to Article 2(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance), as amended.

The scope and substantive provisions of the draft Order are formulated in order to correspond to the general PFAS restriction draft and thus fall within the forthcoming general PFAS restriction at EU level.

Ban on the import and sale: The draft Order contains a ban, applicable from 1 July 2026, on the import and sale of clothing, footwear and waterproofing agents for clothing and footwear, where these consumer products, as the final product, contain PFAS in concentrations greater than 50 mg F/kg.

Scope The ban applies to the import and sale to consumers for private use, including consumers' own imports, e.g. when shopping online. Production and exports are exempted. Reuse and recycling are also exempted, as it will not be possible to ensure that clothing, textiles, and fibres imported and sold before the prohibition applies do not contain PFAS in the recycling situation.

Product categories: The draft Order contains a ban on the import and sale of clothing, footwear, and waterproofing agents for clothing and footwear with PFAS to consumers for private use in Denmark. The product categories have been selected on the basis of the Ministry of Environment and Gender Equality's knowledge that these consumer categories result in significant emissions of PFAS, and thus a ban on them will have a significant environmental impact. At the same time, the Ministry of Environment and Gender Equality has also emphasised that it can be expected that alternatives to consumer uses are available on the market. For professional clothing in the form of

safety clothing, etc. it is not expected that alternatives will be available on the market sufficiently quickly. This type of clothing falls outside the scope of the Order.

Personal protective equipment intended to protect users against the risks specified in Regulation (EU) 2016/425, Annex I, risk category III (a) or (c), is exempted in the draft Order. At the same time, this exemption is contained in the general PFAS restriction draft. Personal protective equipment, where PFAS constitutes a safety function for the user, is also exempted.

Similarly, other textiles, such as home textiles, curtains, textiles in strollers, and accessories, are not included, as there is not the same knowledge about the availability of alternatives, costs, etc. At the same time, the consumption of textiles for clothing is assessed to be significantly larger and a larger source of PFAS in the environment and therefore more important to regulate in order to limit the total amount of PFAS in the environment.

PFAS in clothing, footwear and waterproofing agents, which are already regulated by either Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) or Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (recast), as amended, are also exempted from the draft Order.

Medical devices, as defined in Article 2(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, are exempted. Finally, transit cargo is exempted.

Threshold value: It is proposed that a threshold value be set so that the prohibition regulates PFAS in clothing, footwear, and waterproofing agents for clothing and footwear for consumers where PFAS has been deliberately used in order to achieve a function, such as water-repellent properties. In this way, it is expected that unintended contaminants from production processes will not lead to an exceeding of the threshold value. In choosing the threshold value, the Ministry of Environment and Gender Equality has emphasised that the vast majority of products within textiles for clothing, for example made water-repellent, contain much higher concentrations than 50 mg F/kg, and that concentrations below 50 mg F/kg can be considered unintentional trace contaminants.

At the same time, as mentioned above, the Ministry of Environment and Gender Equality has requested that the Danish draft Order be formulated to correspond to the general PFAS restriction draft. In this context, it is noted that a threshold value of 50 mg F/kg corresponds to one of the threshold values set out in the general PFAS restriction draft.

It is further assessed that the test method for measuring the fluorine content is cheaper for enterprises and control authorities than the method for measuring the sum of the individual measurable PFAS.

Documentary evidence: The general PFAS restriction draft provides that if the total fluorine content exceeds 50 mg F/kg, the manufacturer, importer or downstream user shall, upon request from enforcement authorities, provide evidence that the measured

fluorine content is PFAS or non-PFAS. An exemption clause is introduced in the draft Order from the ban on import and sale for clothing, footwear, and waterproofing agents for clothing and footwear to consumers if the importer or downstream user can demonstrate that the fluorine content comes from a substance that is not PFAS. The Ministry of Environment and Gender Equality has assessed that it would be appropriate to introduce a possible exemption similar to the general PFAS restriction draft, but which does not impose an obligation on the importer or downstream user, but rather provides an opportunity to present documentary evidence that a measured fluorine concentration above the threshold value is a result of the use of PFAS, as the draft Order, unlike the general PFAS restriction draft, only introduces one threshold value against which a measured concentration of fluorine must be compared.

The provision is issued on the basis of Section 38f of the Chemicals Act.

Transitional period: Having regard to trade and industry's global production chains from the design, ordering, production, and distribution sectors, a transitional measure of one year from the entry into force of the Order is introduced, so that the ban on sales and imports will apply from 1 July 2026. The sale of stocks of clothing, footwear and waterproofing agents is allowed until 1 January 2027 in order to facilitate the emptying of enterprises' stock products.

In addition, the Order implements an authorisation in § 45(1) and § 59(4) of the Chemicals Act. Thus, it is the Environmental Protection Agency which supervises compliance with the rules laid down in the Order. In exceptional cases, the Environmental Protection Agency may decide to derogate from the rules laid down in this Order and may impose conditions on the permit. These decisions are not subject to appeal. Since this is a specific assessment of when a particular case arises, it is thus not possible to give an example of situations which could be exempted from the ban.

Infringements of the prohibitions of the Order may be penalised by a fine and imprisonment, depending on the nature of the infringement.

Impact assessment in relation to harmonising EU regulation in the field of chemicals and in relation to the free movement of goods

Relationship with the REACH Regulation

The REACH Regulation regulates chemical substances, on their own, in mixtures and contained in articles. A Member State is not allowed to ban the manufacture, import, placing on the market or use, inter alia, of substances falling within the scope of the REACH Regulation which comply with the requirements of the Regulation, see Article 128(1) of the REACH Regulation. However, it also follows from Article 128(2) of the Regulation that Article 128(1) does not prevent the maintenance or establishment by the Member State of national rules relating, inter alia, to the protection of the environment if the REACH Regulation does not harmonise the requirements on manufacture, placing on the market or use.

On 14 July 2017, the EFTA Court ruled in a case brought by the EFTA Surveillance Authority (ESA) against Norway on the scope of the degree of harmonisation of the

restriction procedure in REACH⁷. Since the judgment was handed down by the EFTA Court, it is binding only on the three EEA countries (Norway, Iceland and Liechtenstein) which are not members of the EU, so the judgment would not change the legal situation in force with regard to imposing temporary national restrictions within the EU.

In response to the then Minister for Environment and Food of Denmark, Jakob Ellemann-Jensen, as to whether the Commission had changed its interpretation of the degree of harmonisation under the REACH Regulation following the decision of the EFTA Court, the Commission replied in a letter of 26 July 2018 that following the EFTA Court's ruling in case E-9/16, EU Member States may impose temporary national restrictions on a chemical substance, while a similar restriction is under consideration under the restriction procedure in the REACH Regulation. Member States may also introduce temporary national restrictions on a chemical substance for which the REACH restriction procedure has not yet been initiated, as long as the country concerned immediately initiates the restriction procedure by notifying its intention to draw up a corresponding proposal for restriction in the EU. These temporary national restrictions must be lifted immediately after the restriction procedure has been completed and any EU restriction applies and irrespective of whether the outcome of the EU process leads to EU restrictions or not.

In this context, it should also be noted that the groups of PFAS already regulated under REACH and Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (POPs Regulation) are not covered by the draft Order.

As described above, work is being done at the European Chemicals Agency (ECHA) on a proposal for a general restriction of PFAS in all applications. The general PFAS restriction draft provides for a transitional period of 18 months from entry into force. Work on the general PFAS restriction draft is estimated to continue until 2025 or beyond, after which the European Commission and EU Member States will have to decide on a PFAS use restriction.

With reference to the Commission's interpretation of the EFTA Court's ruling and the fact that ECHA is working on the general PFAS restriction draft via the restriction procedure in Article 69(1) of REACH, it will be possible to introduce a temporary national ban on the import and sale to consumers of clothing, footwear and waterproofing agents containing PFAS if the substance falls within the scope of the future EU regulation.

The Order shall be repealed when the expected EU rules apply.

Articles 34-36 TFEU - Free movement of goods

Temporary national restrictions must comply with the rules of the Treaty on the Functioning of the European Union (TFEU) on the free movement of goods, including Articles 34 and 35 on the prohibition of quantitative restrictions and measures having equivalent effect between Member States.

⁷ E-9/16 EFTA Surveillance Authority v Norway

The draft Order contains a ban on the import and sale of clothing and footwear to consumers, where at least one article included in the clothing or footwear contains a total of 50 mg F/kg or more. The draft Order contains a similar ban on waterproofing agents for consumers for use on clothing and footwear. The bans constitute an obstacle to trade within the meaning of the Treaty, as referred to in Articles 34 and 35 concerning the prohibition of quantitative restrictions and measures having equivalent effect between Member States.

An obstacle to trade, although contrary to Articles 34 or 35, may be considered lawful if the rules constituting an obstacle pursue an acceptable objective within the meaning of Article 36 of the Treaty. The principle of proportionality must also be observed. This means that the obstacle must be suitable to achieve the legitimate objective, while at the same time the rules must not go beyond what is necessary to achieve the objective.

The obstacle to trade may be justified by overriding reasons in the public interest. Since the objective of the ban is the protection of the environment, the obstacle to trade may be justified by the protection of the environment as the overriding reason in the public interest. See the background to the regulation in the content and purpose section.

The proposal for a general PFAS restriction and the Danish mass flow analysis's assessment of emissions, as described in the content and purpose section, mean that the proposed obstacle to trade is appropriate to achieve a legitimate objective.

The Ministry of Environment and Gender Equality also considers that the ban on the import and sale of clothing, footwear and waterproofing agents in the draft Order is proportionate. This is because the Danish government considers that there are technically and economically available alternatives to the use of PFAS in clothing, footwear, and waterproofing agents for consumers. This is confirmed by the proportionality considerations put forward in the general PFAS restriction draft.

As there are PFAS-free alternatives on the market for all product groups and price ranges, as well as high competition in the industry, costs are expected to be passed on to consumers only to a limited extent. Ordinary clothing such as snowsuits, raincoats, etc. is therefore not expected to increase in price. The alternatives have the same quality in terms of water repellency. The alternatives do not have the same fat-repellent properties as PFAS-containing clothing. However, it should be noted that there are product classes where there are fewer PFAS-free alternatives. It is estimated that a number of high-end outdoor brands, for example, do not have PFAS-free products on the market at the moment.

At the same time, it is considered that the rules laid down in the proposed Order do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. The draft Order lays down rules that apply to any marketing of clothing, footwear and waterproofing agents to consumers containing PFAS in certain concentrations, regardless of whether the product is marketed in Denmark, another EU country or imported from a third country.

Overall, the Ministry of Environment and Gender Equality considers that the draft Order's temporary national restrictions comply with the Treaty rules on the free

movement of goods, including Articles 34 and 35 on the prohibition of quantitative restrictions and measures having equivalent effect between Member States.

Impact on trade and industry

It is proposed to issue a new order banning the import and sale of PFAS in clothing, footwear, and waterproofing agents to consumers in Denmark.

Clothing and footwear

The economic costs of banning PFAS in clothing and footwear for consumers are estimated at DKK 30 million annually from 2025 until the EU prohibition applies. In total, additional costs correspond to 0.2 per cent of the value of Danish imports and production of the products covered. The costs are calculated on the basis of data from the trade association 'Dansk Mode og Textil'.

It is expected that enterprises which exclusively produce, import and sell shoes and outdoor clothing will be more affected than enterprises with a mixed product portfolio. The trade association for the European textile industry EURATEX states that the textile industry in the EU has a profit margin of approximately 30 per cent overall, and it is expected that the increased costs for enterprises can be kept within their profit margins.

Waterproofing agents

For waterproofing agents, the total economic costs are estimated to be DKK 1 million per year. This is an upper estimate. It should also be noted that the cost of producing waterproofing agents represents a relatively small part of the cost of the ready-to-sell product itself, with packaging being the largest cost.

Enforcement

Costs for the enforcement of the rules, amounting to approximately DKK 1 million per year from 2026 until the application of EU legislation, have been financed as part of the PFAS action plan. In this respect, it is noted that the costs for the enforcement will depend on the number of infringements.