TI-064 - Regulation of per- and polyfluorinated substances in Europe

Per- und polyfluorinated1 Substances

Substances of this type are so called fluoro-organic compounds – chains of carbon atoms which are partly or completely surrounded by Fluorine atoms. They are very stable against chemical and biological degradation processes hence persistent. This group of substances is often referred to as PFCs (perfluorinated carbons) or PFAS[2].

Some specimens have meanwhile been identified to be hazardous to human health. This prompted various authorities globally to act on regulating PFAS. Europe's Commission being at the forefront of those initiatives.

REACH as the Bases

Each member of the European Union is empowered to propose substances considered hazardous to the Commission for regulation under REACH[3].

Within a RMOA[4] the Legislator evaluates if the hazards to the environment and human health resulting from the use of the substance require it to be regulated and if so to what degree respectively in which way.

The legal instruments regulating substances cover limitations, permission requirements or even a complete ban for the manufacturing or use of individual substances or an entire substance group. To date two PFC-type substances - each as lead compound of a substance group - have been identified to require being regulated:

PFOS[5]:

PFOS was the first substance of the PFAS group which was regulated in Europe: In December 2006 the EU Commission adopted the regulation (EG) 2006/122 (amending regulation (EC) 76/769) prohibiting the manufacturing and placing on the market of PFOS and its precursors[6] in the EU and installing a threshold limit of 50ppm (=mg/kg) PFOS and /or its precursors in articles and mixtures.

In August 2010 PFOS was put on the POPs[7]-List by the Stockholm Convention. The Commission enforced as European law by amending regulation (EU) 850/2004 with 757/2010 reducing the threshold from 50ppm to 10ppm. Both regulations were covered and replaced in June 2019 by the new (EU) 2019/1021 on *persistent organic pollutants*.

Status Quo:

Products containing **more than 10ppm (=mg/kg) PFOS or its precursors must not be manufactured in the EU or placed on the market** – this particularly includes firefighting foam agents – **with no exemption**.

Firefighting foam agents having been placed on the market prior to 2010 may need to be analysed for their respective content of PFOS.

Any firefighting foam agent exceeding the current limit must be disposed of immediately in agreement with the provisions for a safe disposal set out in (EU) 2019/1021, Article 7. Any further use is prohibited and may become subject to severe fines.

PFOA[8]

The second substance of the PFAS type having been regulated in Europe is the *Perfluoro Octanoic Acid*. This compound is considered to be the end-point of degradations of any so-called C8-compounds[9] hence is defined as the lead substance for the entire group of C8-Fluorosurfactants and –polymers used in firefighting agents. In opposite to the regulation on PFOS this time not just the acid and its metal salts are covered but any molecule having a perfluorinated chain of seven or eight carbons hence literally any C8-Technology.

The provisions of regulation (EU) 2017/1000 from July 13th concerning: "*Perfluorooctanoic acid (PFOA) CAS No 335-67-1 EC No 206-397-9"* and its precursors being *"Any related substance (including its salts and polymers…"*[10] generally prohibit the *manufacturing or placing on the market* of the above defined group of substances as substance in mixtures or articles above a certain threshold.

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[1] The term per-fluorinated means that all Hydrogen atoms in a hydrocarbon molecule are replaced by Fluorine. In poly fluorinated carbons not all Hydrogens were replaced by Fluorine.

[2] PFAS = Perfluoro alkyl substances

[3] Regulation (EG) 1907/2006 on „ Registration, Evaluation, Authorisation and Restriction of Chemicals"

[4] Risk Management Options Analysis – Analysis of Options to minimise the risk caused by a chemical substance or substance group to the environment or human health

[5] Perfluorooctylsulfonic Acid ($C_8HF_{17}SO_2$; CAS 1763-23-1)

[6] Precursors are any substances having the potential to release the particular lead substance during their use or degradation.

[7] POPs = Persistent Organic Pollutants, list of substances identified as persistent organic pollutants according to the Stockholm Convention.

[8] Perfluoroctanoic Acid ($C_8HF_{15}O_2$; CAS 335-67-1)

[9] Fluorine containing firefighting foam agents are either of the C8-type having a chain of eight carbons all of which are surrounded by fluorine. Or they are of the C6-Type (such as the 6:2-Telomers) having a chain of only six perfluorinated Carbons. According to recent studies C6-Type fluorocompunds are reported to be significantly less hazardous yet still persistent.

[10] *"…having a linear or branched perfluoroheptyl group with the formula C7F15- directly attached to another carbon atom, as one of the structural elements. Any related substance (including its salts and polymers) having a linear or branched perfluorooctyl group with the formula C8F17- as one of the structural elements."* ((EU)2017/1000)

These provisions have recently been amended by the delegated Regulation (EU)2020/784 which converts the adoption of PFOA and their precursors onto the POP list into European law now also restricting particularly *the uses*. This will render some of the previously applicable exemptions for firefighting foam agents ineffective.

Status Quo

PFOA and related substances shall not be manufactured nor placed on the market in the EU after July 4th, 2020. Articles or mixtures **must not contain more than 25ppb (=µg/kg) PFOA respectively in total 1000ppb[11] (=1ppm=1mg/kg) of the totality of precursors**.

Exemptions for Firefighting Foam Agents: Firefighting foam concentrates exceeding the above limits that were placed on the market before 4 July 2020 can *be used until January 1st, 2023*. The derogations do not include training purposes. Testing is only derogated, if full retention of all effluents is granted.

After January 1st, 2023, "*fire-fighting foam for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems, including both mobile and fixed systems*" which are exceeding above limits, are allowed to be used until *4 July 2025* if 100% retention of all effluents is granted.

Impact of the PFOA Regulation on foam uses

Stockpiles >50kg of firefighting foam agents which exceed the limits but benefit from one of the aforementioned derogations must be managed in accordance with Art. 5 of (EU) 2019/1021. This includes, among other things, an annual obligation to notify the competent authorities of the "*nature and size*" of the stockpiles. This reporting obligation has been in place since June 2020 and ends with the expiration of the derogation period.

Stocks of excess supplies in extinguishing systems and vehicles that are refilled with new foam extinguishing agents (that meet the requirements of (EU)2017/-1000) must comply with the limit values by July 5, 2025 at the latest. Whether the delegated regulation 2020/-784 also allows for refilling from existing user owned stocks of foam agents exceeding the limits (i.e. canisters, totes, drums, etc.) may require legal clarification[12].

If after 4 July 2020 Stocks exceeding the above thresholds are replenished with new firefighting foam concentrates in compliance with the requirements of (EU)2017/1000, the resulting mixture must meet the thresholds.

Storage containers and media-carrying parts (i.e. pumps, tubes, proportioners, hoses, …) on trucks, trailers or in systems must be exposed to an intense technical cleaning procedure or have to be replaced to not contaminate new filled foam concentrate beyond the acceptable limits[13].

Safety advice:

If a firefighting foam concentrate has been stored in non-disposable technical equipment, all parts of this equipment having or having had contact with the firefighting foam concentrate must be thoroughly cleaned and the cleanliness tested before they can be refilled with new firefighting foam concentrate!

Please note that any contamination of new foam extinguishing agent concentrates by residues of PFOS- or PFOA-contaminated predecessor products beyond the maximum permissible content will render the new product unusable immediately!

C9-C14-PFCA

These group of chemicals consists of six perfluorinated carboxylic acids all of which display similar structural elements like PFOA but have a longer perfluorinated carbon chain of 8-13 carbons.

This group of carboxylic acids „*having a perfluoro group with the formula C_nF_{2n+1}- directly attached to another carbon atom, where n = 8, 9, 10, 11, 12, or 13, including their salts and any combinations thereof*" are subject to restrictions set out by the latest regulation (EU) 2021/1297:

Chemical products containing **more than 25ppb C9-C14-carboxylic acids**Fehler! Textmarke nicht definiert. **including their salts and any combinations thereof, or which contain more than 260ppb for the sum of C9-C14-PFCA-related substances**Fehler! Textmarke nicht definiert. shall not be manufactured, placed on the market or used from February 25th, 2023.

Derogation for firefighting foam agents

Firefighting foam agents are allowed to be used until **July 4th, 2025** (manufacturing and placing on the market remain banned!): for use **on class-B-fires and for testing provided all releases can be contained** (as of January 1st, 2023 foam agents exceeding the legal limet are only allowed to sites where all releases can be contained!). There is **no derogation for training whatsoever!**

Impact of the C9-C14-Regulation on foam uses

Since January 1st, 2023 no firefighting foam agents are allowed to be placed on the market which exceed any of the limits set by this regulation.

Fire-fighting foams that exceed any of the limits must be taken out of service and storage-/handling equipment (tanks, piping, proportioners, etc. of fixed systems, trailers or fire-fighting vehicles) must be

[11] This threshold is a sum parameter i.e. the content of all possible precursors shall not exceed the given limit.

[12] The wording "*already installed in systems, including both mobile and fixed systems*" does not seem to cover foam agent stocked in bulk or packing. However, this interpretation may not be correct.

[13] This affects the cleaning for the purpose of meeting legal requirements with respect to contamination with PFOA and its precursors. The requirement to clean up systems and devices for avoiding negative interactions between two foam agents in accordance with foam manufacturer instructions remains unchanged.

cleaned in such a way that refills with new firefighting foam agents are not contaminated with the regulated substances in excess of their respective legal limits (similar to the situation with PFOA --> see above).

Products made by Dr. STHAMER, Hamburg

All Dr STHAMER products meet these requirements: Levels of PFOS, PFOA and C9-C14 PFCAs are at or below current limits of quantification (LoQ). A complete physical separation of production lines, including different connection systems, eliminates any unintentional cross-contamination of fluorine-free[14] foam agents with fluorinated ones.

Disclaimer

All information in this document is based on our best knowledge at the time of writing. It does not constitute a legally binding statement or assurance of general product characteristics beyond those set out in the relevant product literature. This document is subject to change without notice. Please contact us for the latest version.

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[14] We define fluorine-free products as being manufactured without the intentional addition of fluoro-organic compounds for the purpose of improving performance in such a way that they do not contain any PFAS in excess of the ubiquitous regional background contamination (e.g. in the drinking water used for manufacture).