

European Union



POP regulation

The Stockholm Convention on persistent organic pollutants are implemented in the EU by means of Regulation (EC) No 850/2004 (the 'POP Regulation').

- **PFOS:** since 2009, perfluorooctane sulfonic acid and its derivatives (PFOS) have been included in the Stockholm Convention to restrict their use. PFOS has then been restricted under [Annex I of the EU's Persistent Organic Pollutants \(POPs\) Regulation](#). [Annex I entry for PFOS](#) was amended in 2020 to remove exemptions no longer needed in the EU.
- **PFOA:** since 2019, perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds have been included in the Stockholm Convention to eliminate their use. PFOA has been banned under the [POPs Regulation since 4 July 2020](#).
- **PFHxS:** since 2022 perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds have been included in the Stockholm Convention to eliminate their use. Consequently, PFHxS will be restricted in the EU by the POPs regulation. Formal inclusion is planned in the first half of 2023.
- **LC-PFCAs:** in 2021 Canada proposed to consider long-chain perfluorocarboxylic acids (C9-C21 PFCAs) for inclusion in the Stockholm Convention.

REACH restrictions

The manufacture and use of several PFASs are being restricted under REACH.

There is an ongoing restriction proposal by Germany and Sweden for the following perfluorinated carboxylic acids (C9-14 PFCAs) including their salts and precursors:

- C9-14 PFCAs: Germany and Sweden submitted a restriction proposal for the following perfluorinated carboxylic acids (C9-14 PFCAs) including their salts and precursors:
 - perfluorononan-1-oic acid (PFNA);
 - nonadecafluorodecanoic acid (PFDA);
 - heneicosafuoroundecanoic acid (PFUnDA);
 - tricosafuorododecanoic acid (PFDoDA);
 - pentacosafuorotridecanoic acid (PFTrDA); and
 - heptacosafuorotetradecanoic acid (PFTDA).

ECHA's scientific committees have provided their [opinion on the proposal and supported the restriction](#). The European Commission [amended Annex XVII, entry 68](#), to REACH to restrict this group of substances.

- **TDFAs:** Denmark submitted a restriction proposal for a combination of perfluorinated silanes (TDFAs) and one or more organic solvents in sprays used for the general public. ECHA's scientific committees provided their [opinion on the proposal and supported the restriction](#). The European

Commission [amended Annex XVII, entry 73](#), to REACH to restrict this group of substances.

- PFHxS: Norway has submitted a restriction proposal for perfluorohexane-1-sulphonic acid (PFHxS), its salts and related substances. ECHA's scientific committees provided their [opinion on the proposal and supported the restriction](#) to prevent these substances being used as a regrettable substitute for PFOA. Since PFHxS is included in the Stockholm Convention, PFHxS its salts and related substances will not be included in Annex XVII of REACH (see POP regulation).
- PFHxA: German submitted a restriction proposal for undecafluorohexanoic acid (PFHxA), its salts and related substances. ECHA's scientific committees provided their [opinion on the proposal and partly supported the restriction](#). The European Commission is currently working on an amendment of Annex XVII to REACH to restrict this group of substances.
- PFAS as group (in firefighting foams): in 2020, ECHA announced its intention to prepare a restriction dossier for PFAS in firefighting foams - on request of the European Commission. ECHA's restriction proposal was submitted on 14 January 2022. [Opinion development is ongoing](#).
- PFAS as group (all other uses): since 2020, The Netherlands, Germany, 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 in December 2019. The countries submitted the restriction proposal to [ECHA](#) on 13 January 2023.

The up-to-date information on EU regulatory activities on PFAS (including links to relevant studies) is available on ECHA's webpage.

Substances of very high concern under REACH

A number of PFAS are on the REACH Candidate List of substances of very high concern (SVHC). They are listed in the table below. Some of these PFAS are identified as SVHC because they are considered to be as of equivalent level of concern (ELoC) to carcinogens, mutagens and reprotoxicants (CMRs) and persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBTs/vPvBs) chemicals. This conclusion is based on persistence, mobility and toxicity, which were considered to pose a threat to human health and wildlife when exposed through the environment (including through drinking water).

HFPO-DA (GenX)	-	-	ELoC having probable serious effects to human health and environment (Article 57f)
PFBS (C4)	-	-	ELoC having probable serious effects to human health and environment (Article 57f)
PFHxS (C6)	-	-	vPvB (Article 57e)
PFHpA (C7)	203-615-4	-	Toxic for reproduction (Article 57c) PBT (Article 57d) ELoC having probable serious effect to human health and environment (Article 57 f)
PFOA (C8)	206-397-9	335-67-1	Toxic for reproduction (Article 57c) PBT (Article 57d)
PFNA (C9)	-	-	Toxic for reproduction (Article 57c) PBT (Article 57d)
PFDA (C10)	206-400-3	335-76-2	Toxic for reproduction (Article 57c) PBT (Article 57d)
PFUnDA (C11)	218-165-4	2058-94-8	vPvB (Article 57e)
PFDoDA (C12)	206-203-2	307-55-1	vPvB (Article 57e)
PFTrDA (C13)	276-745-2	72629-94-8	vPvB (Article 57e)

PFTeDA (C14)	206-803-4	376-06-7	vPvB (Article 57e)
Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine	473-390-7	-	vPvB (Article 57e)

Evaluation of substances under REACH

In addition, several PFASs are on the list for evaluation ([Community rolling action plan](#)) over the coming years or have already been evaluated. The evaluation aims to clarify initial concerns on the potential risk to human health or the environment that manufacturing or using these substances could pose. Please check ECHA's website for most recent information.

Substance	EC/list no-	CAS no	Year	Concern	Status
3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) phosphates, ammonium salt (HGC-TLF	700-161-3	-	2013	Suspected PBT/vPvB	ongoing
reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine	473-390-7	-	2016	Suspected PBT/vPvB, Exposure of environment, Wide dispersive use	concluded

HFE 7000 (Trade name: 3M(TM) NOVEC(TM) ENGINEERED FLUID HFE-7000)	484-450-7	-	2019	Suspected PBT/vPvB	suspended
HFE 7100 (Reaction mass of 1,1,2,3,3,3-hexafluoro-1-methoxy-2-(trifluoromethyl)propane and 1,1,2,2,3,3,4,4,4-nonafluoro-1-methoxybutane), Process related name: HFE-7100 3M BRAND SPECIALITY LIQUID	422-270-2	-	2019	Suspected PBT/vPvB	suspended
Potassium 2-(3-trifluoromethoxy-1,1,2,2,3,3-hexafluoropropoxy)-2,3,3,3-tetrafluoropropionate (MV31-Potassium salt)	444-340-1	-	2017	Suspected PBT/vPvB, Exposure of environment	concluded
Polyhaloalkene	468-710-7	754-12-1	2012	Other hazard based concern, exposure of environment, high (aggregated) tonnage, wide dispersive use	concluded
Perfluamine	206-420-2	338-83-0	2020	Suspected PBT/vPvB, Exposure of environment	information requested

Hexafluoropropene	204-127-4	116-15-4	2015	Suspected CMR, High (aggregated) tonnage	concluded
Bis(nonafluorbutyl)phosphinic acid	700-183-3	52299-25-9	2018	Suspected PBT/vPvB, other hazard based concern, exposure of environment	concluded
Amphoteric Fluorinated Surfactant	-	-	2018	Suspected PBT/vPvB, Exposure of environment, Wide dispersive use	ongoing
Ammonium salts of mono- and bis[3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl and/or poly (substituted alkene)] phosphate	700-403-8		2013	Suspected PBT/vPvB, consumer use, wide dispersive use	ongoing
ammonium difluoro[1,1,2,2-tetrafluoro-2-(pentafluoroethoxy)ethoxy]acetate	700-323-3	908020-52-0	2017	Suspected PBT/vPvB, Exposure of environment	concluded
ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate (GenX/ C3 dimer salt)	700-242-3	62037-80-3	2017	Suspected PBT/vPvB, Exposure of environment, Wide dispersive use	information requested

Ammonium 2,2,3 trifluor-3-(1,1,2,2,3,3-hexafluoro-3-trifluoromethoxypropoxy), propionate (Adona)	480-310-4		2017	Suspected PBT/vPvB, Exposure of environment, Wide dispersive use	concluded
HFE 7500 (3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)-hexane), processed fluid	435-790-1	297730-93-9	2018	Suspected PBT/vPvB, Exposure of environment, Wide dispersive use	ongoing
3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate (6:2 FTMA)	218-407-9	2144-53-8	2016	Potential endocrine disruptor, Suspected PBT/vPvB, Other hazard based concern, Exposure of environment, Wide dispersive use	conclusion under preparation
3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate (6:2 FTA)	241-527-8	17527-29	2016	Potential endocrine disruptor, Suspected PBT/vPvB, Other hazard based concern. Exposure of environment, wide dispersive use	conclusion under preparation
2H-Tricosafuoro-5,8,11,14-tetrakis(trifluoromethyl)-	-	37486-69-4	2017	Suspected PBT/vPvB,	concluded

3,6,9,12,15-pentaoxaoctadecane
(TFEE-5)

Exposure of
environment

HFE 7800 (2-Ethoxy-3,3,4,4,5-pentafluoro-2,5-bis[(1,2,2,2-tetrafluoro-1-trifluoromethyl)ethyl] tetrahydrofuran), Trade name: 3M(TM) NOVEC(TM) ENGINEERED FLUID	484-410-9		2019	Suspected PBT/vPvB	ongoing
2-bromo-3,3,3-trifluoroprop-1-ene (2-BTP)	627-872-0	1514-82-5	2019	Suspected reprotoxic, potential endocrine disruptor	concluded
2-[methyl[(nonafluorobutyl) sulpho-nyl]amino]ethyl acrylate (N-Me FBSEA)	266-733-5	67584-55-8	2018	Suspected PBT/vPvB, other hazard based concern, exposure of environment, wide dispersive use	concluded

Classification, Labelling and Packaging (CLP) Regulation

Several PFASs have a harmonised classification and labelling (CLH) under the CLP Regulation, see non-exhaustive table below. Please check ECHA's website for most recent information.

Substance name	EC / List no-	CAS no	LH status	Classification adopted or proposed
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C6-PFCA (PFHxA and its sodium, ammonium and other inorganic salts)	206-196-6 220-881-7 244-479-6-	-	Opinion development	Repr 1B; H360D
C7-PFCA (PFHpA)	206-798-9	375-85-9	Adopted (18 th ATP)	Repr 1B; H360D STOT RE1; H372 (liver)
C8-PFCA (PFOA, APFO)	223-320-4 206-397-9	3825-26-1 335-67-1	Adopted (5 th ATP)	Carc 2; H351 Repr 1B; H360D STOT RE1; H372 (liver) Lact; H362 Acute Tox. 4; H332 Acute Tox. 4; H302 Eye Dam 1; H318
C9-PFCA (PFNA and its ammonium and sodium salts)	206-801-3	375-95-1 4149-60-4 21049-39-8	Adopted (9 th ATP)	Carc 2; H351 Repr 1B; H360Df STOT RE1 (liver, spleen, thymus) Lact; H362
C10-PFCA (PFDA and its ammonium and sodium salts)	206-400-3 221-470-5	335-76-2 3108-42-7 3830-45-3	Adopted (10 th ATP)	Carc 2; H351 Repr 1B; H360Df Lact; H362
6:2 fluorotelomer alcohol (6:2 FTOH) 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctan-1-ol	-	647-42-7	RAC concluded	STOT RE2; H373 (teeth, bones) Aquatoc Chronic 1

European Commission policy initiatives on PFAS

In October 2020, the European Commission published the [Chemicals Strategy for Sustainability](#).

Among its many actions, it includes phasing out the use of PFAS in the EU, unless their use is essential and initiatives to reduce their emissions using all available legislative and non-legislative tools. The details of the future European actions on PFAS are presented in a [specific document that accompanies the Chemicals Strategy](#).

Drinking Water

The agreement by the European Parliament and the Council in December 2019 on the recast of the Drinking Water Directive includes a limit of 0.5 µg/l for all PFAS. This is in line with a grouping approach for all PFAS.

In December 2020, the European Parliament formally [adopted the revised Drinking Water Directive](#). The Directive entered into force on 12 January 2021, and Member States will have two years to transpose it into national legislation.

PFAS in surface water and groundwater

In 2022 the Commission adopted a [proposal](#) to revise the list of priority substances in surface water and groundwater. Several substances are proposed for addition, including a list of PFAS. If the proposal is agreed by the Council and the European Parliament, Member States will be required to take measures to reduce the emissions of all these pollutants where necessary to meet the quality standards.

The proposals are available on the [EC's web page](#).

PFAS and food

PFAS are released into the environment through industrial manufacturing not directly linked to food production and through the use and disposal of PFAS-containing products. However, as often with persistent pollutants, they end up in the food chain. PFAS also accumulate in human bodies through the diet. The main contributors to human dietary exposure are food of animal origin and vegetables but drinking water is also an important source.

In September 2020, the European Food Safety Authority (EFSA) adopted an opinion on the risk to human health related to the presence of PFAS in food and concluded that the main PFAS that accumulate in the body are perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS), perfluorononanoic acid (PFNA), and perfluorohexane sulfonic acid (PFHxS). They can cause developmental effects and may have adverse effects on serum cholesterol, the liver and the immune system and birth weight. It considered the effects on the immune system as the most critical effect and established group tolerable weekly intake (TWI) of 4.4 nanograms per kilogram of body weight per week for the sum of PFOS, PFOA, PFNA and PFHxS, which is also protective against the other effects of those substances. It concluded that the exposure of parts of the European population to those substances exceeds the TWI, which is of concern. Following this opinion the Commission established under [Commission Regulation \(EU\) 2022/2388](#) maximum levels for these 4 PFAS in eggs, fish, crustaceans, bivalve molluscs and meat and offal of terrestrial animals, which are main contributors to the exposure. For other foods amongst which vegetables, which are also relevant contributors to the exposure, under [Commission Recommendation \(EU\) 2022/1431](#), the collection of further occurrence data is recommended, as well as the carrying out of investigations on the sources of the contamination, when Indicative Levels are exceeded.

Note: Please note that the information was provided in January 2023. Therefore, the status of certain projects may have evolved.