

COMMON IMPLEMENTATION STRATEGY FOR THE WATER FRAMEWORK DIRECTIVE AND THE FLOODS DIRECTIVE



First List facilitating Annex I and II review process of the GWD

V. 2.1

(June 2019)

Based on:

“Voluntary Groundwater Watch List Concept & Methodology 12.3”

Disclaimer

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A) Introduction

The “List facilitating Annex I and II review process of the GWD” is the main output of the Voluntary Groundwater Watch List process described in the Groundwater Watch List Concept & Methodology.

The Groundwater Watch List Process was initiated by the European Commission in 2014 as an outcome of the first review of the Groundwater Directive (GWD). In Recital 4 of the revised GWD the European Commission expressed the need to obtain new information on further substances posing a potential risk for groundwater. To support this, the European Commission decided to establish a watch list for pollutants in groundwater. The watch list should facilitate the identification of substances, including emerging pollutants, for which groundwater quality standards or threshold values should be set. The most important output of the Watch List Process is the identification of substances present in groundwater based on sufficient monitoring data available. These substances will integrate the “List facilitating Annex I and II review process of the GWD”. The “List facilitating the Annex I and II review process” will support the EC review of the GWD by identifying substances or groups of substances that may be considered for future regulation via the GWD.

A sub-group of CIS Working Group Groundwater developed selection criteria for a substance to be set on the “List facilitating Annex I and II review process of the GWD”. In chapter 3.8 of the Voluntary Groundwater Watch List Concept Paper (selection of substances for the List facilitating Annex I and II review process of the GWD) it is stated that sufficiently monitored substances should be considered by the EC in a possible future review of Annex I/II of the GWD. A key element for selecting substances for the “List facilitating Annex I/II review process of the GWD” is the availability of appropriate monitoring data. Substances with high quality groundwater monitoring data and detections in at least 4 MS/AC and at 10 or more sites in each MS/AC (i.e. quantified values from > 40 sites) should integrate the “List facilitating Annex I/II review process of the GWD”.

MS/AC reported existing monitoring data for the two substance groups - pharmaceuticals and PFAS (**per- and polyfluoroalkyl substances**). Based on these data collections of submitted data and carried out by the GWWL sub-group, several substances were identified to join the “List facilitating Annex I/II review process”.

WG Groundwater has endorsed this version, the Strategic Coordination Group (SCG) members took note of it on 15 May 2019, and EU Water Directors acknowledged it on 14 June in Constanta, Romania.

B) Pharmaceuticals identified for the “List facilitating Annex I/II review process”

13 MS/AC reported results of groundwater monitoring on pharmaceuticals in 2015 naming ~ 300 different substances. Only two substances were detected in four or more MS/AC and at 10 or more sites in each of these countries (see Tab. 1).

The detailed results can be found in:

Marsland, T. and Roy, S., 2016. Groundwater Watch List: Pharmaceuticals Pilot Study – Monitoring Data Collection and Initial Analysis. Report for the Groundwater watch list Voluntary Group undertaken by Amec Foster Wheeler, pp. 58.
<https://circabc.europa.eu/d/a/workspace/SpacesStore/a1e23792-6ecd-4b34-b86c-dcb6f1c7ad1c/1600204%20Pharm%20Pilot%20Study.docx>

Tab. 1: List of Pharmaceuticals that were found in 4 or more countries and at 10 or more sites in each country.

| No of MS/PC | Substance Name | Acronym | CAS # | Total number of sites analysed | No of sites with findings |
|-------------|------------------|---------|----------|--------------------------------|---------------------------|
| 8 | Carbamazepine | | 298-46-4 | 3732 | 471 |
| 6 | Sulfamethoxazole | | 723-46-6 | 2176 | 114 |

According to the criteria defined in the Groundwater Watch List Concept & Methodology, sufficient monitoring data were available for 2 Pharmaceutical chemicals (Carbamazepine, Sulfamethoxazole) to place these substances on the List facilitating Annex I/II review process” (see Tab. 1).

C) PFAS (per- and polyfluoroalkyl substances) identified for the “List facilitating Annex I/II review process”

For the PFAS data collection, MS/AC were asked to report existing monitoring data on a voluntary basis for selected 52 substances. The data submitted by the MS/AC was collected by the GWWL sub-group in 2017. 19 MS/AC reported their monitoring activities and 11 MS/AC delivered monitoring data. Monitoring data were available for 29 PFAS substances.

PFAS were monitored in 11 countries (MS/AC) (see Tab. 2), in 8 countries these substances were not monitored until 2017. In each country where PFAS were monitored at least one PFAS substance was detected at one or more groundwater monitoring sites.

Tab. 2: MS/AC that reported about monitoring activities

| Country | Monitored | Findings | No findings |
|----------------|-----------|----------|-------------|
| Belgium | Yes | Yes | |
| Bulgaria | No | ---- | ---- |
| Switzerland | Yes | Yes | |
| Czech Republic | Yes | Yes | |
| France | Yes | Yes | |
| Hungary | No | ---- | ---- |
| Italy | Yes | Yes | |
| Netherlands | Yes | Yes | |
| Austria | Yes | Yes | |
| Poland | No | ---- | ---- |
| Romania | No | ---- | ---- |
| Slovakia | No | ---- | ---- |
| Slovenia | No | ---- | ---- |
| Spain | No | ---- | ---- |
| Germany | Yes | Yes | |
| Sweden | Yes | Yes | |
| Finland | Yes | Yes | |
| United Kingdom | Yes | Yes | |
| Luxemburg | No | ---- | ---- |

According to the criteria defined in the Groundwater Watch List Concept & Methodology, for 10 detected PFAS substances sufficient monitoring data were available to place these substances on the List facilitating Annex I/II review process” (see Tab. 3).

Tab. 3: List of PFAS substances detected in 4 or more countries (MS/AC) and at more than ten sites in each country.

| No of MS/AC | Substance Name | Acronym | CAS # | Total number of sites analysed | No of sites with findings |
|-------------|---------------------------|---------|-----------|--------------------------------|---------------------------|
| 10 | Perfluorooctane Sulfonate | PFOS | 1763-23-1 | 6278 | 1430 |
| 10 | Perfluorooctanoic Acid | PFOA | 335-67-1 | 5736 | 1549 |
| 8 | Perfluorohexanoic Acid | PFHxA | 307-24-4 | 4662 | 1175 |
| 7 | Perfluoroheptanoic Acid | PFHpA | 375-85-9 | 4224 | 817 |
| 7 | Perfluorohexane Sulfonate | PFHxS | 432-50-8 | 2328 | 873 |
| 6 | Perfluorobutane Sulfonate | PFBS | 375-73-5 | 2209 | 577 |
| 5 | Perfluorodecanoic Acid | PFDA | 335-76-2 | 2945 | 173 |
| 5 | Perfluorononanoic Acid | PFNA | 375-95-1 | 3752 | 195 |
| 5 | Perfluoropentanoic Acid | PFPeA | 2706-90-3 | 2452 | 701 |
| 4 | Perfluorobutanoic Acid | PFBA | 375-22-4 | 1189 | 552 |

D) Conclusion

As a result of the Pharmaceutical and PFAS Data collections a total of 12 substances were identified fulfilling the criteria to integrate the “List facilitating Annex I/II review process”.

These substances sufficiently monitored will not be put on the Voluntary Groundwater Watch List but MS/AC will be informed. It is up to MS/AC to continue monitoring these substances or – if not analysed so far - integrate these substances in their groundwater monitoring programmes.

It is highly recommended to report new/additional monitoring results of substances included in the “List facilitating Annex I/II review process of the Groundwater Directive (GWD)”.

Annexes

Additional information for substances included in the List facilitating Annex I/II review process of the GWD (see Tab. 1 and 3):

I) PHARMACEUTICALS

Pharmaceuticals - Type of substances

Carbamazepine and Sulfamethoxazole are Pharmaceuticals. Carbamazepine is a human-pharmaceutical whereas Sulfamethoxazole is also use as a veterinary pharmaceutical.

Carbamazepine among others is an [anticonvulsant medication](#) used primarily in the treatment of [epilepsy](#) and [neuropathic pain](#).^[1] It is used in [schizophrenia](#) along with other medications and as a second-line agent in [bipolar disorder](#).^[1] Carbamazepine appears to work as well as [phenytoin](#) and [valproate](#).

Sulfamethoxazole is an [antibiotic](#). It is used for [bacterial infections](#) such as [urinary tract infections](#), [bronchitis](#), and [prostatitis](#) and is effective against both gram negative and positive bacteria such as [Listeria monocytogenes](#) and [E. coli](#).^[1]

Pharmaceuticals - Amount of Carbamazepine and Sulfamethoxazole produced, sold or released to the environment

At present, there is no European wide summary of the amount of pharmaceuticals sold in Europe. In Germany about 87.000 kg of Carbamazepine and about 58.000 kg of Sulfamethoxazole were sold in 1999 (<http://www.bio.uni-frankfurt.de/55037987/Schulte-Oehlmann-et-al-2007-UWS>)

Pharmaceuticals - Findings in Groundwater

The data summarised below are based on the data reported in 2015 by 12 MS/PC. For Carbamazepine 12 MS/PC detected the substance in a total of 471 sites out of 3732 sites analysed.

Sulfamethoxazole was detected in 10 MS/PC at a total of 114 sites out of 2176 sites analysed. At 3261 sites the concentration of Carbamazepine was below the limit of quantification (LOQ). For Sulfamethoxazole the concentration was below LOQ at 2062 sites. As shown below Carbamazepine was found in a concentration range from the LOQ to 0.05 µg/l at 353 sites. At 35 sites the concentration was in the range of > 0.05 to 0,1 µg/l. At another 35 sites the concentration of Carbamazepine was in the range of > 0.1 to 1 µg/l. At a total of 22 sites Carbamazepine was found in a concentration of >1 µg/l. Carbamazepine was detected but not quantified at 26 sites.

Sulfamethoxazole was less frequently found than Carbamazepine. At 100 sites the Sulfamethoxazole concentration ranged from > LOQ to 0,05 µg/l. At 5 sites the concentration of Sulfamethoxazole exceeded 0.05 µg/l. At 9 sites Sulfamethoxazole could be detected but was not quantified.

Tab. 4: Summary of Groundwater monitoring data for Carbamazepine and Sulfamethoxazole reported by MS/PC

| Substance or metabolite | No of MS/PC | total number of sites | < (LOQ) | > LOQ to 0.05 µg/l | > 0.05 to 0.1 µg/l | > 0.1 bis 1.0 µg/l | > 1,0 bis 3.0 µg/l | > 3.0 bis 10.0 µg/l | > 10.0 µg/l | detected but not quantified | total No of findings | No countries with findings |
|-------------------------|-------------|-----------------------|----------|--------------------|--------------------|--------------------|--------------------|---------------------|-------------|-----------------------------|----------------------|----------------------------|
| Carbamazepine | 12 | 3732 | 3261 | 353 | 35 | 35 | 13 | 5 | 4 | 26 | 471 | 12 |
| Sulfamethoxazole | 12 | 2176 | 2062 | 100 | 1 | 4 | 0 | 0 | 0 | 9 | 114 | 10 |

This summary is based on existing monitoring data only. It is assumed that the total number of sites with detected concentrations of Carbamazepine and/or Sulfamethoxazole would be significantly higher if a systematic European wide monitoring of these substances would be carried out.

Pharmaceuticals - Pathways into groundwater

Pharmaceuticals used for human and veterinary application are released to the environment mainly through excrement. Human excrement frequently goes to sewage systems and is treated in sewage plants. But pharmaceuticals are not totally eliminated in wastewater treatment plants. Treated sewage waters may contain pharmaceuticals or their degradation products. Frequently treated sewage waters are discharged into surface water. Some pharmaceuticals may harm surface and groundwater organisms. Pharmaceuticals may reach groundwater via bank filtration. If surface water is used for drinking water production (e.g. via bank filtration or groundwater recharge), pharmaceuticals may also enter drinking water.

Veterinary pharmaceuticals are also released via excrement into the environment. With excrements (including sewage sludge) used as fertiliser, pharmaceuticals may enter soil, the unsaturated zone and finally groundwater. This might be an important pathway into groundwater especially in regions with intensive livestock farming.

Pharmaceuticals - Elimination rate in sewage plants

For Carbamazepine the elimination rate from sewage water is close to zero. For Sulfamethoxazole about 24 % of the substance is eliminated in sewage plants. ([https://www.iksr.org/fileadmin/user_upload/Dokumente_de/Symposien u. Workshops/Ternes EAWAG d.pdf](https://www.iksr.org/fileadmin/user_upload/Dokumente_de/Symposien_u_Workshops/Ternes_EAWAG_d.pdf)).

PFAS (PER- AND POLYFLUOROALKYL SUBSTANCES)**PFAS - Type of substances**

The 10 substances listed below belong to the group of per- and polyfluoroalkyl substances (**PFAS**). According to the OECD there are at least 4730 different substances in this group.

| Substance Name | Acronym |
|---------------------------|---------|
| Perfluorooctane Sulfonate | PFOS |
| Perfluorooctanoic Acid | PFOA |
| Perfluorohexanoic Acid | PFHxA |
| Perfluoroheptanoic Acid | PFHpA |
| Perfluorohexane Sulfonate | PFHxS |
| Perfluorobutane Sulfonate | PFBS |
| Perfluorodecanoic Acid | PFDA |
| Perfluorononanoic Acid | PFNA |
| Perfluoropentanoic Acid | PFPeA |
| Perfluorobutanoic Acid | PFBA |

PFAS have been manufactured and used in a variety of industries around the globe, including in the United States since the 1940s. PFOA and PFOS have been the most extensively produced and studied of these chemicals. Both chemicals are persistent in the environment and in the human body. There is evidence that exposure to PFAS can lead to adverse human health effects.

PFAS can be found in:

- **Food** packaged in PFAS-containing materials, processed with equipment that used PFAS, or grown in PFAS-contaminated soil or water.
- **Commercial household products**, including stain- and water-repellent fabrics, nonstick products (e.g., Teflon), polishes, waxes, paints, cleaning products, and fire-fighting foams (a major source of groundwater contamination at airports and military bases where firefighting training occurs).
- **Workplace**, including production facilities or industries (e.g., chrome plating, electronics manufacturing or oil recovery) that use PFAS.
- **Drinking water**, typically localized and associated with a specific facility (e.g., manufacturer, landfill, wastewater treatment plant, firefighter training facility).
- **Living organisms**, including fish, animals and humans, where PFAS have the ability to build up and persist over time.

PFAS - Amount produced, sold or released to the environment

There are no data on the production rate of all PFAS-substances. PFAS are used in a variety of products and production processes. From 1966 to the 1990s, the production and use grew due to their unique chemical stability and their surface tension/levelling properties. The annual production rate of PFOS increased significantly from 500 tonnes/year in the 1970's to almost 5000 tonnes/year in 2000 (Carloni, 2009) (see in CONCAWE report no. 8/16 - Environmental fate and effects of polyand perfluoroalkyl substances (PFAS)).

PFAS - Findings in Groundwater

Tab. 5: Summary of Groundwater monitoring data for the 10 PFAS on the List facilitating Annex I/II review process reported by MS/PC

| No of MS/PC | Substance Name | Acronym | Total number of sites analysed | Detection < LOQ | Detection ≥ LOQ to 0.05 µg/L | Detection ≥ 0.05 to 0.1 µg/L | Detection ≥ 0.1 to 1.0 µg/L | Detection ≥ 1.0 to 3.0 µg/L | Detection ≥ 3.0 to 10.0 µg/L | Detection ≥ 10.0 µg/L | Detected but <u>not</u> quantified* | No of findings |
|-------------|---------------------------|---------|--------------------------------|-----------------|------------------------------|------------------------------|-----------------------------|-----------------------------|------------------------------|-----------------------|-------------------------------------|----------------|
| 11 | Perfluorooctane Sulfonate | PFOS | 6278 | 4903 | 1155 | 132 | 65 | 11 | 5 | 7 | 55 | 1430 |
| 11 | Perfluorooctanoic Acid | PFOA | 5736 | 4225 | 1127 | 97 | 197 | 73 | 13 | 4 | 38 | 1549 |
| 9 | Perfluorohexanoic Acid | PFHxA | 4662 | 3525 | 777 | 53 | 246 | 49 | 8 | 4 | 38 | 1175 |
| 9 | Perfluoroheptanoic Acid | PFHpA | 4224 | 3444 | 505 | 89 | 169 | 13 | 4 | 0 | 37 | 817 |
| 8 | Perfluorohexane Sulfonate | PFHxS | 2328 | 1579 | 553 | 108 | 80 | 4 | 2 | 2 | 124 | 873 |
| 7 | Perfluorobutane Sulfonate | PFBS | 2209 | 1725 | 455 | 6 | 21 | 0 | 0 | 2 | 93 | 577 |
| 8 | Perfluorodecanoic Acid | PFDA | 2945 | 2773 | 169 | 0 | 3 | 0 | 0 | 0 | 1 | 173 |
| 8 | Perfluorononanoic Acid | PFNA | 3752 | 3559 | 179 | 6 | 7 | 1 | 0 | 0 | 2 | 195 |
| 7 | Perfluoropentanoic Acid | PFPeA | 2452 | 1770 | 334 | 52 | 242 | 46 | 7 | 1 | 19 | 701 |
| 5 | Perfluorobutanoic Acid | PFBA | 1189 | 637 | 303 | 79 | 166 | 3 | 1 | 0 | 0 | 552 |

This summary is based on existing monitoring data only. It is assumed that the total number of sites with findings of PFAS would be significantly higher if a systematic European wide monitoring of these substances would be carried out.

PFAS - Exposure of people to PFAS and pathways into groundwater

There is a variety of ways that people and the environment can be exposed to these chemicals. For example, people can be exposed to low levels of PFAS through *food*, which can become contaminated through:

- Contaminated soil and water used to grow the food,
- Food packaging containing PFAS, and
- Equipment that used PFAS during food processing.

People can also be exposed to PFAS chemicals if they are released during normal *use, biodegradation, or disposal of consumer products* that contain PFAS. People may be exposed to PFAS used in commercially-treated products to make them stain- and water-repellent or nonstick. These goods include carpets, leather and apparel, textiles, paper and packaging materials, and non-stick cookware.

People who *work* at PFAS production facilities, or facilities that manufacture goods made with PFAS, may be exposed in certain occupational settings or through contaminated air.

Drinking water can be a source of exposure in communities where these chemicals have contaminated water supplies. Such contamination is typically localized and associated with a specific facility, for example,

- an industrial facility where PFAS were produced or used to manufacture other products, or
- an oil refinery, airfield or other location at which PFAS were used for firefighting.

PFOA, PFOS, and GenX have been found in a number of drinking water systems due to localized contamination. More information about exposures to PFAS through drinking water on [Drinking Water Health Advisories for PFOA and PFOS page \(see EPA\)](#).

It is also reported, that groundwater, soil and plants are contaminated by PFAS after the application of sewage sludge contaminated with PFAS. (https://www.gdch.de/fileadmin/downloads/Netzwerk_und_Strukturen/Fachgruppen/Umweltchemie_OEkotoxikologie/mblatt/2017/b1h317.pdf)

PFAS - Elimination rate in sewage plants

Municipal wastewater treatment plant effluents and infiltration of urban runoff and leaching piping are probably the major sources of diffuse pollution to rivers and aquifers (Eschauzier et al., 2012). Loos et al. (2013) stated: "Often PFAS concentrations increase in wastewater treatment plants as a result of biodegradation of precursors during the activated sludge process. PFOA is generally fully discharged into receiving rivers, while about half of PFOS is retained in the sewage sludge". (see in CONCAWE report no. 8/16 - Environmental fate and effects of polyand perfluoroalkyl substances (PFAS)).