

Methodology for the determination of hazardous substances for the purposes of the Groundwater Directive (2006/118/EC)

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Foreword

Under their respective domestic legislation, the UK environment agencies are responsible for considering whether, for the purpose of groundwater protection, a potential pollutant (a substance liable to cause pollution) should be determined to be a hazardous substance or a non-hazardous pollutant. That domestic legislation transposes the Water Framework Directive (2000/60/EC) and Groundwater Directive (2006/118/EC)

The methodology presented here to determine whether a substance is hazardous, is based on the intrinsic properties of the substance, and provides a common framework for the UK agencies on which they can make assessments. How hazardous substances and non-hazardous pollutants are regulated does not form part of the methodology. Further information on how substances are regulated can be sought from the respective Agencies.

This methodology is relevant to anyone who has responsibilities for inputs of pollutants to groundwater or who conducts any activity that could give rise to such inputs. This includes professional advisers to operators of such activities, trade associations and anyone else with an interest in groundwater protection, including members of the public.

The Agencies' methodology together with the assessment and determination of specific substances are peer reviewed by the Joint Agencies Groundwater Directive Advisory Group (JAGDAG), and submitted to public consultation. Final recommendations on the determination of a substance as either a hazardous substance or non-hazardous pollutant are then made to the UK administrations.

JAGDAG comprises the Environment Agency (EA), Natural Resources Wales (NRW), the Scottish Environment Protection Agency (SEPA) and the Northern Ireland Environment Agency (NIEA, an agency within the Department of Agriculture, Environment and Rural Affairs) ("the Agencies"), together with the Department of Environment, Food and Rural Affairs (Defra), Welsh Government (WG), the Environmental Protection Agency Ireland (EPA), Public Health England (PHE) and industry representatives.

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1 Background

Under the domestic legislation that transposes the Water Framework Directive (WFD) (2000/60/EC) and Groundwater Directive (2006/118/EC), the UK environment agencies are responsible for considering whether a potential pollutant should be determined to be a hazardous substance or a non-hazardous pollutant. They must publish a list of the substances that they consider to be hazardous.

In 2012, following a public consultation exercise, the UK environment agencies published a methodology to consistently assess substances to determine if they are hazardous substances under the above legislation. In 2013, 20 substances were assessed using that methodology, and the assessments were made available for public consultation. Taking account of the comments received during those consultations, proposals to refine the methodology were presented for further consultation between February and May 2016. The revisions identified through this process have been incorporated into the methodology described in section 2.

The legislative framework that led to the development of this methodology is described in the next three subheadings.

Groundwater Directive (80/68/EEC)

Under the 1980 Groundwater Directive (80/68/EEC) substances were classified according to whether they belonged to either the List I or List II groups or families which were defined within the Directive. List I consisted of substances that should be prevented from being introduced into groundwater and List II comprised substances whose introduction should be limited so as to avoid pollution of groundwater. Substances on List I could be assigned to List II on the basis of low risk of toxicity, persistence and bioaccumulation. Where a substance fell into more than one group or family then the higher (List I) classification took precedence. Some substances were considered to not fall into either List I or List II and therefore were out of scope of the Directive.

This Directive was repealed in December 2013.

Water Framework Directive (2000/60/EC) & Groundwater Directive (2006/118/EEC)

Hazardous substances are defined in the Water Framework Directive as “*substances or groups of substances that are toxic, persistent and liable to bioaccumulate, and other substances or groups of substances which give rise to an equivalent level of concern*”. Non-hazardous pollutants are not defined in the Directive but are taken to be any potential pollutant other than a hazardous substance.

The Groundwater Directive (2006/118/EEC), a so-called daughter directive of the Water Framework Directive, states that necessary measures must be taken to prevent hazardous substances from entering groundwater and to limit the input of non-hazardous pollutants to ensure that groundwater does not become polluted or deteriorate in status.

The introduction to the Water Framework Directive states that “*the implementation of this Directive is to achieve a level of protection of waters at least equivalent to that provided in certain earlier acts*”. Therefore, the methodology for the determination of hazardous substances for the purpose of the Groundwater Directive (2006/118/EEC) must achieve a level of protection that is at least equivalent to that of the 1980 Groundwater Directive. As a transitional measure, substances that were confirmed under the Groundwater

Regulations 1998 as falling within List I under the 1980 Groundwater Directive (80/68/EEC) are taken to be hazardous substances, following adoption of guidance issued by Defra (Defra, December 2010).

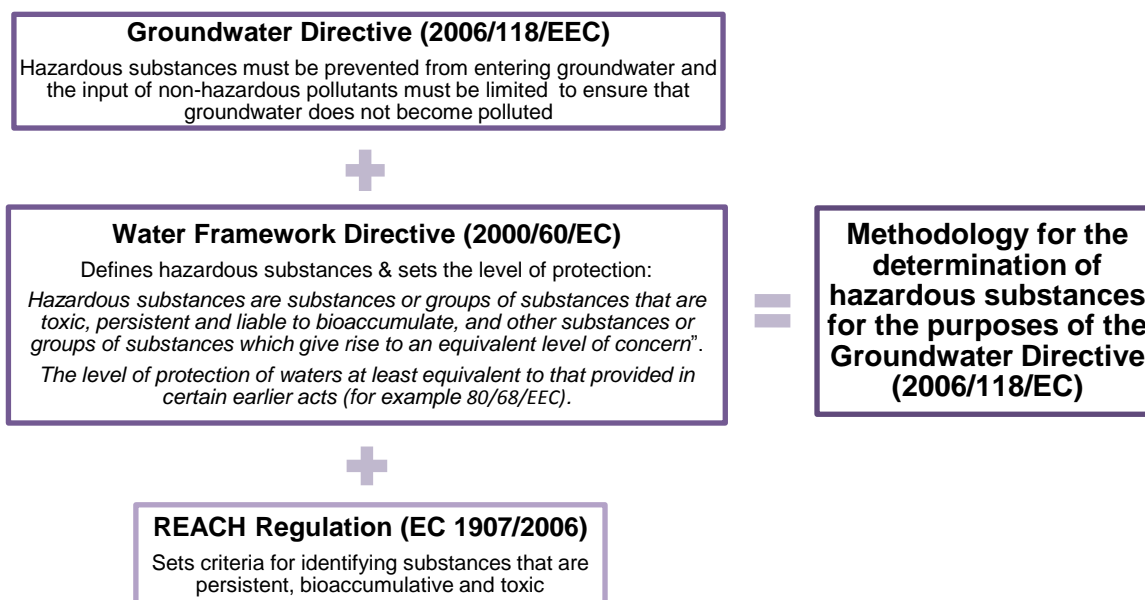
REACH Regulation

Criteria for assessing whether a substance is persistent, bioaccumulative and toxic (PBT) are set out in the REACH Regulation (EC 1907/2006) and described further in the European Chemicals Agency guidance (ECHA, 2014). These criteria are also cited in the Plant Protection Products Regulation (EC1107/2009) and the Biocidal Products Directive (EU528/2012), and are the standard criteria for PBT in the EU. These criteria have therefore been used as a basis for the methodology for the determination of hazardous substances for the purpose of the Groundwater Directive (2006/118/EEC). Use of the criteria under the REACH legislation enables consistency with other regulatory regimes.

Methodology

This methodology takes account of the requirements of the Water Framework Directive (2000/60/EC) and Groundwater Directive (2006/118/EC). The Groundwater Directive notes that protecting groundwater dependent ecosystems and groundwater used in water supply for human consumption are particularly important and the methodology takes account of these accordingly. The methodology incorporates relevant criteria from REACH to ensure consistency with other relevant EU legislation when determining whether a substance is persistent, toxic and bioaccumulative. The links between the legislation are shown in figure 1.

Figure 1 - Legislative requirements and influences on the methodology



This methodology concerns the determination of substances in relation to the protection of groundwater and takes account of the risks posed to people and the environment via groundwater. For example, when considering toxicity of a substance to humans, only those exposure pathways relevant to groundwater are considered. This means there is the possibility that the list of substances identified as hazardous in groundwater will be different from those considered to be harmful in other media.

2 The Methodology

Details of the criteria used to assess substances as hazardous for the purposes of the Groundwater Directive (2006/118/EC) are documented in this section. These criteria are summarised in figure 2.

Under the Groundwater Directive any substance which is not determined as a hazardous substance is a non-hazardous pollutant.

2.1 Ensure level of protection is at least equivalent to that of previous legislation

The methodology must achieve a level of protection that is at least equivalent to that of the 1980 Groundwater Directive (80/68/EEC). As a transitional measure, to achieve this, substances that were confirmed under the Groundwater Regulations 1998 as falling within List 1 are taken to be hazardous substances. Where it is apparent that the existing determination needs review, or new data or evidence becomes available, a new assessment using the methodology described here may be undertaken. This may result in a change to the determination for a substance. Substances formerly identified as List I, for example, may become non-hazardous pollutants or List II substances may become hazardous substances. It is reasonable to expect that the determination of some substances will be different from those of the 1980 Groundwater Directive (80/60/EEC), because the criteria and approach for determination are different.

2.2 Substances to be assessed using the methodology

The methodology applies to individual substances. Determinations are based on a specific chemical form of the substance and should not be applied to other chemical forms unless evidence is provided that this is a valid extension of the assessment. The criteria to be considered in the determination are outlined in sections 2.3 and 2.4. There may be cases, for example, where a substance is self-evidently not hazardous and therefore a full assessment is not required. Factors influencing such decisions will include, for example, understanding of intrinsic properties of a substance, whether the substance is a key major ion present in groundwater or whether a substance is included on Annex IV of REACH, e.g. fructose.

The methodology applies to organic and inorganic substances. Specific issues relating to metals and inorganics are discussed in section 2.6. Mixtures and groups of substances are discussed further in section 2.7.

2.3 Substances that are toxic, persistent, and liable to bioaccumulate

The Water Framework Directive defines a hazardous substance as one which is toxic, persistent and liable to bioaccumulate, so a substance has to meet all three criteria to be determined as hazardous. The Directive also states that other substances or groups of substances which give rise to equivalent concern are hazardous substances and these are discussed further in section 2.4.

For the purposes of the methodology the criteria used to define persistence, bioaccumulation and toxicity are based on those used within REACH (Annex XIII). These are further described in guidance published by the European Chemicals Agency (ECHA,

2014). The latter includes guidance regarding suitable laboratory tests for endpoints relevant for the assessment of persistence, bioaccumulation and toxicity. The criteria for human toxicity are those in the CLP regulation (classification, labelling and packaging of substances and mixtures; EC 1272/2008) and European Chemicals Agency Guidance on CLP (ECHA, 2009).

The criteria for persistence, bioaccumulation and toxicity are as follows:

Persistence

A substance is considered persistent if any of the following conditions apply:

- i. the degradation half-life in marine water is higher than 60 days
- ii. the degradation half-life in fresh or estuarine water is higher than 40 days
- iii. the degradation half-life in marine sediments is higher than 180 days
- iv. the degradation half-life in fresh or estuarine water sediments is higher than 120 days
- v. the degradation half-life in soil is higher than 120 days

If conflicting data are presented (for example the substance has a half-life in freshwater of 60 days but a half-life in freshwater sediments of 100 days), the substance will be classed as persistent, because the criteria state “if any of the conditions apply”.

Bioaccumulation

A substance is considered bioaccumulative if the bioconcentration factor (BCF) for aquatic species on a wet weight basis is greater than 2000.

The REACH PBT guidance (ECHA, 2014) states that if no BCF data are available, the log K_{ow} (octanol-water partition coefficient) is used in a screening assessment. In the absence of measured BCF data, a log K_{ow} greater than 4.5, is used to categorise a substance as meeting the criterion in this methodology.

Toxicity

A substance is considered toxic if any of the following conditions apply:

- i. the no observable effects concentration (NOEC)/EC10 (long term) for freshwater or marine organisms is less than 0.01 mg/l
- ii. the substance meets the criteria for classification as carcinogenic (Carc 1A or 1B), germ cell mutagenic (Cat 1A or 1B) or toxic for reproduction (Cat 1A, 1B or 2) according to the CLP Regulation (CLP Regulation 1272/2008)
- iii. there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to CLP Regulation (EC 1272/2008)

When assessing whether a substance meets the criteria relating to human health, the mechanism of toxicity, e.g. carcinogenicity, should be considered. The pathway of toxicity needs to be relevant to groundwater, e.g. oral exposure, (unless it can be demonstrated for a particular substance that another route, such as inhalation, is also

relevant to potential exposure from groundwater).

2.4 Substances that give rise to an equivalent level of concern

Some substances are considered to pose an equivalent level of concern to substances that are persistent, bioaccumulative and toxic. The criteria for these are presented below and will be considered where substances do not already meet the persistent, bioaccumulative and toxic criteria.

Very persistent and very bioaccumulative

Substances that are very persistent and very bioaccumulative shall be determined to be hazardous. Criteria for very persistent and very bioaccumulative (vPvB) substances form part of Annex XIII to the REACH regulation and are described in ECHA guidance (2014).

A substance is considered very persistent if any of the following conditions apply:

- i. the degradation half-life in marine, fresh or estuarine water is higher than 60 days
- ii. the degradation half-life in marine, fresh or estuarine water sediment is higher than 180 days
- iii. the degradation half-life in soil is higher than 180 days

or (although not part of the REACH regulation) groundwater monitoring data indicate that:

- iv. the substance has an average degradation half-life in groundwater of more than three years

A substance is considered very bioaccumulative if the BCF for aquatic species is greater than 5000.

Substances that are mutagenic or have no determinable threshold for adverse effects on human health

Mutagenic

Mutagenic substances are regarded as having no (effectively a zero) threshold for adverse health effects. A single molecule of a mutagenic substance could interact with DNA, which can produce a cell mutation and subsequently lead to the development of cancer. Mutations can also be inherited and therefore are of concern if the mutation is harmful, as it could harm current and future generations. It is widely accepted that exposure should be as low as reasonably practicable and these substances are considered to be hazardous in groundwater. Mutagenic is defined as meeting criteria for Muta 1A, 1B or 2 set out by the classification, labelling and packaging regulation.

No determinable threshold

The term 'no determinable threshold' is used here to capture substances which do not meet the criteria for mutagenic that are set out in the previous paragraph, but where exposure should be as low as reasonably practicable to avoid adverse effects on health and the environment. Substances that meet these criteria can be regarded as having a similar level of concern as associated with mutagens noted above. This is due to a

threshold for adverse effects not being able to be identified due to the properties of the substance. Examples include:

- inorganic arsenic which is associated with an increased risk of cancer at low drinking water concentrations and for which a threshold has not been identified
- inorganic lead which is associated with developmental neurotoxicity, kidney effects, and effects on blood pressure at low levels of exposure, for which a threshold has not been identified.

Substances that are persistent in groundwater and are bioaccumulative and toxic

This criterion for equivalent concern is designed to capture substances that may persist in groundwater even though they do not in other media. A substance shall be determined to be hazardous if it meets the criteria for toxicity and bioaccumulation noted in section 2.3, and is persistent in groundwater. Groundwater is not specifically discussed in the persistence criteria outlined in REACH (see section 2.3) for the assessment of P, B and T. As part of the assessment of equivalent concern, a substance is considered to be persistent in groundwater if any of the following conditions apply:

- i. if representative groundwater monitoring data indicate that the substance has an average degradation half-life in groundwater of more than one year;
- ii. if representative regional groundwater monitoring data show that the substance is present in aquifers in a manner that is indicative of high persistence in the subsurface environment (as a guideline, more than 5% of groundwater samples show concentrations of the substance greater than the limit of quantification (LOQ), or more than 15% of sites have at least one sample where the substance is detected above the LOQ).

The assessment of persistence in the sub-surface environment shall be based on available degradation data collected under the relevant conditions, which will include both aerobic and anaerobic conditions.

The intention is that this criterion is only considered in those situations where a clear result for the determination is not available from the assessment of the other criteria outlined in the methodology.

Substances that are radioactive

All radioactive substances have mutagenic properties therefore are considered to be hazardous in groundwater. For the purpose of this methodology, radioactive substances are taken to be any substance that contains one or more radionuclides, the activity or concentration of which cannot be disregarded as far as radiation protection is concerned. This definition is set out in Council Directive 96/29/Euratom. Radionuclides which can be disregarded as far as radiation protection is concerned are not treated as hazardous substances in groundwater.

In addition to the radiological properties, substances may also have non-radiological properties that meet the criteria in this methodology and therefore could be hazardous substances for non-radiological reasons. The non-radiological properties would need to be considered separately and in addition to the radiological properties.

2.5 Availability of data to undertake assessment

In assessing a substance, consideration should be given to all relevant and valid information for the specific substance. This can include international reviews such as those by the European Food Safety Authority and World Health Organisation which can be used, for example, to provide additional evidence in relation to the CLP classifications.

If no or very limited information is available for a substance in relation to a specific criterion, use can be made of approaches such as predicted data and read-across, and/or expert opinion where appropriate. The weight-of-evidence would therefore be used to make an assessment. Substances that are assessed using the approach described in this paragraph may be reassessed once more specific information becomes available.

Where no or insufficient information is available via the above approaches a precautionary approach is adopted, and substances are determined to be hazardous unless there is good reason to indicate otherwise.

2.6 Metals and other inorganics

The assessment of persistence, bioaccumulation and toxicity for metals and other inorganics involves special considerations. The tools used to assess bioaccumulation e.g. $\log K_{ow}$ and BCF, were primarily developed based on an understanding of certain lipophilic organic compounds. These tools therefore, work less well for metals and some other inorganic compounds, as these substances are accumulated by a number of physiological processes in addition to passive sorption in fats. This increased complexity for metals means the potential for bioaccumulation of metals needs to be assessed on a case-by-case basis.

Similarly, chemical persistence as a concept was originally derived for organic chemicals and referred to abiotic or biotic degradation that affects a chemical's identity. Metal ions are intrinsically persistent, although their oxidation state, form and availability may change.

The toxicity of a metal is dependent on the form present and some metals are influenced by other water quality parameters, which influence their bioavailability. These factors need to be taken into account on a case-by-case basis.

Assessments shall be undertaken on a specific form of a metal or inorganic substance that is most relevant for groundwater. The determination will therefore relate to any metal compound which forms these ions in the water environment.

Substances that are present naturally in groundwater or essential elements are not exempt from assessment and may also be determined to be hazardous when the scientific evidence supports that conclusion.

2.7 Mixtures

The methodology applies to individual substances. It does not apply to mixtures.

Where a substance inherently includes other substances entrained within it as

impurities, the methodology is applied to the main substance and, separately, to any entrained impurities. Where a substance that is classed as a non-hazardous pollutant is known to routinely contain entrained substances that are classed as hazardous, a note will be made on the determination record for the main substance.

In some circumstances a determination may be based on a group of substances. Such examples include dioxins and PCBs. In these cases the chemicals within these groups have similar structures and properties and are often found together, for example as a result of manufacture.

2.8 Breakdown products

As noted above (section 2.7) assessments are undertaken on individual substances. Breakdown products for a substance will be assessed separately. Breakdown products will only be assessed where information is brought to the Agencies' attention, through environmental monitoring data for example, or if they are commonly known and/or studied. It is acknowledged that it is not possible to assess every breakdown product.

If any of the breakdown products of a substance are determined as hazardous this will be noted on the determination record for the parent compound to highlight this fact. This is particularly important for substances that are determined as non-hazardous but have hazardous breakdown products.

2.9 Process flow diagram & assessment template

The methodology for determining if a substance is a hazardous substance in groundwater is summarised in the flow diagram, figure 2. The methodology generally applies to individual substances, including those naturally present in groundwater and essential elements. Section 2.7 describes how this methodology applies to mixtures and section 2.6 explains how the methodology applies to metals and inorganic substances.

A blank version of the template that is used to record determinations is in figure 3.

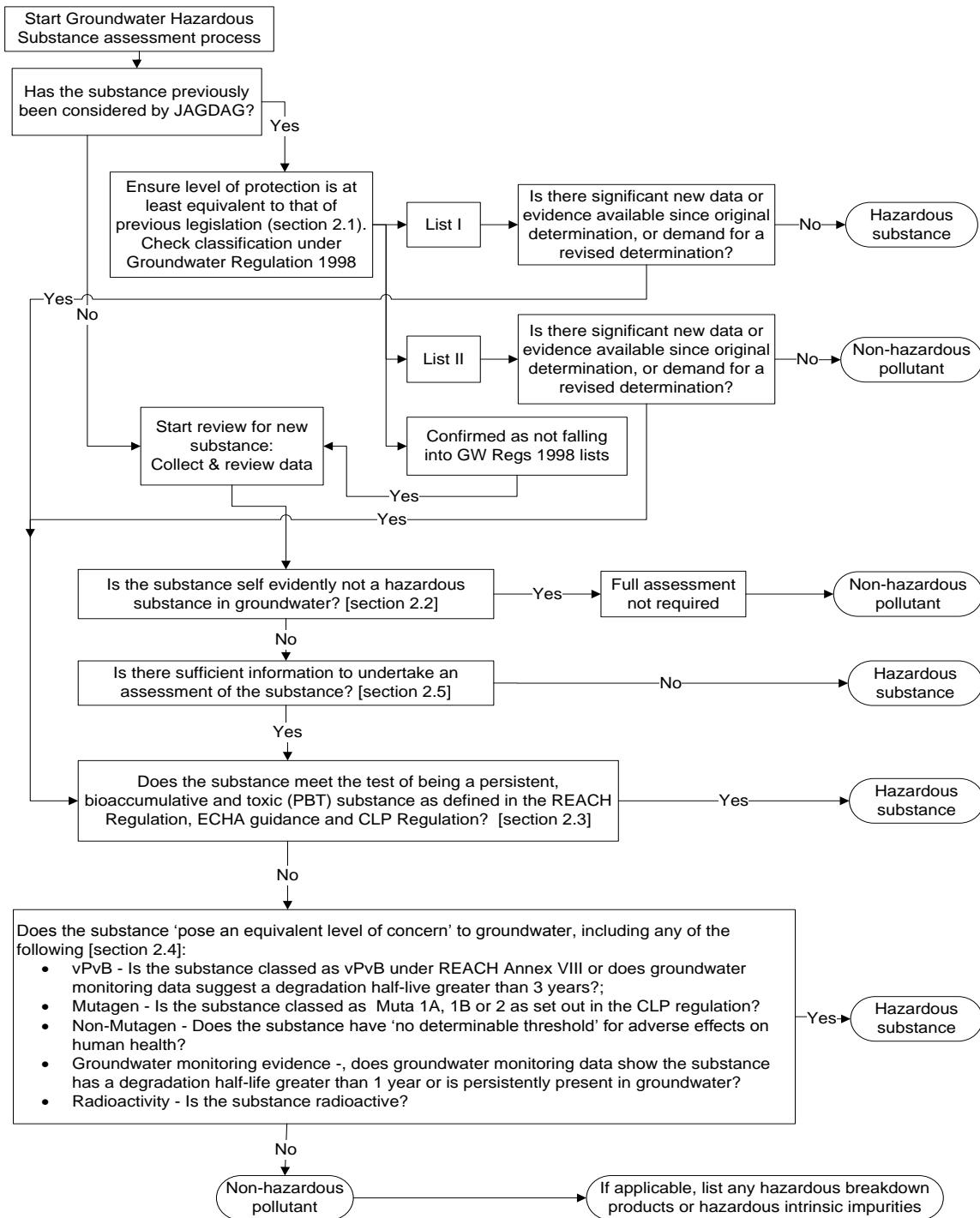


Figure 2 – Process for the determining hazardous substances in groundwater

	Substance + CAS number			Comments
	Yes / No / Insufficient data / Borderline / assume yes or no?	Value	Reference	
Is substance persistent, bioaccumulative and toxic?				
Persistence				
Passes ready biodegradation test				
Passes inherent biodegradation test				
<i>If answer to either question is YES, substance is not persistent</i>				
<i>If answer to both questions is NO, additional data on half life is required</i>				
Half life marine water ≥ 60 days				
Half life fresh or estuarine water ≥ 40 days				
Half life marine sediment ≥ 180 days				
Half life fresh or estuarine sediment ≥ 120 days				
Half life in soil ≥ 120 days				
<i>If answer to any question is YES, substance is persistent</i>				
<i>If answer to all questions is NO, substance is not persistent</i>				
Is sufficient data available? (if not assume substance is persistent)				
Is substance persistent?				
Bioaccumulation				
Bioconcentration factor (BCF) for aquatic species (wet weight) ≥ 2000				
Does field data show evidence for biomagnification?				
<i>If answer to either question is YES, substance is bioaccumulative</i>				
If no BCF data, is log Kow ≥ 4.5?				
<i>If answer is YES, substance is bioaccumulative</i>				
Does the weight of evidence from the following criteria indicate bioaccumulation unlikely?				
Substance is chronically non-toxic in mammals				
Molecular size ≥ 4.3nm				
Molecular weight ≥ 1100g/mol				
Octanol solubility ≤ 0.002mmol/l				
<i>If weight of evidence indicates bioaccumulation unlikely (i.e. YES answers) substance is not bioaccumulative</i>				
<i>If weight of evidence indicates bioaccumulation a possibility (i.e. NO answers), BCF data should be obtained</i>				
Is sufficient data available? (if not assume substance bioaccumulates)				
Is substance bioaccumulative?				
Toxicity				
Is the lowest chronic NOEC for freshwater or marine organisms ≤ 0.01mg/l				
Is there substantial evidence of long term toxicity (STOT RE1 or STOT RE2)				
Is substance carcinogenic (Carc 1A, 1B), mutagenic (Muta 1A, 1B) or toxic for reproduction (Repr 1A, 1B, 2)				
<i>If answer to any question is YES, substance is toxic</i>				
<i>If answer to all questions is NO, substance is not toxic</i>				
Is sufficient data available? (if not assume substance is toxic)				
Is substance toxic?				
IS SUBSTANCE PERSISTENT, BIOACCUMULATIVE AND TOXIC?				
Does substance pose an equivalent level of concern?				
Very persistent and very bioaccumulative?				
Half life in marine, fresh or estuarine water ≥ 60 days				
Half life in marine, fresh or estuarine sediment ≥ 180 days				
Half life in soil ≥ 180 days				
<i>If answer to any question is YES, substance is very persistent</i>				
Is bioconcentration factor ≥ 5000				
<i>If answer is yes, substance is very bioaccumulative</i>				
Is substance very persistent and very bioaccumulative?				
Does substance pose a specific risk to groundwater?				
Does groundwater monitoring data show half life in groundwater ≥ 1 year				
Do ≥ 5% of groundwater samples show levels of the substance greater than the LOQ?				
Do ≥ 15% of sites have at least one sample where the substance is detected above the LOQ?				
<i>If answer to any question is YES, substance is persistent in groundwater</i>				
Is substance persistent in groundwater?				
<i>If substance is persistent in groundwater, bioaccumulative AND toxic, substance is hazardous</i>				
Does substance pose a specific risk to groundwater?				
Is substance very toxic?				
Is substance mutagenic (Muta 1A, 1B, 2) or have no determinable threshold for adverse effects on human health				
<i>If answer to any question is YES, substance is very toxic and hazardous</i>				
Is sufficient data available? (if not assume substance is very toxic)				
Is substance very toxic?				
Is substance hazardous to groundwater?				
Is substance hazardous, if so, state on what basis				
Does substance have breakdown products of concern?				
REFERENCES				

Figure 3 – Blank assessment template for recording assessments on

3 References

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