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

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

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Foreword

Under the domestic legislation that transposes the Water Framework Directive (2000/60/EC) and Groundwater Daughter 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. These changes in legislation mean that the method formerly used to determine the classification of substances as falling in List 1 or 2 under the old Groundwater Directive (80/68/EEC) has been revised. This document details the new methodology.

This document sets out the methodology for determining the status of a substance as hazardous or non-hazardous. Regulation to protect groundwater is a matter that is being considered separately by the respective environment agencies. The environment agencies will work together to seek a consistent approach where this is appropriate.

This document has been produced by the Joint Agencies Groundwater Directive Advisory Group (JAGDAG). JAGDAG comprises the Environment Agency (EA), 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 Assembly Government (WAG), the Environmental Protection Agency Ireland (EPA), Health Protection Agency (HPA) 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 issued with the agreement of the UK Administrations.

The methodology is relevant to anyone who discharges pollutants to groundwater or conducts any activity that could give rise to such a discharge. This includes professional advisors to operators of such activities, trade associations and anyone else with an interest in groundwater protection, including members of the public.

This document is available on the JAGDAG website: http://www.wfduk.org/search/content/jagdag. If you would like a hard copy of this document, please write or email to the addresses below

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- By post: Environment Agency, Groundwater and Contaminated Land Team, Land and Water Quality, Horizon House, Deanery Road, Bristol BS1 5AH

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1 Background

Under the domestic legislation that transposes the Water Framework Directive (2000/60/EC) and Groundwater Daughter 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. These recent changes in legislation mean that the method formerly used to determine the classification of substances under the old Groundwater Directive (80/68/EEC) has been revised.

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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 issued with the agreement of the UK Administrations.

Groundwater Directive

Previously substances were determined in accordance with the 1980 Groundwater Directive (80/68/EEC) by the Joint Agencies Groundwater Directive Advisory Group (JAGDAG).

The determination method involved identifying whether a substance belonged to the List I or List II groups or families of substances. List I substances should be prevented from being introduced to groundwater and List II substances should be controlled to prevent pollution of groundwater. Individual substances that were in List I groups could be downgraded to List II on the basis of low risk of toxicity, persistence and bioaccumulation. These criteria were drawn up by the Agencies via JAGDAG and subject to public consultation. Some substances were considered to not belong to the List I or List II groups, and therefore were out of scope of the Directive.

This Directive will be repealed in December 2013.

Groundwater Daughter Directive

The Groundwater Daughter Directive (2006/118/EC) states that hazardous substances must be prevented from entering groundwater and the input of non-hazardous pollutants must be limited to ensure that groundwater does not become polluted.

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 can be taken as meaning any potential pollutant other than a hazardous substance; this meaning

has also been used in domestic legislation. The criteria for identifying substances that are persistent, bioaccumulative and toxic are established in the Technical Guidance Document for Risk Assessment and the REACH Regulations (see list of references).

The Water Framework Directive also 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 it is essential to ensure that the new method will achieve a level of protection that is at least equivalent to that of the 1980 Groundwater Directive.

Implications

The introduction of new legislation means that the way substances are determined has changed. The criteria for persistence, bioaccumulation and toxicity are different, and it is no longer necessary for a substance to be part of a family or group before its input to groundwater needs to be prevented or controlled.

This document provides the revised method to determine substances in accordance with the new legislation, whilst providing an equivalent level of protection to the 1980 Groundwater Directive. It describes the new method to determine whether a potential pollutant is a hazardous substance or a non-hazardous pollutant. The method is summarised in Figure 2.

This methodology was the subject of consultation for 12 weeks from Tuesday 1 June 2011 to Wednesday 24 August 2011 and the consultation response can be found on the JAGDAG website (http://www.wfduk.org/search/content/jagdag).

2 The methodology

2.1 Methodology

The methodology is summarised in Figure 2. All new substances and the substances that were previously considered by JAGDAG to not belong in the List I or List II groups will be assessed using this approach.

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

Substances that were formally confirmed as falling within List I under the 1980 Groundwater Directive will become hazardous substances, following adoption by JAGDAG of guidance on this matter issued by Defra to the Environment Agency. Those confirmed to fall within List II will become non-hazardous pollutants, unless new data or evidence becomes available that would materially change a classification.

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

Under the1980 Groundwater Directive and UK domestic legislation, a substance that 'passed' all three criteria for low persistence, bioaccumulation and toxicity could be demoted from List I to List II. In contrast the Water Framework Directive states that substances that are persistent, bioaccumulate and toxic are hazardous, so a substance must 'fail' all three criteria to be determined as hazardous.

The criteria for persistence, bioaccumulation and toxicity are those given in the Technical Guidance Document and the REACH regulation. Guidance regarding suitable tests has been published by the European Chemicals Agency (ECHA, 2008). The criteria for human toxicity are those in the CLP regulation (classification, labelling and packaging of substances and mixtures) and European Chemicals Agency Guidance on CLP (ECHA, 2009). The criteria are as follows:

High persistence

A substance has high persistence if any of the following conditions apply:

i. the half-life in marine water is greater than 60 days;

ii. the half-life in fresh- or estuarine water is greater than 40 days;

iii. the half-life in marine sediments is greater than 180 days;

iv. the half-life in fresh- or estuarine water sediments is greater than 120 days;

v. the half-life in soil is greater than 120 days.

Note that 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 states "if any of the conditions apply".

High bioaccumulation

A substance has high bioaccumulation if the bioconcentration factor for aquatic species (BCF) on a wet weight basis is greater than 2000, or if no BCF data are available, log Kow (octanol-water partition coefficient) is greater than 4.5.

High toxicity

A substance has high toxicity if any of the following conditions apply:

i. the no observable effects concentration (NOEC) for freshwater or marine organisms is less than 0.01 mg/l;

ii. the substance is carcinogenic, mutagenic or toxic (CMT) for reproduction and assigned the hazard class category codes Muta. 1A, Muta. 1B, Muta. 2, Carc. 1A, Carc. 1B, Repr. 1A or Repr. 1B (CLP Regulation 1272/2008), or the results of toxicity testing identify these properties;

iii. the substance is fatal or toxic if swallowed – so if it has been assigned the hazard class category code Acute Tox 1, Acute Tox 2, Acute Tox 3, STOT SE1 or STOT RE1, or the results of toxicity testing show an equivalent level of concern, such as lethality or significant adverse functional or morphological changes to a tissue or organ (as indicated in Regulation EC No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures).

2.1.3 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:

Substances that are highly persistent in groundwater and are highly bioaccumulative and toxic

This takes into account any groundwater monitoring data. A substance shall be determined to be hazardous if it has high toxicity and high bioaccumulation and has high persistence in groundwater. Criteria for high persistence in groundwater are:

i. if representative groundwater monitoring data indicate that the substance has an average degradation half-life in groundwater of more than one year; or

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 JAGDAG process is concerned.

Very highly persistent and very highly bioaccumulative

Substances that are very persistent and very bioaccumulative shall be determined to be hazardous. A substance has very high persistence if any of the following conditions apply:

i. the half-life in marine, fresh- or estuarine water is higher than 60 days;

ii. the half-life in marine, fresh- or estuarine water sediment is higher than 180 days;

iii. the 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 has very high bioaccumulation if the BCF for aquatic species is greater than 5000.

Substances that are carcinogenic, mutagenic or toxic for reproduction

This is to ensure that the new method provides at least an equivalent level of protection as the previous method. Substances that are carcinogenic, mutagenic or toxic for reproduction as defined under high toxicity (ii) above shall be determined to be hazardous.

Substances that are very acutely toxic to aquatic biota

This criterion is included to protect aquatic ecology in subterranean or surface water environments from the most eco-toxic substances. A substance will be determined to be hazardous if the lethal concentration that kills 50% of the test population (LC50) or the median effective concentration for an adverse effect other than death (EC50) is less than 0.1mg/l.

Substances that are persistent and very toxic

This criterion is included to protect groundwater resources for current and future potable supply and prevent any potential harm to humans. A substance will be determined to be hazardous if it is persistent in freshwater or groundwater, and it is fatal or toxic if swallowed, or it causes significant adverse effects as defined under high toxicity (iii) above.

2.1.4 Sufficient data available to complete assessment

A precautionary approach is adopted, in that all new substances are provisionally determined to be hazardous, unless data are provided to indicate otherwise. It could be that data are available for some criteria but not others; in this situation it would be assumed that the substance ‘fails’ the criteria for which there are insufficient data. Substances provisionally determined to be hazardous will be reviewed when sufficient data become available

The only exception to this is in regard to the groundwater monitoring persistence criterion (see 2.1.3), because monitoring data that indicate groundwater persistence are generally only available for substances that are already known to be of 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.

2.1.5 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 Kow and BCF, were primarily developed based on an understanding of certain lipophilic organic compounds. This needs to be borne in mind when assessing the potential for bioaccumulation of metals as the bioaccumulation of some metals is more complex than for many organic substances.

In addition the toxicity of metals can be dependent on other water quality parameters, e.g. pH and calcium, which influence the bioavailability and therefore toxicity of some metals. This needs to be taken into account on a case by case basis during the determination of metals.

2.1.6 Substances with intrinsic impurities

JAGDAG will not determine mixtures but will determine individual substances (which may form part of a mixture). However, JAGDAG does differentiate between mixtures and where a substance inherently carries another substance entrained within it.

Where a substance inherently carries other substances entrained within it as impurities, we would assess the substance and its entrained impurities separately. 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.

2.1.7 Breakdown products

If a substance is determined to be a non-hazardous pollutant but its breakdown products are hazardous, the original substance will remain as non-hazardous but the determination list will refer to the fact that the breakdown products are hazardous.

Breakdown products will only be determined 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.

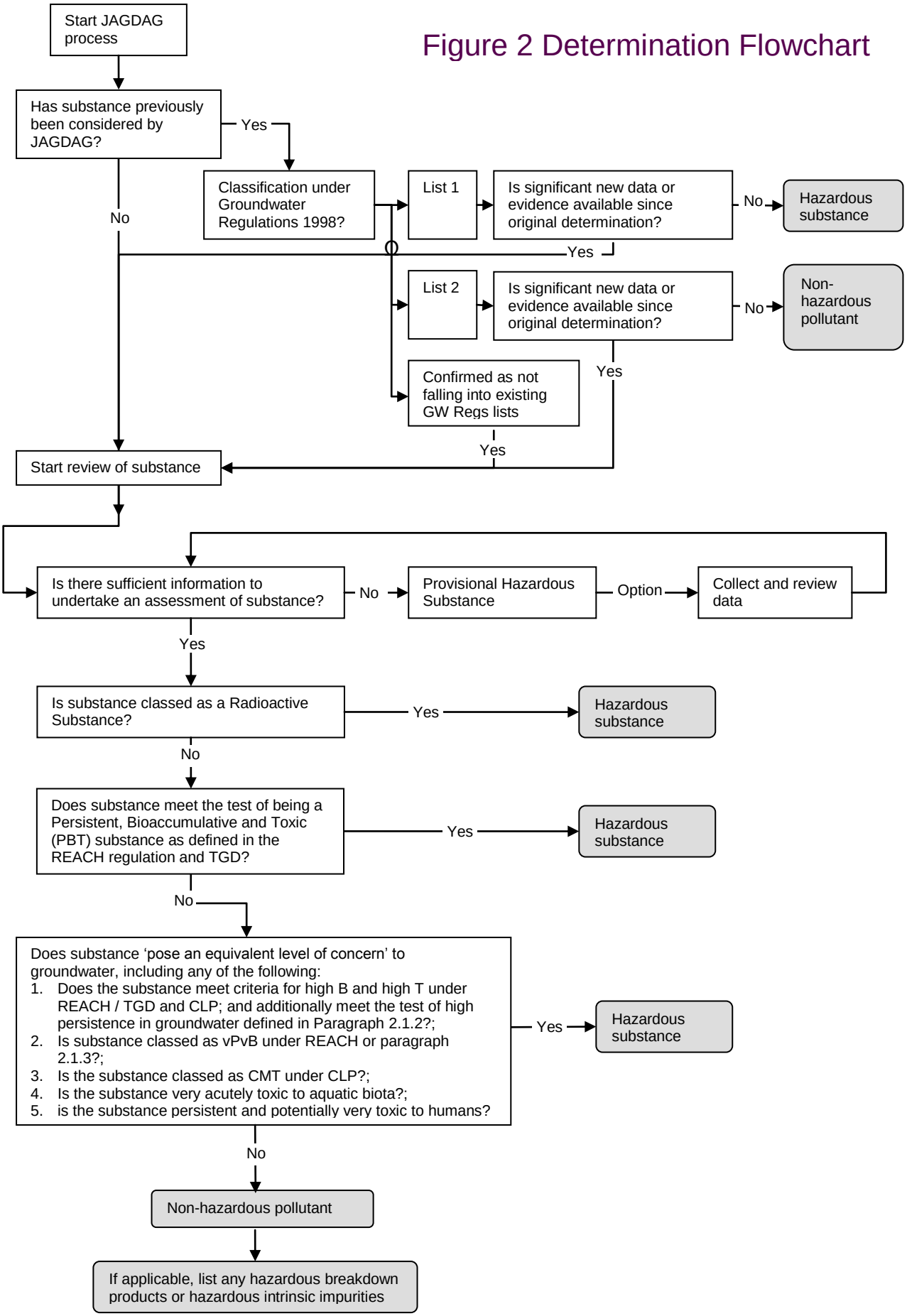
Where there are intermediary products or uncommon breakdown products (which may only be of local significance for example), they would be reviewed on a case by case basis.

2.1.8 Radioactive substances

Radioactive substances are defined under the Environmental Permitting Regulations (2010) in England and Wales and under the Radioactive Substances Act 1993 (Scotland and Northern Ireland). Radioactive substances are now included within the scope of the Water Framework and Groundwater Daughter Directives. JAGDAG has accepted the position (as noted in statutory guidance to the Environment Agency from Defra) that all radioactive substances are hazardous, because the basis of radiation

protection is to assess the dose to humans and non-human species from all radionuclides in combination. Any radioactive substance possesses carcinogenic or mutagenic properties, and therefore gives rise to an equivalent level of concern.

Figure 2 Determination Flowchart



3 References

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 2008
ECHA Guidance for the implementation of REACH. Guidance on information requirements and chemical safety assessment. Chapter R.11: PBT Assessment. May 2008.

ECHA Guidance 2009
ECHA Guidance on the application of CLP (Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures) 2009

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

EQS Directive
Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council.

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

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.

Technical Guidance Document
European Chemicals Bureau Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. 2003

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.

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