

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

A consultation proposal

Issued by the Joint Agencies  
Groundwater Directive Advisory  
Group (JAGDAG)

February 2016

# Foreword

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

In June 2012, a methodology was published for determining if a substance is a hazardous substance or a non-hazardous pollutant. Using that methodology, 20 substances were assessed and the results made available for public consultation between February and March 2013. Comments received on that public consultation have been taken into account in proposing revisions to the methodology. The revisions were prepared by the Joint Agencies Groundwater Directive Advisory Group (JAGDAG) and the explanations for these revisions can be found in the supporting document - *Summary of the main changes to the methodology and the considerations that led to those changes*.

JAGDAG comprises of the Environment Agency (EA), Natural Resources Wales (NRW), the Scottish Environment Protection Agency (SEPA) and the Northern Ireland Environment Agency (NIEA) ("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. The purpose of JAGDAG is to peer review the Agencies' assessments of specific substances and advise the UK administrations on their classification as either hazardous substances or non-hazardous pollutants.

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.

This methodology provides a framework to assess whether a substance is hazardous in groundwater. 48 substance assessments using this methodology have been done and are available as part of this consultation. How hazardous substances and non-hazardous pollutants are regulated does not form part of this methodology. Further information on how substances are regulated can be sought from the respective Agencies.

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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 in groundwater. 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 the 2013 consultation, proposals to review the methodology for the determination of hazardous substances were made. This review has been done and the revised method is described in this document.

## *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 as defined within the Directive. List I consisted of substances that should be prevented from being discharged into groundwater and List II comprised substances that should be controlled to prevent 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 category 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, 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, to achieve this level of protection, 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

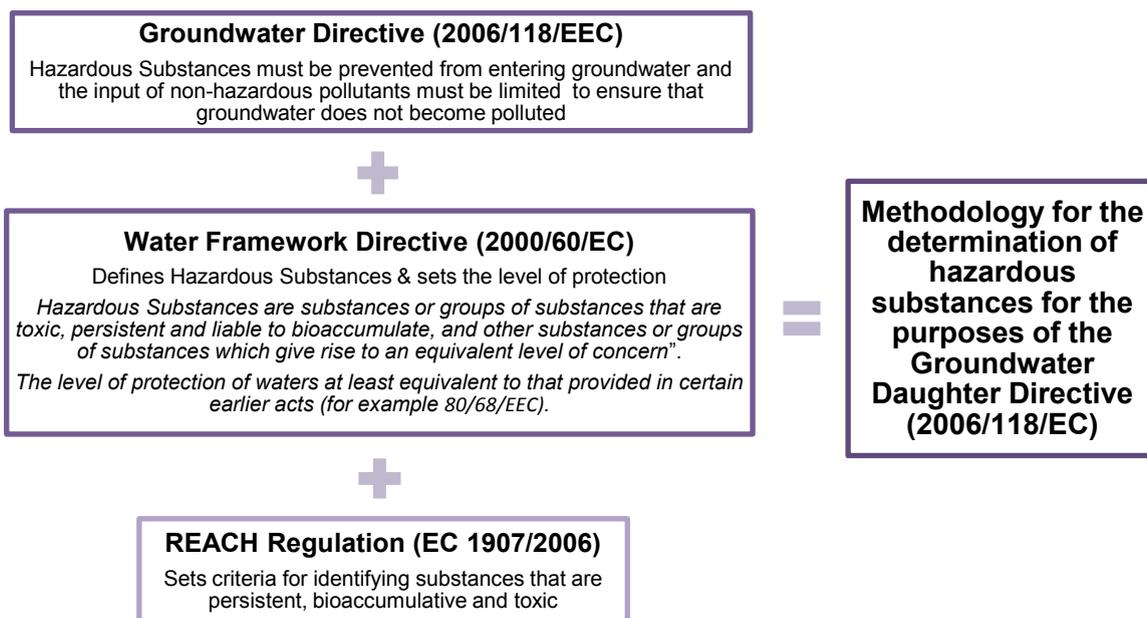
adoption of guidance (Defra, December 2010) issued by Defra to the Environment Agency.

## REACH Regulations

The Water Framework Directive defines hazardous substances as those that are toxic, persistent and liable to bioaccumulate. Criteria for assessing whether a substance is persistent, bioaccumulative and toxic (PBT) are set out in the REACH Regulation (EC 1907/2006) and further described 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.

## Consultation

This methodology has been developed to take into account the requirements of the Water Framework Directive (2000/60/EC) and Groundwater Directive (2006/118/EC). It has incorporated relevant criteria from REACH to ensure consistency with other relevant EU legislation when determining whether a substance is persistent, toxic and bioaccumulative. These links 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 to humans of a substance, only those exposure pathways relevant to groundwater are considered. Exposure via inhalation would not be considered as there is no pathway to a person via groundwater. 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.

This document is available for public consultation for 12 weeks from 22 February 2016.

It has been produced by the Agencies; peer reviewed by the Joint Agencies Groundwater Directive Advisory Group (JAGDAG) and is hosted on the UK Technical Advisory Group (UKTAG) website. Responses will be collected via a downloadable questionnaire and can be submitted online. The consultation response will be reported on the UKTAG website (<http://www.wfduk.org/search/content/jagdag>).

## 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. A summary of the criteria are in figure 2. Once a substance has been assessed, if it is not determined to be a hazardous substance it will be classed as a non-hazardous pollutant.

Determination relates to the chemical form of the substance that is being assessed and should not be applied to other chemical forms unless evidence is provided that this is a valid extension of the assessment. Therefore, based on the accepted definition of a substance, mixtures have been excluded from the scope of the determination methodology except in specific circumstances (see section 2.7).

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

As noted in Section 1, 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 done. 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 to those of the 1980 Groundwater Directive (80/60/EEC), because the criteria and approach for determination are different.

### 2.2 Substances self evidently not potential pollutants in groundwater

Hazardous substances and non-hazardous pollutants can both cause pollution of groundwater. The Water Framework Directive defines a pollutant as “*any substance liable to cause pollution...*”, where 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.*”.

If a substance can be present in groundwater at saturation (i.e. at aqueous solubility), and it does not give rise to pollution at that concentration, then it is not a potential pollutant in groundwater. Further assessment under this methodology should not therefore be required. Possible examples of such substances include  $\text{Ca}^{2+}$ ,  $\text{Mg}^{2+}$ ,  $\text{SiO}_2$ ,  $\text{HCO}_3^-$  [all naturally present at or near saturation in groundwater in most aquifers],  $\text{O}_2$ ,  $\text{H}_2\text{O}$ . Some other substances are also almost ubiquitous in groundwater and although may be considered polluting at unusually high concentrations, are not considered to be candidate hazardous substances, including  $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{Cl}^-$ ,  $\text{SO}_4^{2-}$ ,  $\text{NO}_3^-$ .

## 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.

For the purposes of the methodology the criteria used to define persistence, bioaccumulation and toxicity are based on those used within REACH (Annex XIII) to define PBT substances and further described in ECHA guidance (ECHA, 2014). Guidance regarding suitable laboratory tests for endpoints relevant for the assessment of persistence, bioaccumulation and toxicity has been published by the European Chemicals Agency (ECHA, 2014). 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 data, it is proposed that this same screening criterion (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 No 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, rather than inhalation exposure.

## **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 proposed criteria for these are discussed below.

### *Substances that are persistent in groundwater and are bio-accumulative 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 REACH regulation. However, 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. Where reliable groundwater half-life data exist these should also be taken into account and take precedence over data from other media as far as the determination process is concerned.

### *Very persistent and very bio-accumulative*

Substances that are very persistent and very bio-accumulative shall be determined to be hazardous. Criteria for very persistent and very bio-accumulative (vPvB) substances form part of Annex XIII to the REACH regulation and are described in ECHA guidance (2014). They are considered as equivalent to PBT in terms of environmental protection and hence have been included as criteria of 'equivalent concern'.

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 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 bio-accumulative 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*

Substances that meet the criteria for classification as germ cell mutagen (Cat 1A, 1B or 2) in accordance with the CLP Regulation, or for which a threshold for adverse effects on human health cannot be identified, shall be determined to be hazardous.

However, where there is sufficient mechanistic evidence to identify a threshold for adverse effects on human health (e.g. known mutagenicity and carcinogenicity data) then a substance can be deemed to be non-hazardous.

### *Substances that are radioactive*

All radioactive substances have mutagenic properties therefore are considered to be hazardous in groundwater.

## **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 EFSA and WHO 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 however, a precautionary approach is adopted for substances being assessed, in that substances are determined to be hazardous unless there is good reason to indicate otherwise.

The only exception to this is in regard to the groundwater monitoring persistence criterion (see 2.4). This is because monitoring data that indicate groundwater persistence are generally only available for substances that are already known to be of

actual or potential concern in groundwater. Where there are insufficient groundwater persistence data to make this determination, it is assumed that the substance does not fail this criterion.

## 2.6 Metals and other inorganics

The determination of a substance as hazardous involves the consideration of its persistence, bioaccumulation and toxicity. 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 will 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 will form 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

In general, the methodology applies to individual substances and not to mixtures.

Therefore 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 however a determination may be based on a group of substances. Such examples include dioxins and PCBs. In these circumstances 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 determined only if they are brought to our attention, through environmental monitoring data for example, or if they are commonly

known and/or studied. It is accepted that it is not possible to assess every breakdown product.

If any of the breakdown products of a substance are determined to be 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 break down products.

## 2.9 Process flow diagram

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. For how this methodology applies to mixtures see section 2.7.

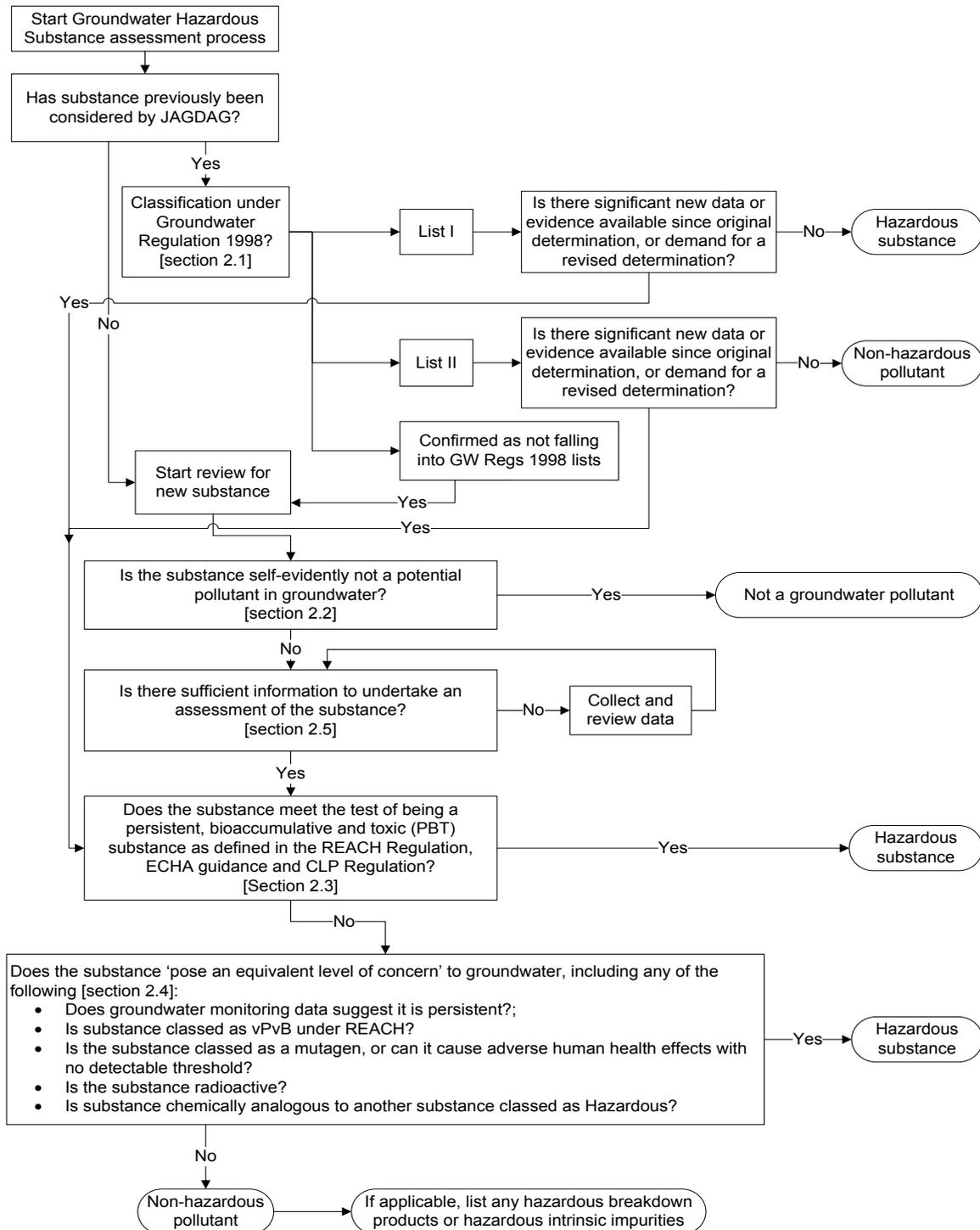


Figure 2 – Process for the determining hazardous substances in groundwater

# 3 References

## [CLP Guidance](#)

ECHA Guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures) 2013

## [CLP Regulation](#)

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.

## [Defra, December 2010](#)

Environmental Permitting Guidance - Groundwater Activities

## [ECHA guidance 2014](#)

[Guidance on information requirements and chemical safety assessment. Chapter R.11: PBT Assessment. \(Version 2\)](#)

[November 2012. ECHA Guidance for the implementation of REACH](#)

[Guidance on information requirements and chemical safety assessments. Chapter R6: QSARs and grouping of chemicals.](#)

## [EPR 2010](#)

Statutory Instruments 2010 No. 675 Environmental Protection, England and Wales. The Environmental Permitting (England and Wales) Regulations 2010.

## [Groundwater Directive \(2006/118/EC\)](#)

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.

## [Groundwater Directive \(80/60/EEC\)](#)

Council Directive of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances (80/60/EEC). Repealed in December 2013.

## [REACH Regulation](#)

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Regulation, 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

## [Water Framework Directive](#)

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.