Status Box

Title: Voluntary Groundwater Watch List Concept & Methodology

Based on final draft Groundwater Watch List Concept & Methodology 12.3

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The SCG is invited to:Take note of this report agreed by CIS Working Group Groundwater.

Background:

The CIS Work Programme 2016-2018 includes for WG Groundwater (GW) the activity 'Groundwater Watch List (GWWL)', with the objective of developing a methodology for identifying substances to be included in a GWWL.

WG GW agreed on the terms of reference for this activity at the end of 2016.

The Groundwater Directive (GWD) specifies the aim and the measures to protect groundwater. In Annexes I and II of the GWD detailed methodologies are defined to assess the chemical status of groundwater resources. Annex I establishes a list of groundwater quality standards and Annex II defines the need to establish threshold values for additional substances. During the first revision of the GWD in 2014 the European Commission expressed the need to obtain new information on further substances posing a potential risk for groundwater. To support this, the Commission decided to establish a watch list for pollutants of 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 CIS Working Group on Groundwater (WG GW) was mandated to elaborate a concept for the establishment of this Groundwater Watch List (GWWL). In addition, criteria were defined to identify substances with sufficient high-quality monitoring data at EU level, being thus eligible for a further assessment in the context of the review of Annex I and II of the GWD.

This final draft version was circulated within the group of volunteers and presented and discussed at the WG GW Plenary Meeting 8/9 October 2018. An additional final period to comment the report was provided prior to the SCG.

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CIS WG GW – Voluntary Group "Groundwater Watch List GWWL"

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Executive Summary

The protection of groundwater is an important objective of the Water Framework Directive WFD (2000/60/EC). The Groundwater Directive GWD (2006/118/EC) specifies the aim and the measures to protect groundwater. In Annexes I and II of the GWD detailed methodologies are defined to assess the chemical status of groundwater resources. Annex I establishes a list of groundwater quality standards and Annex II defines the need to establish threshold values for additional substances. During the first review of the GWD in 2014 the European Commission expressed the need to obtain new information on further substances posing a potential risk for groundwater. To support this, the Commission decided to establish a watch list for pollutants of 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 CIS Working Group on Groundwater (WG GW) was mandated to elaborate a concept for the establishment of this Groundwater Watch List (GWWL). In addition, criteria were defined to identify substances with sufficient high-quality monitoring data at EU level, being thus eligible for a further assessment in the context of the review of Annex I and II of the GWD. A sub-group of WG GW (Group of Volunteers GWWL) developed a simple and transparent methodology which took into account that the Groundwater Watch List process is a voluntary process and Member States (MS) and Associated Countries (AC) are free to participate. The “Group of Volunteers” is composed by representatives of MS, AC, Stakeholders and the Commission, and regularly reports to WG GW.

The methodology is based on i) the occurrence of substances in groundwater (based on monitoring data) and ii) the theoretical leaching potential of substances (based on the substance properties). The combined outcome of these two assessments (“Combined groundwater leaching potential score”) is linked with the hazard potential of these substances to form a ranked list of “Integrated groundwater score”. This list serves as a basis for the determination of substances either to be selected for the Groundwater Watch List, or to be listed to facilitate the Annexes I and II review process of the GWD.

The methodology developed was tested via two pilot studies for Pharmaceuticals and per- and poly-fluoroalkyl substances (PFAS). The present concept will be applied for the establishment of the first Groundwater Watch List and to facilitate the Annexes I and II review process of the GWD and – based on new experiences – adapted regularly.

Contents

List of abbreviations

AC – EU Associated Countries
CAS – Chemical Abstracts Service
CIS – Common Implementation Strategy for the Water Framework Directive
CMR – Carcinogenic, Mutagenic, Reprotoxic
DWD – Drinking Water Directive (Directive 98/83/EC)
EC – European Commission
ECHA – European Chemicals Agency
ED – Endocrine Disrupting
EQS – Environmental quality standard
GC-MS – Gas Chromatography - Mass Spectrometry
GD – Guidance Document within the CIS
GUS index – Groundwater Ubiquity Score
GW – Groundwater
GWAAE – Groundwater Associated Aquatic Ecosystem
GWB – Groundwater body
GWD – Groundwater Directive (2006/118/EC, as amended by Directive 2014/80/EC)
GWDTE – Groundwater Dependent Terrestrial Ecosystem
GWQS – Groundwater Quality Standard (GWD Annex I)
GWWL – Groundwater Watch List
ID – Anonymised Participating Country Identification Number
LC-MS – Liquid Chromatography - Mass Spectrometry
LOD – Limit of Detection
LOQ – Limit of Quantification
MS – EU Member States
PBT – Persistent, Bioaccumulative and Toxic
PC – Participating Countries (in groundwater monitoring)
PFAS – Per- and poly-fluoroalkyl substances
PMT – Persistent, Mobile, Toxic
PNEC – Predicted no effect concentration
PS – Priority Substance
QA/QC – Quality Assurance and Quality Control
REACH – Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SCG – Strategic Co-ordination Group
TV – Threshold Value (GWD Annex II)
vPvB – very Persistent and very Bioaccumulative
WD – Water Directors
WFD – Water Framework Directive (2000/60/EC)
WG GW – CIS Working Group on Groundwater

1. Introduction

1.1 The role of the Groundwater Watch List

The Groundwater Directive GWD (2006/118/EC) states that:

"Groundwater is a valuable natural resource and as such should be protected from deterioration and chemical pollution. This is particularly important for groundwater-dependent ecosystems and for the use of groundwater in water supply for human consumption." – Recital 1

"Groundwater is the most sensitive and the largest body of freshwater in the European Union and, in particular, also a main source of public drinking water supplies in many regions." – Recital 2

To achieve the protection needed for groundwater (GW), a number of objectives are set out in the Water Framework Directive WFD (2000/60/EC), Article 4. These are to:

- prevent or limit the input of pollutants into groundwater;
- prevent the deterioration in status of groundwater bodies;
- achieve good groundwater status;
- reverse any significant and sustained upward environmentally significant trends in pollutant concentrations;
- meet the requirements of protected areas.

In setting out the detailed mechanisms by which groundwater chemical status should be assessed, the GWD:

1) Establishes a list of groundwater quality standards (GWQS) that must be met for pollutants of EU-wide concern (Annex I), and

2) Requires Member States (MS) to define Threshold Values (TVs) for additional substances identified as putting a groundwater body at risk of not achieving/maintaining good status. In setting TVs, MS must take account of the pollutants listed in Annex II of the GWD, as amended by Directive 2014/80/EU (2014GWD). They must update their list of TVs as new information on pollutants becomes available (GWD Article 3(6)). Further information on GWQS, TVs and groundwater status assessment can be found in Guidance Document No. 18 of the Common Implementation Strategy (CIS).

Under GWD Article 10, the European Commission will also periodically review Annexes I and II taking account of all relevant information including the results of WFD monitoring programmes, community research programmes and new scientific findings. In addition, it is expected that any upcoming review will take into account results of the WFD and daughter directives fitness check (evaluation) process.

The first review resulted in Commission Directive 2014/80/EU of 20 June 2014 that amended Annex II of the 2006 GWD. Recital 4 of the new Directive also identifies *"the need to obtain and respond to new information on other substances posing a potential risk".* In order to support this, it establishes a requirement to define a groundwater *"**watch list** for pollutants of groundwater to increase the availability of monitoring data on substances posing a risk or potential risk to bodies of groundwater".* This list should thereby "*facilitate the identification of substances, including emerging pollutants, for which groundwater quality standards or threshold values should be set*".

Once defined, the Groundwater Watch List (GWWL) will be a list of new or emerging pollutants (substances) that Member States and Associated Countries should consider adding to their monitoring programmes on the basis that these pollutants may present an obstacle to the achievement of the environmental objectives of the WFD. For pollutants shown to pose a risk, a mechanism exists for establishing threshold values (Annex II of Directive 2006/118/EC). Future formal review of Annexes I and II of Directive 2006/118/EC, as amended by Directive 2014/80/EU, may lead to the substance(s) or groups of substances being listed (Annex II) or groundwater quality standards being defined (Annex I).

On this basis, the CIS Working Group – Groundwater (WG GW) included in its work programme (Mandate 2016-2018) the development of a methodology for identifying substances to be included in a GWWL. A Voluntary Group has been convened to progress this issue, commencing with this "Concept and Methodology Paper". The Group comprises representatives from different MS, AC, stakeholders and the Commission. An intense exchange on the progress of the Watch List concept has taken place and the concept paper was discussed and refined at several meetings of the Voluntary Group. Progress was presented, discussed and agreed in the plenary meetings of WG GW. In parallel, a first pilot study on the occurrence of pharmaceuticals in groundwater has been undertaken, for which an initial report on monitoring has already been published (Marsland and Roy 2016). A second pilot study on the occurrence of per- and poly-fluoroalkyl substances (PFAS) in groundwater was carried out in 2017.

The implementation of the Groundwater Watch List Process will be steered by the Voluntary Group. WG GW will propose the future lists of substances for inclusion in the GWWL and the List facilitating the Annex I/II review process. These proposals will be presented to the Strategic Coordination Group (SCG)/Water Directors (WD).

It is foreseen to review the GWWL concept regularly and, if necessary, to improve and modify the concept.

WG GW has finalised and agreed on the current Groundwater Watch List Concept and decided to forward the concept to SCG for information.

1.2 Purpose and scope of this report

Beyond the statement in Directive 2014/80/EU there is no further explanation concerning the GWWL in other legislation or CIS Guidance Documents (GD). This report aims to fill this gap by:

- Describing the concept of a GWWL;
- Proposing a methodology to determine which substances should be included in the GWWL;
- Developing an implementation plan.

The policy, legislative and technical background to the GWWL is described in Chapter 2, and the conceptual basis for the determination process is set out in Chapter 3. Data collection and quality issues are described in Chapter 4.

Note: For surface water, a Watch List mechanism has been established under the Environmental Quality Standards Directive (2008/105/EC as amended by 2013/39/EU), and a first list was adopted in March 2015 (Commission Implementing Decision (EU) 2015/495). Monitoring of substances on the surface water Watch List is obligatory. In contrast, the GWWL constitutes a voluntary mechanism and under current legislation, monitoring would not be obligatory. The surface water and groundwater Watch Lists are not the same in terms of their functioning, use, substances or obligations on MS (see Chapter 2.6).

2. Policy, legislative and technical background

In addition to the overview given in Chapter 1.1, further details of the policy and legislative background are provided below.

2.1 The 2014 amendment of the GWD

The process of developing a GWWL was initiated following the amendment of the existing GWD by Directive 2014/80/EU. Article 10 of the GWD states that Annexes I and II should be reviewed by the Commission every six years. Part of the latest review procedure was based on a MS consultation coordinated by WG GW (CIS Technical Report No. 7[1]), the outcomes of a stakeholder conference held in Brussels in October 2013 (Bogaert, Adriaenssens and Scheidleder, 2013) and a report produced by Scheidleder and Bogaert (2013).

Outcomes from these activities identified that new scientific and technical information on substances of concern might require adjustment of the pollutant lists (GWD Annex I and Annex II, part B) and that the knowledge base should be increased on the occurrence and fate of substances of concern.

The first Annex I/II review resulted in a few changes; two substances (nitrite and total phosphorous) were added to Annex II but none to Annex I. Recital 1 of the 2014/80/EU noted that *"based on the first review under Article 10 of Directive 2006/118/EC, not enough information is available to set new groundwater quality standards in Annex I to that Directive for any pollutants, but technical adaptations in accordance with Article 8 of that Directive are necessary in its Annex II."*
As noted in Chapter 1.1, Recital 4 of the 2014/80/EU reaffirmed the need for review of new data on groundwater pollutants and first used the term 'Watch List' in this context.

2.2 Purpose and scope of the GWWL

After the amendment to the GWD in 2014, the WG GW initiated discussions on how to implement the GWWL, which established the purpose of the GWWL as follows, to:

- Identify new/emerging substances in groundwater which have the potential to cause a failure of a WFD objective, based on new information;
- Assist MS in selecting substances to improve groundwater monitoring programs;
- Provide information to support future European Commission reviews of Annexes I and II of the GWD.

The aim of the GWWL is to support MS in developing their monitoring programmes so that sufficient data are collected to improve the evidence base across the EU on substances for which there is currently not sufficient data, information or knowledge. This improved evidence base can then be used for further risk assessment and the establishment of TVs, and contribute to the identification of

[1] CIS Technical Report No. 7: Technical report on recommendations for the review of Annex I and II of the Groundwater Directive 2006/118/EC.

new substances (pollutants) of EU-wide concern that may require GWQS to be set following a future review of the GWD annexes.

The development of a GWWL is not an isolated activity, but can be seen as one aspect of groundwater protection, adding to the existing WFD/GWD protection framework and linking with other processes such as monitoring and characterisation, as well as works and results for the 'fitness check (evaluation)' of the WFD, daughter directives and Floods Directive in 2019. The detailed requirements and interpretation of these processes and objectives are set out in a number of existing CIS guidance documents (GD), which are listed in the references of this report. Of particular note are GD15 (Monitoring), GD17 (prevent or limit), GD18 (Status and Trends) and GD26 (Risk Assessment and Conceptual Models).

One of the key factors in meeting good status of a groundwater body is to ensure that effective 'prevent or limit' measures are applied to protect groundwater from potentially polluting activities. Thus, whilst the GWWL may influence the operational and surveillance monitoring programs, it will also inform monitoring associated with any 'prevent or limit' measures.

Taking a wide view of the GWWL in terms of its use in meeting WFD objectives, a substance could be a candidate for the GWWL where it has the potential:

1. Through its (intended or unintended) input to groundwater, to compromise the 'prevent or limit' objective or represent a wider risk to the groundwater body;
2. To cause deterioration from good to poor chemical status, taking account in particular of the human uses of groundwater (e.g. as a source of drinking water), and of impacts on Groundwater Associated Aquatic Ecosystems (GWAAE) and Groundwater Dependent Terrestrial Ecosystems (GWDTE) (as outlined in GD18);
3. To prevent a groundwater body from achieving good status;
4. To produce a statistically and environmentally significant upward trend in concentrations;
5. To cause failure of objectives for protected areas, including the WFD Article 7(3) objective for abstractions used for drinking water supply (which could result in the need for further treatment).

If it has been determined that a substance has caused a failure of one of the above objectives or has, as a result of the characterisation process, been identified as posing a high risk of causing such a failure, then this substance is a pollutant that requires an immediate response by the MS. This includes the establishment of TVs. If a pollutant is shown to be of Europe-wide concern, it is for the European Commission to assess whether this substance is to be put into Annex I or II of the GWD.

The main focus of the GWWL is on substances that are currently not considered in the WFD risk assessment process due to lack of information on their presence in the environment (monitoring data) and/or their properties and fate in the environment. They have therefore yet to be considered in status assessment but may have the potential to cause harm. The process for addressing this is set out in Chapter 3.

The whole procedure for the development and implementation of the GWWL, including the criteria, data and methodology used, and the results, has to be transparent for MS and other stakeholders.

The GWWL is not:

- A long list of substances that is generated by the substance prioritisation process described in Chapter 3 (methodology),
  - but rather a smaller subset (for example n=30) of compounds decided on through the prioritisation process;
- A list of substances that will go automatically for consideration under Annexes I and II.
  - There will, by definition, be inadequate data for this on substances on the GWWL;
- A permanent list of substances.
  - The GWWL will be reviewed periodically and substances can be deselected based on the prioritisation process outlined in this paper;
- Meant as a 'blacklist' of substances which are of proven high concern for groundwater in the EU.
  - The GWWL monitoring data generated will be available for use in a later, and separate, risk assessment process.

2.3 Prevention, pollution and harm

As a spatially extensive natural resource, groundwater may be exposed to a wide variety of sources of pollution. Due to both the slow downward movement of water in the unsaturated zone and the long residence time of groundwater within many aquifers, once polluted, groundwater may take a long time to recover, as it may not be feasible or cost effective to take remedial action. This necessitates a focus on the prevention of groundwater pollution, as reflected in GWD Recital 1 (noted in Chapter 1.1) and Recital 5:

> *"In order to protect the environment as a whole, and human health in particular, detrimental concentrations of harmful pollutants in groundwater must be avoided, prevented or reduced."*

Article 1 of the GWD also makes reference to the need to "prevent and control groundwater pollution". This focus on prevention can also be set within the context of the precautionary principle and the principle that preventative action should be taken, as set out in Article 191 of the Treaty on the Functioning of the European Union and reiterated in Recital 11 of the WFD. The establishment of a GWWL is therefore consistent with a precautionary approach to the potential presence of harmful pollutants. This raises the issues of what is a pollutant and what is harmful, including what factors should be considered in the context of harm.

Under the WFD,

> "'*Pollutant' means any substance liable to cause pollution, in particular those listed in Annex VIII* (Indicative List of the main Pollutants)" (Definition 31), and
>
> "'*Pollution' means the direct or indirect introduction, as a result of human activity, of substances or heat into the air, water or land which may be harmful to human health or the quality of aquatic ecosystems or terrestrial ecosystems directly depending on aquatic ecosystems, which result in damage to material property, or which impair or interfere with amenities and other legitimate uses of the environment*" (Definition 33).

Harm is thus considered in the context of a very wide range of dependent receptors and uses. In terms of focusing on groundwater pollution, for which there is no specific definition in the WFD or

GWD, the receptors could be groundwater itself or those ecosystems directly dependent on groundwater and the direct use of groundwater itself. This is underpinned by WFD Annex V, 2.3.2, which sets out the conditions for good groundwater chemical status, noting the need to avoid failure of the objectives of associated surface waters (GWAAE) and significant diminution of the quality of these, as well as avoiding any significant damage to GWDTE. In GWD Article 4(2), the extensive use of groundwater as a relatively clean source of drinking water in the EU is emphasised by the inclusion of the Drinking Water Protected Area (DWPA) objective (WFD Art. 7(3)) in the conditions for meeting good groundwater chemical status. These conditions also include the impairment of human uses by pollution of a groundwater body.

Therefore, in the context of the GWWL, a groundwater pollutant is a chemical substance that presents a risk of harm to human health, to associated surface waters and groundwater dependent ecosystems or for groundwater use. Substances from a wide range of chemical groups and uses may in principle be considered. Examples would include substances such as pharmaceuticals, PFAS, such as perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA), pesticide degradation products so far not explicitly regulated in the Groundwater Directive (i.e. non-relevant metabolites), hormonally active substances which are increasingly being detected in groundwater, even at very low concentrations (<0.1 µg/l)[2] and other new industrially-synthesised chemicals. A key issue is that for many of these new or emerging[3] substances there is insufficient data to determine whether and/or at what concentration they pose a significant risk of harm to the receptors noted above.

2.4 Conceptual models and monitoring

During the 2014 GWD review, an explanatory note[4] was written by the EC, accompanying the revision proposal. This note states that substances on the GWWL do not necessarily need to be monitored across the EU, but that "*the mechanisms should focus on (…) a limited number of monitoring sites, but should provide representative data.*"

To establish monitoring for the GWWL in an effective way, risk assessment and conceptual models should be used (see GD 15 and GD26) to identify where new/emerging substances may be present (localised or widespread) or absent. For example, these substances would not normally be expected in significant concentrations in sparsely populated, low intensity use or pristine environments, but may be encountered in more intensively developed areas, whether this be for household, industrial or agricultural purposes. The use(s) of substances will be important. For example, veterinary medicines may be found in rural areas whereas human medicines are more likely to be encountered in urban areas and close to septic tank and waste water treatment plant (WWTP) discharges. This kind of information should be considered when selecting monitoring points. However, in keeping

2 For many of these substances data on the long term effects on humans and ecosystems are sparse (BIO 2013, *Study on the environmental risks of medicinal products, Executive Agency for Health and Consumers)*

3 The term 'emerging pollutants' in this context refers to substances previously not considered or known to be significant to groundwater (in terms of distribution and/or concentration) which are now being more widely detected.

4 Explanatory Note accompanying the draft proposal for a Commission Directive amending Annex II to Directive 2006/118/EC of the European Parliament and of the Council on the protection of groundwater against pollution and deterioration.

with good risk assessment practice, it is important that representative monitoring be undertaken across the risk spectrum, to ensure the conceptual model and its underlying assumptions are tested. Practical and budgetary constraints that are common to the implementation of monitoring programmes also have to be taken into account.

The Groundwater body (GWB) Surveillance Monitoring network is used to support the WFD Article 5 characterisation of GWBs and should also provide information for the assessment of long term trends in naturally occurring substances, and in pollutant concentrations resulting from human activity (GD15). As such, it should be suitable for GWWL monitoring at the GWB scale. The same applies to the Operational Monitoring network, which is used between periods of surveillance monitoring e.g. to assess GWB at risk. However, these networks may not necessarily detect point source pollution, such as sewage treatment works discharges. For specific substances, and informed by the nature of their specific input activity, MS might consider including 'prevent or limit' monitoring sites as well.

'Prevent or limit' monitoring is used to demonstrate that the ‘prevent or limit’ objectives are being met and, where they are not, to characterise site-specific impacts and design and assess remedial action programmes. This type of monitoring therefore has the potential to detect localised point-source impacts of new/emerging substances and provide information to assess the inputs and impact on groundwater. The acceptability of inputs is determined by the nature of the substance, the type of input and whether pollution as defined by the WFD or other EU Directives occurs. The need for and extent of 'prevent or limit' monitoring will in many cases be determined by individual MS national legislation on the permitting of potentially polluting activities and the remediation of contaminated sites (GD17).

Data from sampling points used to monitor Drinking Water Protected Areas (DWPA) under the WFD/GWD could also be included because they may give additional information and be linked with monitoring results for drinking water resources under the Drinking Water Directive (DWD). Water operators may further have non-statutory investigational or operational monitoring data that could also be of interest. In any case, confidentiality issues have to be addressed.

At this stage, monitoring for GWWL substances is not obligatory under the WFD or GWD, but the previously mentioned explanatory note states that “*Once the experience of the Watch list mechanism is more mature, an obligatory mechanism might be considered*.” If characterization indicates that there is a significant risk of failure of WFD environmental objectives from a substance, then this substance should be considered within the existing WFD/GWD mechanisms, i.e. TVs established, and considered during future review of the GWD for inclusion in a revised Annex I or II. Where a substance is considered to pose a risk to groundwater this should trigger its inclusion in the surveillance and operational monitoring programs.

2.5 Monitoring and analytical techniques

Monitoring results may reveal that certain substances not expected to be found in groundwater are in fact present, thus providing a reality check and raising questions about the conceptual understanding of the sources, pathways, fate and transport of these substances. Monitoring data is essential for the GWWL process as well as for exposure assessment, but groundwater monitoring can be costly and there are practical limits to the range of substances that can be monitored.

As analytical techniques improve, previously undetected organic and inorganic pollutants are being observed in the water environment. These include nanomaterials, pesticides and their transformation products, pharmaceuticals and their transformation products, industrial additives and by-products, personal care products and fragrances, water treatment by-products, flame/fire retardants and surfactants, as well as caffeine and nicotine metabolites and hormones. Many of the compounds are relatively small polar molecules which are not effectively removed by drinking water treatment even when equipped with activated carbon. Some of these pollutants can have negative human or ecological health effects and therefore there is a need for better understanding of their fate in environmental systems and the risks they pose.

A particular concern is the cost of developing and then applying analytical techniques to identify many of the substances noted above, which are often found only at low concentrations, but which could also be harmful at low concentrations, individually or as mixtures.

Some existing Environmental quality standards (EQS) were originally set at or close to the Limit of Detection (LOD) or Limit of Quantification (LOQ) (for example, the 0.1 µg/l limit for pesticides and their relevant metabolites, degradation and reaction products or the 1.3×10^{-4} µg/l annual average EQS surface water limit for perfluorooctane sulfonic acid and its derivatives (Directive 2013/39/EU)) and at such concentrations, the sampling procedure and the sensitivity of analytical techniques becomes a major concern. Data quality issues will be discussed in more detail in Chapter 4.

The overall cost and resource implications of monitoring are strong drivers for the sharing of monitoring data between MS for the purpose of developing a GWWL. The lessons learnt from compiling data from different MS during the pilot studies are described in Chapter 4.

In addition to using quantitative accredited laboratory methods, it is also possible to make use of semi-quantitative scanning, or screening techniques. These techniques enable a very wide range of substances to be identified in a single sample. This ability to consider such a broad range of substances makes these techniques particularly well suited for GWWL monitoring. From just one sample, some 1000 substances can potentially be detected using one or two analytical methods. There are two main types of screening: GC-MS (gas chromatography-mass spectrometry) and LC-MS (liquid chromatography-mass spectrometry). By using the two techniques together, a very broad range of substances can be assessed. LC-MS is particularly useful for detecting more polar organic substances such as PFOS or non-relevant metabolites of pesticides. However, caution is needed when interpreting the results of scan methods as the results are semi-quantitative and cannot therefore directly be used to assess groundwater body status. The strength of the scan method(s) is

that it can detect the presence of a substance and provide an indication of the magnitude of its presence. This can then be used to better target monitoring and improve its cost-effectiveness.

2.6 Interface with other regimes and projects

Surface Water Watch List

Many substances that may become candidates for the GWWL, such as pesticides, biocides, industrial compounds and heavy metals are already subject to regulation under other EU legislation, in particular that relating to surface water quality. Thus, there may be environmental quality standards and other assessment processes that may be of interest to, and inform, the GWWL process.

For surface water, a Watch List mechanism has been established under the Environmental Quality Standards Directive (2008/105/EC as amended by Directive 2013/39/EU), leading to the adoption of the first and second surface water watch lists: Decisions (EU) 2015/495 and (EU) 2018/840, respectively. As noted in the introduction to this report, the surface water and Groundwater Watch Lists and their usage are not the same; the key differences are outlined in Table 2.1. Despite these differences, some of the technical data and assessment process used to determine whether a substance appears on the surface water Watch List could be relevant to the GWWL process.

Drinking Water Directive

The Drinking Water Directive (Directive 98/83/EC as amended by Regulation (EC) No 1882/2003, Regulation (EC) No 596/2009 and Commission Directive (EU) 2015/1787) requires Member States to assess the need to monitor additional parameters (Article 7(6)) and to set additional quality standards for additional parameters (Article 5(3)) when relevant with respect to the protection of human health. According to the review of Annex II (EU 2015/1787), monitoring of drinking water resources should include a risk-based approach. The risk management approach and the list of parameters that have to be monitored could soon be amended as detailed in the recent Commission proposal to further revise the drinking water directive (recast proposal, COM/2017/0753 final - 2017/0332 (COD)). Additional parameters should be included in the monitoring program when relevant for human health. The general goal of the DWD is to ensure that drinking water is wholesome and clean. In general, there is a strong focus on the precautionary principle when it comes to 'avoidable' contaminations. Drinking water should be as clean as possible in addition to being safe. The consumer's acceptance of drinking water quality is an important factor to be taken into account.

The GWWL concept clearly supports Member States in the implementation of the DWD since it will identify relevant compounds and consider the hazards associated with those compounds (see Chapter 3.1). The protection of human health is one of the goals of the GWD since groundwater is one of the most important sources of drinking water across Europe. Therefore, in addition to an analysis of ecotoxicological hazard, a (human) toxicological assessment is foreseen in the GWWL concept. In order to ensure synergy between the GWWL concept and DWD implementation, it is crucial to have a common understanding and vision of the relevance of a compound for human health and for drinking water policy. Close and good cooperation with the competent authority for drinking water quality is therefore highly recommended.

Table 2.1 Comparison between Surface Water and Groundwater Watch Lists

	Surface Water Watch List	**Groundwater Watch List**
Source Directive	2013/39/EU – in the Directive articles	2014/80/EU – in recital 4
Purpose	To gather EU-wide monitoring data *"for the purpose of supporting future prioritisation exercises in accordance with Article 16(2) of Directive 2000/60/EC…"*	"*…to increase the availability of monitoring data on substances posing a risk or potential risk to bodies of groundwater, and thereby facilitate the identification of substances, including emerging pollutants, for which groundwater quality standards or threshold values should be set*"
Decision process (including periodic review and format of WL)	Technical work by EC (JRC – Joint Research Centre) with input from CIS WG Chemicals. Review every two years. Proposal subject to vote in WFD Regulatory Committee before adoption by the Commission as Commission Implementing Decision.	Technical work by CIS WG GW to develop a recommended approach for establishing a GWWL. Endorsement of concept paper by WG GW and submission to SCG. Endorsement of watch list by SCG and Water Directors (CIS process).
Monitoring/reporting by MS obligatory?	Yes	No
Follow-up: setting of standards?	Environmental Quality Standard (EQS) set in Priority Substances Directive (2008/105/EC) if a WL substance is identified as a priority substance (PS) during next (six-yearly) review of the PS list. Monitoring data might lead some MS to identify substances as river basin specific pollutants and set national standards instead.	MS consider establishing TVs using existing GWD mechanism where a risk to WFD objectives has been identified. Consideration of sufficiently monitored and detected substances for inclusion in Annex I or II during European Commission six-yearly review of GWD.
Substances	See Commission Implementing Decision (EU) 2018/840 of 5 June 2018 establishing a watch list of substances in the field of water policy pursuant to Directive 2008/105/EC.[5] 1. 17-Alpha-ethinylestradiol (EE2) (CAS 57-63-6) 2. 17-beta-estradiol (E2) (CAS 50-28-2) 3. Macrolide antibiotics (erythromycin, clarithromycin, azithromycin) 4. Methiocarb (CAS 2032-65-7) 5. Neonicotinoids (imidacloprid, thiacloprid, thiamethoxam, clothianidin, acetamiprid) 6. Metaflumizone 7. Amoxicillin 8. Ciprofloxacin	None yet defined

3. The Groundwater Watch List process

3.1 Outline and structure

The GWWL process was initiated by the European Commission, in accordance with Recital 4 of the 2014 amendment to the GWD. The GWWL process aims to increase the availability of monitoring data on (anthropogenic) substances to identify those substances posing a risk or potential risk to groundwater. At the end of this process, substances identified should be considered as part of WFD/GWD implementation, e.g. TVs established by MS. They should also be considered during the European Commission's 6-yearly review of Annexes I and II of the GWD.

The CIS Working Group on Groundwater (WG GW) was mandated to elaborate a concept for the establishment of this Groundwater Watch List (GWWL). A sub-group of WG GW – the Group of Volunteers GWWL - developed a simple and transparent methodology which took into account that the Groundwater Watch List process is a voluntary process and Member States (MS) and Associated Countries (AC) are free to participate. The Group of Volunteers is composed by representatives of MS, AC, Stakeholders and the Commission, and regularly reports to WG GW. The methodology developed was tested via two pilot studies for Pharmaceuticals and per- and poly-fluoroalkyl substances (PFAS). The present concept will be applied for the establishment of the first Groundwater Watch List in 2019 and – based on new experiences – adapted regularly.

The concept for the determination of a GWWL brings together current knowledge about:

- Detection of new/emerging pollutants in groundwater;
- Relevant properties of the pollutants (mobility, persistence);
- Their sources and their pathways into the environment; and
- Toxicity/ecotoxicity considering properties and criteria such as Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB), Persistent, Mobile, Toxic (PMT), Carcinogenic, Mutagenic and Reprotoxic (CMR), Endocrine Disrupting (ED) etc.

The GWWL process aims to enlarge the current knowledge and data on (new/emerging) pollutants in groundwater. In addition, the GWWL process will support MS in improving their monitoring programmes. Based on the "Groundwater Watch List process" (see below) monitoring data from all participating countries (PC) will be aggregated and made available for central review. Information will be shared with MS/AC on the occurrence of (new/emerging) substances in other European countries. Information on any observed pathways of specific substances into groundwater will help MS/AC to identify regions where there might be high occurrence, and inform their characterisation and risk assessment work and monitoring programme design.

Each element of the Groundwater Watch List process (Figure 3.1) consists of individual steps identifying substances posing a potential risk to groundwater, GWDTEs or GWAAEs or the uses of groundwater. The Watch List process may be applied for single substances, chemical groups of substances or use groups of substances.

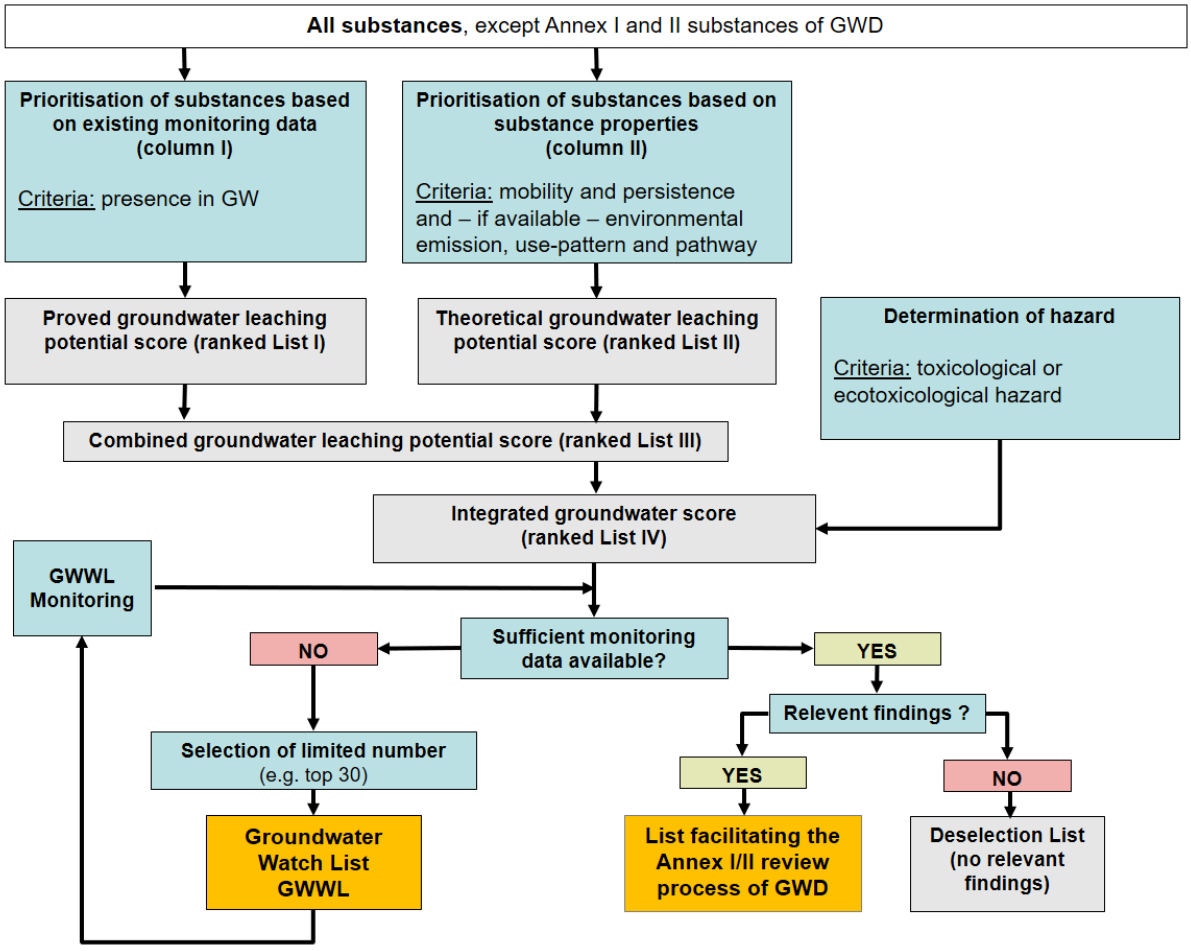
[5] https://ec.europa.eu/jrc/en/science-update/updated-surface-water-watch-list-adopted-commission

The collection of substances analysed in PC GW monitoring programs (local or regional) in Column I leads to a ranked List I (Proved groundwater leaching potential score). In Column II substances are scored and ranked to a List II (Theoretical groundwater leaching potential score) according to their potential ability to reach groundwater based on their properties (and if possible their environmental exposure). In Column I and II no substance is eliminated from further processing.

The scored and ranked Lists I and II are combined to a scored and ranked List III (Combined groundwater leaching potential score) expressing the groundwater leaching potential.

For all substances of List III (Combined groundwater leaching potential score) a hazard assessment is carried out as the next step taking into account toxicity and ecotoxicity. The final result of the assessment is the scored and ranked List IV (Integrated groundwater score) based on the combined leaching potential and the hazard of the assessed substances.

Figure 3.1 Structure of the Groundwater Watch List (GWWL) process.



Based on the scored and ranked List IV (Integrated groundwater score) the following decision can be taken:

- A substance is sufficiently monitored and detected (i.e., the findings are “relevant”): The substance will enter the “List facilitating the Annex I and II review process of the GWD”. This list

supports the Commission's work on deciding which substances or groups of substances should be considered for Annex I or II of the GWD. If a substance is sufficiently monitored but no relevant findings have been detected, no further action is required (deselection).

- A substance is not sufficiently monitored: The substance will be considered to enter the Groundwater Watch List (GWWL) to be monitored in the frame of the MS monitoring programmes.

The results from the GWWL monitoring will furthermore be considered as an additional data set in the above mentioned decision process.

There could be substances highly ranked in List IV that cannot be analysed due to missing or cost-disproportionate analytical methods or methods with an inadequate Limit of Quantification (LOQ). These substances have to be addressed in different ways (e.g. flagged for further development of analytical methods) and might not be added to the GWWL.

It is expected that there will be knowledge gaps that impair the different assessments of the GWWL process. Some of them may be filled by initiation of monitoring, or targeted requests to the scientific community, MS or manufacturing groups for information. Some knowledge gaps might be addressed by further research. All knowledge gaps or missing information should be recorded systematically and pointed out to the Commission.

The explanatory note on the amendment to the GWD states that, on average, a substance would be likely to remain on the GWWL for several years. This suggests that at least annual monitoring of substances on the GWWL is necessary. If changes in groundwater quality are unlikely to occur within 2 to 4 years, the monitoring may be performed at lower frequencies but over a longer period.

The Watch List process will be cyclic. It is foreseen that the whole process is repeated every 6 years (Figure 3.2). Data collection by the GWWL activity will be continuous and MS and AC will be informed about the outcome regularly. Within the first five years of the cycle, monitoring results of the MS will be collected and assessed. Based on this assessment and considering the input from the GWWL activity (e.g. pilot studies and substance group assessments) a "List facilitating the Annex I and II review process of the GWD" will be set up.

Figure 3.2 Timeline of the Groundwater Watch List GWWL process.

Year	Activities and input of MS/AC to GWWL Group	Activities of GWWL Group	Output from GWWL Group to WG GW, EC, SCG, WD and MS/AC
	• Monitoring • Identification of groups of substances for further GWWL activities	Steering of Watch List Cycle • Selection of substances for data collection • Data collection • Data assessment • Substance selection for GWWL • Substance selection for List facilitating Annex I and II review process	• Groundwater Watch List • List facilitating Annex I and II review process
Year 1	Setup monitoring		
Year 2	Monitoring —data→	Assessment of monitoring data —results→	Summary of data/results
Year 3	Monitoring —data→	Assessment of monitoring data —results→	Summary of data/results
Year 4	Monitoring —data→	Assessment of monitoring data —results→	Summary of data/results
Year 5	Monitoring —data→	Assessment of monitoring data —results→	Summary of data/results
Year 6	Monitoring —data→	Set up of GWWL and List facilitating Annex I/II review process →	GWWL and List facilitating Annex I/II review process
		Following GWWL Cycle	

3.2 Ranking based on existing monitoring data (Column I)

Column I comprises the collection of data on substances already analysed and detected (and also not detected) in groundwater by PC. Detection of a substance in groundwater demonstrates that it has the ability to reach the groundwater table, and if it is a pollutant, also the potential to harm groundwater resources and its groundwater receptors.

Aggregated data are delivered by MS/AC voluntarily and are compiled in an agreed format. As well as collating quantitative results from accredited laboratories, semi-quantitative GC-MS and LC-MS scan data can also be collated as part of Column I. The summary-report of data is updated regularly and presented to the Groundwater Watch List Group, WG GW and MS.

Based on data collated in Column I (List I), as a first step of the GWWL procedure, substances of specific concern could be identified including the number of sites where a substance was detected and its concentration.

The Column I data needs to be supplemented by identifying the pathways to groundwater of the detected substances. The relevant information should be collected through a targeted request or a conceptual model development/refinement. Known pathways or potential pathways should be

summarized and where the pathway is uncertain, relevant information about the location and catchment of monitoring locations where a substance was detected should be collected. Knowledge of pathways to groundwater is helpful in assessing whether the occurrence of a substance or a group of substances is a local, regional or Europe-wide issue. This information will contribute to the decision on whether a substance or group of substances should be included in the "List of substances facilitating the Annex I and II process" for future consideration when Annex I and Annex II of the GWD are reviewed. Additionally, this information is helpful for MS in the task of aligning their monitoring programmes to locations/situations where these pathways might be relevant and where there is a risk of specific substance(s) entering groundwater and causing harm.

The output of Column I is a ranked and scored list (List I – Proved groundwater leaching potential score) based on the number of countries where a substance has been detected and the percentage of monitoring sites with detections.

The procedure is detailed in Annex 1.1.

3.3 Ranking based on substance properties (Column II)

Column II is an assessment of the theoretical ability of a substance to reach groundwater, based primarily on the intrinsic properties of that substance. In principle, Column II can be applied to all substances. For substances that are not or are only rarely analysed in GW (e.g. new and/or emerging substances) and thus cannot be assessed in Column I, Column II delivers additional results. In order to assess the theoretical groundwater leaching potential presented by such substances, information on persistence, mobility and usage is required (Stuart et al., 2011). To identify substances that can easily infiltrate aquifers, persistence and mobility are the most relevant properties (e.g. Gustafson, 1989):

- The mobility of a substance, expressed by its potential not to be adsorbed to organic and (clay) minerals or oxides (ranking based on the ionic form of the molecules for polar and charged compounds);
- The persistence of the substance in the soil and the subsurface, expressed by the half-life in soil or water/sediment depending on the physico-chemical conditions of the environment and the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) classification.

In general, substances with a high persistence and a low absorption coefficient have a high potential to infiltrate groundwater. Thus, to assess theoretical groundwater leaching potential, persistence and mobility of substances have to be considered.

The suggested prioritisation procedure is a classical point system ranking. Sub-scores are assigned to each available indicator for persistence and mobility. A score titled "Theoretical groundwater leaching potential" is calculated based on these sub-scores. The output of Column II is a ranked and scored list (List II – Theoretical groundwater leaching potential score). Substances that have the highest potential to reach GW are those with the highest leaching potential scored in List II. The procedure is detailed in Annex 1.2.

Further aspects to consider are the emission to the environment of the specific substance, the use-pattern and the most probable pathway to groundwater (if available). If the emissions are unknown, the amount of the substance sold at national and EU level – including the amount of the substance in goods - could be considered. Substances used in closed processes (i.e. with no intentional release to the environment) might be less relevant compared to those applied directly to the environment (i.e. air, soil and water) such as pesticides or used by humans or in animal husbandry, e.g. pharmaceuticals. Irrigation with wastewater, groundwater recharge with treated wastewater, land spreading, forced bank filtration etc. might be important pathways of groundwater inputs, and should be considered when assessing exposure.

The pilot studies on pharmaceuticals and PFAS showed the difficulties in gathering this information. For this reason, the actual concept doesn't yet consider environmental emissions, use-patterns and pathways (see Annex 1.2 for further considerations).

3.4 Combined groundwater leaching potential score (List III)

The assessments of Column I and II (scored and ranked Lists I and II) are aggregated to a scored and ranked List III (Combined groundwater leaching potential score). If results of both assessments are available, the resulting score is the mean of the proved and the potential leaching score.

If only one dataset is available (e.g. no monitoring data is available) the combined score is equivalent with the proved groundwater leaching potential score or the theoretical groundwater leaching potential score. If only data from theoretical leaching assessments are available, expert judgement may be necessary to assess the reliability of the ranking result, especially if e.g. usage data is missing or potential pollution pathways are unclear.

The procedure is detailed in Annex 1.3.

3.5 Determination of hazard

A hazard score will furthermore be determined for all substances assessed in List III taking into account data on human toxicity, ecotoxicity and other relevant properties, e.g. PBT, PMT, CMR and ED potential.

The aim is to identify substances that might pose a risk to the environment, human health or the potential use of groundwater, i.e. they are determined as being pollutants. The environmental and human toxicity properties of substances are both important in assessing hazard. Three main indicators are identified for assessing the environmental and health hazards of substances (after Dulio and Von der Ohe, 2013). Human health hazard evaluation will be conducted using the same methods as used by the competent authorities for drinking water (DWD Article 12 Committee).

PBT/vPvB criteria

Substances that are at the same time Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) pose an additional risk to the environment. Besides their toxicity, they can remain present in the environment for a long time and/or, once they are in the environment, they

can quickly accumulate in biota. The first source of information for the designation of a substance as PBT or vPvB is its classification as a PBT or vPvB compound in international conventions and EU legislation (Stockholm Convention, Aarhus Convention – UNECE[6], and Annex XIII of the REACH Regulation). Any new development/revision in the PBT criteria should be taken into account. In addition, the P, B and T criteria should be assessed individually in order to identify substances with PBT or vPvB potential, even if they are not classified as PBT/vPvB compounds in the international lists. However, even for this assessment a substance must fulfil all the criteria at the same time to be classified as potential PBT or vPvB on EU lists.

Carcinogenicity, Mutagenicity and Reprotoxicity (CMR) properties

CMRs are substances that are carcinogenic, mutagenic, or toxic to reproduction, and which therefore have inherent properties that can cause cancer, alter DNA or damage reproductive systems. These properties correspond to Article 57(a-c) of REACH Regulation. The classification of a substance as carcinogenic, mutagenic or reprotoxic under the EU Regulation on Classification, Labelling and Packaging (Regulation (EC) 1272/2008 in its current version) or the other international classification systems (e.g. USEPA, IARC) could be used here as an indicator of toxicity to human health.

Endocrine Disrupting effects (ED)

Evidence of Endocrine Disrupting effects for the substances is taken into consideration in the final score. Any new development/revision in the assessment of ED properties should be taken into account.

Substances are ranked depending on their significance as a hazard to human health and/or the environment. The prioritisation is based on the calculation of a "hazard" score that merges the three indicators PBT, CMR and ED.

At the end of the hazard assessment for each of the substances considered, information on its hazard to the environment, to human health and the use of groundwater will be available.

The procedure is detailed in Annex 1.4.

3.6 Integrated groundwater score (List IV)

As a final list for decision making, an Integrated ranked and scored list (List IV) is established as a combination of the Combined groundwater leaching potential score (List III) and the hazard score for

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[6] Stockholm Convention on Persistent Organic Pollutants (POPs) [1] was adopted in May 2001 in the framework of the United Nations Environment Programme (UNEP). The European Union and its Member States[2] are parties to the Convention[3] and the provisions of the Convention have been implemented in EU law by Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants.

[1] http://www.pops.int/documents/convtext/convtext_en.pdf.

[2]The 1998 Aarhus Protocol on Persistent Organic Pollutants (POPs) under the Convention on Long-range Transboundary Air Pollution (CLRTAP)

[3]http://www.unece.org/env/lrtap/pops_h1.html

the same substances. List IV is calculated as the mean of the leaching and the hazard score. If a hazard score cannot be calculated, the Integrated groundwater score is calculated based on the monitoring and/or leaching score. In this case the Integrated groundwater score is flagged for further assessment and expert judgement on reliability of ranking results.

The Integrated groundwater score is the basis for the selection of substances for the Groundwater Watch List and for the List facilitating the Annex I and II review process of the GWD.

The procedure is detailed in Annex 1.5.

3.7 Selection of substances for the Groundwater Watch List

In List IV, substances are ranked according to their Integrated groundwater score. Prior to selecting substances for the Groundwater Watch List, all substances with sufficient monitoring data available will be identified. These substances have to be considered to join the List facilitating Annex I and II review process of the GWD (see chapter 3.8) or are subject to deselection (see chapter 3.9).

The remaining substances are not yet (sufficiently) monitored and potential candidates for the Groundwater Watch List. They potentially compromise the objectives of the WFD/GWD and warrant the collection of representative groundwater monitoring data at EU level. To keep the Groundwater Watch List manageable, the list should comprise only a limited number (e.g. 30) of substances. Predominantly top ranked substances of List IV without sufficient monitoring data should go to the Groundwater Watch List. In addition, it may be possible to add further substances to the Groundwater Watch List in case of robust supporting evidence that a (new) substance or group of substances not top ranked in List IV (or of unknown hazard) is nevertheless worth to be intensively monitored (criteria to be defined).

MS/AC will be asked to monitor the substances of the Groundwater Watch List on a voluntary basis. Monitoring should be carried out over a sufficiently long period and include sites where the occurrence of monitored substances can be expected according to the conceptual model. As described in Figure 3.2, monitoring results should be reported to the EC (or an organisation in charge) regularly (e.g. once a year) on a voluntary basis.

At the end of the monitoring period GWWL substances will be individually assessed and allocated to one of the following three groups (Figure 3.1):

- Substances to be considered in the review process of Annex I/II of the GWD (List facilitating the Annex I/II review process of the GWD), as relevant detections were recorded and sufficient monitoring data were collected;
- Substances which still have insufficient and/or inconclusive monitoring data and which need to remain on the GWWL;
- Substances deselected from the GWWL process (deselection List), as the monitoring data does not show relevant detections and sufficient monitoring data were collected.

MS/AC must be informed about the reasons for adding or removing substances to/from the Groundwater Watch List.

The selection procedure is detailed in Annex 1.6.

3.8 Selection of substances for the List facilitating Annex I and II review process of the GWD

The result of the complete GWWL assessment process will be a list of substances scored and ranked according to their potential to compromise the objectives of the WFD/GWD (List IV). The top ranked substances have the highest potential to compromise the WFD/GWD objectives. They are already present in groundwater and/or have at least a medium or high potential to reach groundwater. In addition, they present a hazard based on toxicological or ecotoxicological criteria as described under Chapter 3.5.

Sufficiently monitored substances of List IV have potentially to be considered by the EC in the review of Annex I/II of the GWD. Therefore, a "List facilitating the Annex I and II process" as an output of the GWWL process will support EC review of the GWD by identifying substances or groups of substances that may be considered for future regulation via the GWD. This list has to be reported to MS/AC regularly.

If the outcome of the EC review is that a substance (or group of substances) is not added to Annex I or II, MS should decide whether to continue to monitor these substances on a voluntary basis (and set TVs) based on the risk that these substances present. When the EC adds a substance to Annex I or II, monitoring will be obligatory unless it can be clearly demonstrated that there is no risk to groundwater at MS level.

The selection criteria are detailed in Annex 1.7.

3.9 Deselection of substances from the Groundwater Watch List process

The primary aim of the Groundwater Watch List is to collect sufficient monitoring data to assess whether a substance or group of substances should be considered for the review of Annexes I and II of the GWD (via the List facilitating Annex I/II process) or not. During each GWWL cycle, MS will deliver monitoring data. At the latest, five years after the start of a monitoring cycle, the existing data per substance have to be evaluated. The EC (or an organisation in charge) supported by WG GW will check regularly whether the amount of monitoring data for a substance assessed in the GWWL process is sufficient to be considered as representative at EU level. A substance could be considered as not of potential concern and be put on the deselection List when this substance is not detected after extensive monitoring. Consequently the substance will be deselected from the Groundwater Watch List Process unless new evidence suggests otherwise.

In general, a substance is also removed from the Groundwater Watch List Process when the substance is added to the List facilitating the Annex I and II review process of the GWD .

The deselection criteria are detailed in Annex 1.8.

4. Data capture and quality issues

4.1 Data sources

It is important that the monitoring data reported is reliable and of good quality. MS are responsible for the quality of their data and should ensure that sampling and sample analysis for the submitted data has been carried out according to accepted standards (e.g. GD15).

Data should primarily relate to the MS WFD monitoring programmes, but can also include semi-quantitative GC-MS and LC-MS data or specific monitoring programmes/studies (e.g. pharmaceuticals), and summary details should be provided (such as whether this is surveillance/operational or 'prevent or limit' type monitoring). Where feasible, to get a broader overview of the occurrence of a substance in groundwater, additional data should be included, in agreement with the MS/AC, from for example, drinking water companies, health administrations and research institutes.

4.2 Data capture (conclusions from the pilot study on pharmaceuticals)

As described in the introduction, a Pilot Study on pharmaceutical substances in groundwater has been conducted in parallel with the development of this paper. As a first step, data on the analysis and occurrence of pharmaceutical substances in groundwater were collected via a very simple questionnaire and summarized monitoring results were collected. The initial report of the study (Marsland and Roy, 2016) concluded a number of requirements in relation to data capture and quality, including:

- Clear definition of the substance group under consideration;
- Guidance notes and a worked example to accompany the data request template;
- Provision of separate start and end date columns for the submitted dataset;
- Fixed formatting of text and numeric fields in the data template;
- Adaptation of the concentration/detection fields in the data template to the substance group of concern (smaller groups of substances may need to be identified);
- All substances submitted for inclusion should be accompanied by Chemical Abstracts Service (CAS) Numbers;
- An initial reference list of substances with unique CAS Numbers provided with the data request, which PC can refer and add to if necessary;
- Agreement on the definitions of Limit of Detection (LOD) and Limit of Quantification (LOQ), as noted in the Quality Assurance and Quality Control Directive (QA/QC Directive, 2009/90/EC), and how these should be used in the assessment process;
- A check by PC of the data submitted to confirm whether the LOQ has been used or not.

For the purposes of the pilot study, PC were requested to submit all available data and indicate the nature of the data sources, to assess the scale of the contamination when necessary. Nearly all datasets submitted originated from WFD monitoring or specific monitoring programmes.

A second pilot study for PFAS has been carried out. The data collection was based on a list of PFAS substances with CAS numbers. The PC were asked to fill out the same questionnaire as used for the pilot study on pharmaceuticals. In addition, PC were asked for information on the proven or estimated pathways of PFAS into groundwater and whether threshold values, limit values or comparable regulatory values exist for PFAS in their countries.

4.3 Data checking

The requirements and definitions noted in the QA/QC Directive for chemical analysis and monitoring of water status in accordance with the WFD are also applicable to the GWWL process, except where further specifications concerning relevant items of this Directive are defined in the context of this process (e.g. use of semi-quantitative analytical methods).

As noted in the pilot study report on pharmaceuticals, a significant uncertainty in the data provided could be due to the differences in reported LODs/LOQs. The report points out several possible explanations leading to the variety in LODs and LOQs and recommends that the values provided by the laboratories should be checked.

The following definitions for LOD and LOQ are given by the QA/QC Directive:

- ***LOD**: the output signal or concentration value above which it can be affirmed, with a stated level of confidence that a sample is different from a blank sample containing no determinant of interest.*
- ***LOQ**: a stated multiple of the limit of detection at a concentration of the determinant that can reasonably be determined with an acceptable level of accuracy and precision. The LOQ can be calculated using an appropriate standard or sample, and may be obtained from the lowest calibration point on the calibration curve, excluding the blank*.

To guarantee comparability and correctness, all monitoring data delivered should have a quality check by the PC (e.g. GD 15). It is not necessary to deliver the metadata mentioned below, but this should be available by request. The following criteria should be included in these checks:

- General
  - Clear identification of substance (agreed chemical name e.g. in European Chemicals Agency database, CAS Registry Number or other reference number in case this is not available) (minimum requirement);
  - Clear identification of the measurement unit (e.g. ng/l or µg/l) (minimum requirement);
  - Date of sampling and/or analysis;
  - Information about the sampling point (e.g. station number (unique ID)/name, aquifer type, well type, casing and screening material, depth and length of screen, depth of groundwater table; proximity and nature of known point source pollution sources/pressures, including abstraction/infiltration).
- Sampling
  - Done by national/regional recognised organisations;
  - Clear identification of accredited sampling methods (e.g. ISO 5667), or if not available of good practice methods;
  - Clear information about sample containers and substance-relevant preservatives;

  - Correct storage (e.g. temperature required and minimal time between sample collection and analysis).
- Water analysis
  - Done by national/regional accredited laboratories (e.g. EN ISO/IEC 17025);
  - Clear identification of accredited methods delivering acceptable LOQ. If no accredited methods are available, good practice methods should be used, as recommended by, for example, producers of substances, reference laboratories or research units;
  - Clear identification and traceability of reference materials (standards);
  - Reporting of LOQ and method used by the laboratory;
  - Additional reporting of LOD preferably if:
    - predicted no effect concentration (PNEC) is lower than LOQ, but not lower than LOD;
    - all measurements are below LOQ;
  - Measurement accuracy (at least to minimum targets as given by the QA/QC Directive);
  - Separate reporting about results of semi-quantitative GC-MS and LC-MS techniques.

4.4 Recent and 'historical' data

Recent and especially 'historical' data (>10 years old) may not fulfil all the criteria mentioned in paragraph 4.3. Data with too much uncertainty concerning essential criteria should be rejected (e.g. an incorrect name or missing CAS Number, incorrect or missing measurement units, missing LOQ and/or LOD etc.). However, even incomplete data, missing 'less essential elements', could provide useful information for certain purposes in the scope of the development of the GWWL, e.g. informing the need for improved monitoring. Where incomplete recent data is provided by a PC it will be up to the data collector to define the criteria for the use of the data.

4.5 Future monitoring

For future monitoring, it will be necessary to collect sampling and analysis methods of all new/emerging pollutants in a common (EU) database. There should be an agreement for every substance on common or at least comparable methods, with LODs and LOQs in the same range, leading to maximum possible quality assurance and control. Even though MS are ultimately responsible for the quality of their data, they should introduce the commonly accepted methods into their monitoring programmes. In the scope of an on-going dynamic process of the development of the GWWL, in the future only data that fulfil the agreed requirements should be provided and used.

As a first step to designing future monitoring, commonly accepted methods of chemical analysis of new/emerging pollutants should be identified in the scope of the Groundwater Watch List and related databases. This could also lead to a certain level of comparability of analytical monitoring of different water systems subject to the water quality objectives of the WFD.

When the minimum requirements for uncertainty of measurement according to Article 4(1) of the QA/QC Directive (maximum 50% of the quality standard, LOQ of maximum 30% of the quality standard) cannot be reached, a further adaptation and fine-tuning of analytical methods of best

practice is recommended. This will lead to a higher level of accuracy and reliability of the results for new/emerging pollutants.

List of references

EU legislation and CIS Guidance Documents

COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (in its current version).

DIRECTIVE 2000/60/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 October 2000 establishing a framework for Community action in the field of water policy.

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 Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Regulation (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.DIRECTIVE 2006/118/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on the protection of groundwater against pollution and deterioration.

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Annexes

Annex 1 Ranking and scoring procedures for individual substances or groups of substances in the GWWL process

A 1.1 Column I: Ranking based on existing monitoring data (List I – Proved groundwater leaching potential score)

GW monitored substances are ranked depending on results of their monitoring in GW. Two indicators are calculated to rank substances that have been monitored in GW:

- A) Number of countries with concentrations > LOQ
- B) Percentage of sites with concentrations > LOQ

The "Proved groundwater leaching potential score" is calculated for each monitored substance as mentioned in the table below

Indicators	Sub-score	Proved groundwater leaching potential score
A) Number of countries with concentrations > LOQ (Score N°PC)	(Values between 0 and 1) no country = 0 1 country = 0.2 2 countries = 0.4 3 countries = 0.6 4 countries = 0.8 5 or more countries = 1	**[(Score N°PC) + (Score %° sites)] / 2** Value between 0 and 1
B) Percentage of sites with concentrations > LOQ (Score %° sites)	(Values between 0 and 1) 0% 0 ≤ 0,25% 0.1 ≤ 0,5% 0.2 ≤ 1% 0.3 ≤ 2.5% 0.4 ≤ 5% 0.5 ≤ 10% 0.6 ≤ 25% 0.7 ≤ 50% 0.8 ≤ 75% 0.9 ≤ 100% 1	

The final score is a value between 0 and 1. It is calculated as follows:

Proved groundwater leaching potential score = [(Score N°PC) + (Score %° sites)] / 2

A 1.2 Column II: Ranking based on substance properties (List II – Theoretical groundwater potential leaching score)

Substances that have not been monitored in GW or for which data in GW are not sufficient, are ranked using theoretical indicators of their potential to leach into groundwater.

Point system procedure

It is suggested to use a classical point system procedure. Persistence and mobility indicators have the same weight in the final score. The ranking procedure is simplified to the maximum.
The table below shows indicators and corresponding individual scores for ranking substances depending on their persistence and mobility properties.

Indicators		Sub-scores	Theoretical groundwater leaching score
Persistence	Half-life ($t_{1/2}$) in soil	Value between 0 and 1 $t_{1/2}$ > 1 year = 1 4 months < $t_{1/2}$ < 1 year = 0.5 $t_{1/2}$ < 4 months = 0	Persistence score = MAX [(t1/2 sed) ; (t1/2 wat) ; (P/vP REACH regulation)]
	Half-life ($t_{1/2}$) in water/sediment	Value between 0 and 1 $t_{1/2}$ > 6 months = 1 2 months < $t_{1/2}$ < 6 months = 0.5 $t_{1/2}$ < 2 months = 0	
	REACH, Annex XIII of the Regulation No 1907/2006	Value between 0 and 1 vP = 1 P = 0.5 Not classified = 0	
Mobility	log_{koc}	Value between 0 and 1 log_{koc} < 1 = 1 1 < log_{koc} < 2 = 0.6 2 < log_{koc} < 3 = 0.3 3 < log_{koc} = 0	Mobility Score = MAX [(log_{koc}) ; (log_{kow})]
	log_{kow}	Value between 0 and 1 log_{kow} < 2 = 1 2 < log_{kow} < 3 = 0.6 3 < log_{kow} < 4 = 0.3 4 < log_{kow} = 0	

The final score is calculated for each substance from Column II as follows:

Theoretical groundwater leaching potential score = (Persistence score + Mobility score) / 2

Considerations on amount of substances released to the environment, use-patterns and pathways: For further assessments in the Groundwater Watch List Process additional parameters, such as the amount of a substance released to the environment and its use-pattern should be analysed (if information available).

In general, the amount of a substance that is produced, as well as the amount used has to be considered – if available - in determining the risk for the environment. As already established by assessments of substances under Regulation (EC) No 1907/2006 concerning REACH, annual consumption tonnage at European scale could be used to rank substances regarding their risk of being accidentally released in the environment. The pharmaceuticals pilot study (Marsland and Roy, 2016) showed that alternative indicators, such as the therapeutic dose, could also be used to determine the amounts used.

In addition, the pattern of use of a substance is relevant to assessing groundwater exposure. For example, pesticides are released directly into the environment and pose a risk through diffuse input via leaching from agricultural land or from other areas where they are applied. In contrast, many pharmaceuticals are used in smaller quantities and are mainly released to the environment via municipal WWTP, resulting in localised risks from point sources (leakage from WWTP or small (household) sewage treatment plants) and diffuse inputs via bank filtration, irrigation with river waters or groundwater recharge.

Different categories for patterns of use include (to be completed by REACH definitions):

- Use in the environment – batch releases within the environment (e.g. pesticides for outdoor uses);
- Widely distributed point source (dispersive) use – many mainly diffuse source releases to the environment (e.g. substances present in personal care products, pharmaceuticals, etc. and which are regularly discharged to the environment via WWTPs;
- Non-distributed point source (dispersive) use – small number of releases to the environment – e.g. used at industrial or other identifiable sites, resulting in controlled point source emission and localised releases to the environment;
- Controlled system – isolated unintentional releases to the environment, e.g. substances that are used in industry but in a controlled process without direct release to the environment, point source contamination, old landfills, etc.

In case of lack of data on the amount of use and the pattern of use, surface water monitoring data could be used as an alternative to estimate whether the substance is widespread in the environment.

The assessment of the leaching potential and its modification should be carried out and documented separately because the amount of a substance released to the environment (or sold) might differ significantly between MS and temporally. If MS know the amount of a substance used (or not used), for example, they can assess its relevance in their country or individual region. This might avoid the monitoring of substances that are highly ranked in Europe but not used in individual MS, although consideration should be given to transboundary flows/contamination. It should also be considered that a substance can be used in more than one way (e.g. as a biocide and as a pesticide), that use types can differ between MS, and that the amounts used can differ significantly between use types.

A 1.3 Combined groundwater leaching potential score (List III)

The assessments of Column I and II (scored and ranked Lists I and II) will be aggregated to a scored and ranked List III (Combined groundwater leaching potential score). If results of both assessments are available the resulting score is the mean of the proved and the theoretical groundwater leaching potential score:

Combined groundwater leaching potential score = (Proved groundwater leaching potential score + Theoretical groundwater leaching potential score) / 2

If only one dataset is available (e.g. no monitoring data available) the combined score is equivalent with the proved groundwater leaching potential score or the theoretical groundwater leaching potential score.

A 1.4 Determination of hazard (Hazard score)

For substances having the proved and/or theoretical capacity to reach GW (List III) human health and environmental hazards are determined.

Three different indicators are used to score substances depending on their hazard:

- PBT/vPvB = Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB)
- CMR = Carcinogenicity, Mutagenicity, Reprotoxicity
- ED = Endocrine Disrupting effects

The "Hazard score" is calculated for each substance of the List III as mentioned in the table below.

Indicators	Value	Sub-score	Hazard score
PBT/vPvB	Overall PBT/vPvB score = [(P + B + T) individual scores + (PBT/vPvB) score]/4	PBT: vP or P (1) + vB or B (1) + T+ or T (1) + vPvB or PBT (1) = 1 vPvBT: vP or P (1) + vB or B (1) + T+ or T (1) + vPvB or PBT (1) = 1 vPvB: vP or P (1) + vB or B (1) + T+ or T (0) + vPvB or PBT (1) = 0.75 PB: vP or P (1) + vB or B (1) + T+ or T (0) + vPvB or PBT (0) = 0.5 PT+: vP or P (1) + vB or B (0) + T+ or T (1) + vPvB or PBT (0) = 0.5 Not PBT, not vPvB = 0	[("PBT / vPvB" score) + ("CMR" score) + ("ED" score)] / number of fulfilled "criteria" Value between 0 and 1
CMR	The CMR final score is derived as the highest value among the individual carcinogenicity, mutagenicity and reprotoxicity scores	CMR, category 1 A/B = 1 CMR, category 2 = 0.5 Under examination = 0.25 Examined and info not sufficient = 0.25 Not examined = 0.25 Examined and not classified = 0	
ED		Proven ED = 1 Suspected ED = 0.5 Not examined = 0.25 Proven not ED = 0	

The final Hazard score is calculated as follows:

Hazard score = [("PBT / vPvB" score) + ("CMR" score) + ("ED" score)] / number of fulfilled "criteria"

A 1.5 Integrated groundwater score (List IV)

As a final list for decision making an Integrated ranked and scored list (List IV) is established as a combination of the Combined groundwater leaching potential score (List III) and the hazard score for the same substances. List IV is calculated as the mean of the leaching and the hazard score. The Integrated Groundwater score is the basis for the selection of substances for the Groundwater Watch List and for the List facilitating the Annex I and II review process of the GWD.

Integrated groundwater score = (Combined groundwater leaching potential score + Hazard score) / 2

If a hazard score cannot be calculated, the integrated score is calculated based on the monitoring and/or leaching score. In this case the integrated score is flagged for further assessment.

A 1.6 Selection criteria for the Groundwater Watch List

As the number of substances on the Groundwater Watch List should be limited (e.g. 30) an additional selection of substances could be necessary. In general, the 30 top ranked substances could be selected for the Groundwater Watch List process. If there are many substances remaining on the integrated List IV with identical or very similar scores, further selection should be based on an enhanced expert judgement. Besides the integrated score additional information should be taken into account. That could be, for example, the amount of a substance released to the environment and its use-pattern referred to in Chapter 3.3. If there are different groups of substances e.g. pharmaceuticals and PFAS in List IV, it might be reasonable to select high ranked and representative substances of each group.

The selection of substances will be carried out by a group of experts mandated by the WG GW (e.g. the Group of Volunteers). Results should be presented to and agreed with the WG GW and the Water Directors.

A 1.7 Proposed selection criteria for List facilitating the Annex I and II review process of the GWD

A key element for selecting substances for the “List facilitating Annex I/II review process of the GWD” is the monitoring data. All substances with high-quality groundwater monitoring data that show that the substance occurs in at least 4 MS/AC and at 10 or more sites in each MS/AC (i.e. quantified values from > 40 sites) should be listed in the “List facilitating Annex I/II review process of the GWD”.

A 1.8 Proposed deselection criteria for the Groundwater Watch List process

Reliable groundwater monitoring data from at least 8 MS/AC and from at least 20 monitoring sites in each MS/AC where the substance might reasonably be expected to occur have to be available. In addition, monitoring data from at least 1000 sites have to be available (aggregated from all participating MS/AC) indicating measurable concentrations (≥LOQ) in less than 0.1% of sites overall **and** no more than 1% in any one MS/AC. Substances fulfilling these criteria will be deselected from the GWWL process. The criteria could be adjusted based on evidence and the collaborative work within WG GW (e.g. the proportion of MS within monitoring data could be considered as well).