

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

A Consultation Response

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

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Executive summary

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.

The Joint Agencies Groundwater Directive Advisory Group (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. The purpose of JAGDAG is to peer review the individual Agencies' methodology for determining whether a substance is hazardous in groundwater, and the Agencies' assessment of specific substances; and to advise the UK administrations on the determination of potential pollutants as either hazardous substances, or non-hazardous pollutants.

From 22 February to 31 May 2016 a consultation was held on revisions to the Agencies' 2012 methodology for the determination of hazardous substances in groundwater and proposed determinations for 50 substances. The results of the consultation are summarised and discussed here.

The consultation had 3 parts which invited comments and further contributions to:

1. the revisions to the methodology for the determination of hazardous substances
2. the proposed determination of hazardous substances and non-hazardous pollutants, and
3. any other comments consultees wanted to contribute to the consultation

Eighteen responses came from a range of sectors including academia, water companies, waste companies, consultancies and trade bodies. Changes have been made to the methodology report as a result of those responses. A summary of the comments received from the consultation, JAGDAG's response and the revisions made to the methodology report are in this report.

There was general support for the specific changes to the 2012 methodology proposed in the consultation and these are discussed in part 1 of this response document. Consultees' responses to the 3 specific questions asked in part 1 of the consultation are displayed in figure 1.

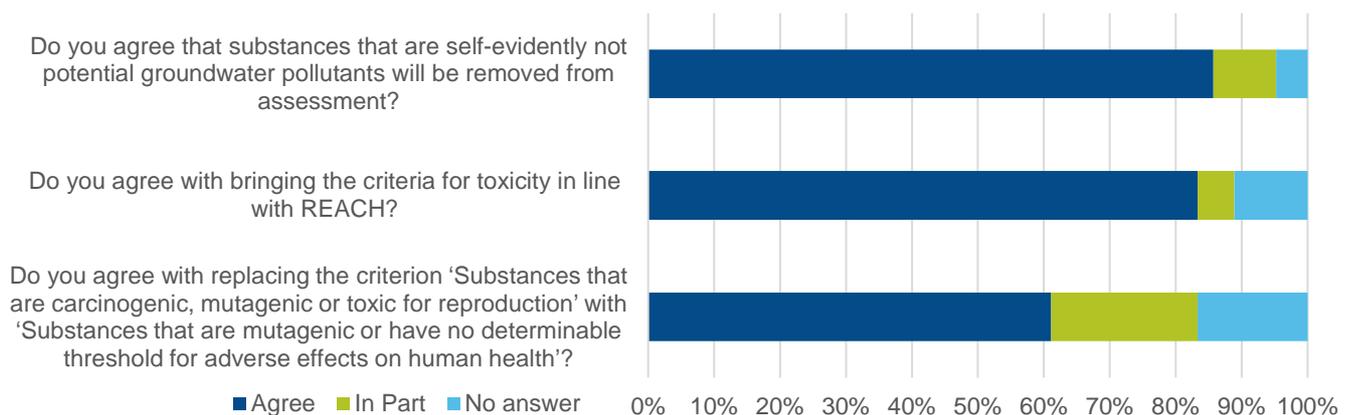


FIGURE 1 - CONSULTEES' RESPONSES TO THE THREE SPECIFIC QUESTIONS ASKED IN PART 1 OF THE CONSULTATION

In part 2 of the consultation, comments were received on 11 substance assessments and they led to greater clarification of the criteria in the methodology. In part 3 of the consultation comments were received on the applicability of the methodology to metals, the meaning of 'no determinable threshold' and situations where breakdown products are more hazardous than the original substance. Further comments received on the consultation included requests to revise the current approach to how radioactive substances are determined, and requests for further information on

regulatory changes or impacts that may occur. Both of these are subject to further separate discussions, however the latter is beyond the scope of JAGDAG.

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1. Comments & response on the proposed revisions to methodology for the determination of hazardous substances

Consultees were invited to respond to 3 questions on the most significant changes to the 2012 JAGDAG methodology for the determination of hazardous substances in groundwater.

1.1. Do you agree that substances that are self-evidently not potential groundwater pollutants will be removed from assessment (see section 2.2 of the proposed methodology)?

Of the 18 responses, 15 (83%) agreed with the proposal, 2 (11%) agreed 'in part' and 1 (6%) did not provide a response to this particular question.

The responses were generally supportive, identifying the approach as sensible and fitting with risk-based regulation. Further comments noted that it was appropriate to exclude substances that are ubiquitous in groundwater from assessment, so that only those that are most harmful are considered to be hazardous substances. One response mentioned major ions being excluded by this criterion, although it is not the intention of the criterion to exclude all major ions.

Two suggestions were made to amend this aspect of the methodology. Firstly that reference should be made to exclusion from hazardous classification on the grounds of toxicity, persistence, liability to bioaccumulate or equivalent concern for substances. Secondly that this criterion should be restricted to those substances which are found at aqueous solubility concentrations, as some other elements could be hazardous at high concentrations and therefore should not be removed.

JAGDAG considered the suggestions and in response to the comments, some major ions and substances present naturally in groundwater could be harmful and fall within the other criteria to make them hazardous substances, therefore it is not appropriate to exclude them. Substances will need to be considered on a case by case basis. In addition there is a need for transparency in decision making and a record of the decisions on whether a substance is hazardous or non-hazardous.

Consideration of the feedback received during the consultation has led JAGDAG to revise the wording so the intent is clearer (see section 2.2 of the methodology).

The criteria to be considered in the determination are outlined in Sections 2.3 and 2.4 below. 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.

1.2. Do you agree with bringing the criteria for toxicity in line with REACH (see section 2.3 of the proposed methodology)?

Of the 18 responses, 15 agreed (83%), 1 agreed 'in part' (6%) and 2 (11%) did not provide a response to this particular question.

The comments received generally supported the alignment with the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation, and adopting a standardised approach for assessing substances in the environment.

Further work on radioactive substances and consistency with the Classification, Labelling and Packaging Regulation was requested from the Nuclear Decommissioning Authority and Nuclear Industry Group for Land Quality. In response, the consultation document maintained the pre-existing situation for radioactive substances, namely that all radioactive substances are hazardous. It is JAGDAG's intention to review the current approach and JAGDAG will consult as necessary.

1.3. Do you agree with replacing the criterion 'Substances that are carcinogenic, mutagenic or toxic for reproduction' with 'Substances that are mutagenic or have no determinable threshold for adverse effects on human health' (see section 2.4 of the proposed methodology)?

Of the 18 responses, 11 (61%) agreed, 4 (22%) agreed 'in part' and 3 (17%) did not provide a response to this question.

Several consultees raised concerns about equivalent level of concern being determined based on mutagenicity or 'no determinable threshold'. Further explanation was requested of the reasoning behind 'having no determinable threshold for adverse effects on human health', why it was introduced, and why mutagens are more of a concern than carcinogens or substances that are toxic for reproduction.

Concerns were also raised over the use of 'no determinable threshold for adverse effects on human health', citing a considerable difference between a substance that has been determined as having "no determinable threshold" for adverse effects and a substance where a threshold is either not deemed necessary or is not able to be determined as yet. In other words, the absence of a threshold value may not directly imply there is "no threshold". Concern about consistent application of these criteria across all substances and the impact of this criterion on the determination of radioactive substances were also raised.

In response to the comments received, it is noted that due to their mode of action, mutagens are assumed to have no threshold for adverse health effects and therefore exposure should be as low as reasonably practicable (ALARP). This is because it is assumed that a single molecule could interact with DNA and produce a mutation. That mutation could subsequently lead to the development of cancer within an individual. Mutations can also be inherited and therefore are of concern if the mutation is harmful, as it could harm current and future generations.

Radioactive substances by their nature also have mutagenic properties. Prior to consultation, JAGDAG acknowledged that transparency for radioactive substances could be improved and agreed to further discussion on how to provide that. Time constraints however, meant the short pre-existing statement that all radioactive substances are hazardous was maintained in the consultation. Subsequently, greater clarification has been added to section 2.4 of the methodology.

For carcinogenic or reproductive toxicants, it is widely accepted that a threshold below which no adverse effects occur exists for:

- substances that are carcinogenic via a non-mutagenic mode of action (non-genotoxic carcinogens)
- substances that are reproductive toxicants via a non-mutagenic mode of action

Substances that are carcinogenic and/or reproductive toxicants via a non-mutagenic mode of action are assumed to have a threshold below which they do not cause adverse effects. That threshold can be used to identify a concentration below which no harm is assumed to occur. Hence, these substances are not intrinsically hazardous in groundwater below certain concentrations and limits can be set for their input. The wording in the methodology has been

amended to provide greater clarification on mutagenicity, and the removal of carcinogenic and reproductive toxicants from this criterion.

The wording in the methodology has also been amended to better describe what is meant by 'no determinable threshold'.

The term 'no determinable threshold' is used to capture non-mutagenic substances where the available data indicates that a threshold for harm cannot be determined, even at very low levels of human exposure. For example developmental neurotoxicity for lead or cancer for inorganic arsenic. The term does not relate to situations where either a threshold has not been derived, or where a threshold cannot be derived due to a lack of available data. If a substance meets the criteria for mutagenicity it is considered to have 'no determinable threshold', except where there is convincing evidence available to indicate otherwise.

2. Comments on the proposed determination of specific substances as hazardous or non-hazardous pollutants

In this part of the consultation, consultees were asked to provide comments on the proposed determination of substances with reference to one or more of the assessed substances. Responses were received on 11 of the 50 substances that formed part of the consultation.

Substance	Agree	In part	Disagree	Summary of consultee comments (collated from various consultees)	Response and determination
Arsenic	2			No comments provided	N/A Arsenic was determined to be hazardous under the revised methodology.
Cadmium	2			At first I was surprised at this outcome but after reading the assessment I agree with it. If there is a drinking water standard which states 5ug/l Cd is safe, it seems over-prescriptive to make this a hazardous substance and prevent input to groundwater completely, and impose a threshold in groundwater samples of 0.1ug/l (the minimum reporting value). We agree with the assessment. However, the criteria used often do not apply for metals and also the 'specific risk to groundwater' was not undertaken. This is also the case for lead (only other metal/inorganic viewed).	Cadmium was determined to be non-hazardous under the revised methodology. The application of persistence, bioaccumulation and toxicity (PBT) to metals and 'specific risk to groundwater' are discussed in part 3 of this document.
Chromium VI		1	2	We understand that the determination is based on a "no determinable threshold" deemed by the UK Committee for Mutagenicity (UK COM) in 2012. The	Chromium (VI) is determined to be hazardous under the revised methodology based on the fact it has been

			<p>evidence underlying this decision by UK COM is not clear and is contrary to guidance provided by both the World Health Organisation (WHO) and the United States Environmental Protection Agency (US EPA) Integrated Risk Information System (IRIS). These specify a no observed adverse effect level (NOAEL) of 2.5 mg/kg/day for oral exposure, rather than a “no determinable threshold” status. We acknowledge that, in a UK context, more studies are needed to increase the evidence base; however we consider the UK is taking an overly precautionary approach in this instance. Instead, Cr (VI) should currently be deemed Non-Hazardous until further evidence is gathered.</p> <p>The line drawn between Ni and Cr is on the basis of a fine distinction on mutagenicity. Arguably the two metals should take the same classification given the WHO stance, but the UK COM view supports the distinction and on balance is probably appropriate.</p>	<p>noted to be mutagenic.</p> <p>The proposed determination of Cr(VI) as hazardous takes into account the available data and guidance given by a range of organisations including WHO. It is acknowledged that different opinions exist on Cr(VI). The decision made was to be consistent with the current UK position on Cr(VI) as described by UK COM</p> <p>Nickel is determined as non-hazardous. Like chromium it does not meet the criteria for P, B and T. It is classified as Muta 2 under the Classification, Labelling and Packaging Regulation. The weight of evidence from the European Food Safety Authority indicates that the genotoxicity and mutagenicity of nickel is likely to occur via indirect mechanisms. This means that it is considered that nickel does not interact directly with the DNA in human cells, and thus a threshold can be assumed for its observed genotoxicity/mutagenicity.</p>
Cobalt		2	<p>Concern was raised that no information is provided on whether a threshold value exists, or if studies have been undertaken to derive a no-observed adverse effect level (NOAEL). Cobalt is considered an essential trace dietary mineral and we would question whether it can actually be considered as a “non-threshold” substance. We believe that further evidence and explanation is required before any final determination is made.</p>	<p>Cobalt was determined as hazardous based on it being classified as Muta 2 under CLP. Following the comments received a further review of the available information has been undertaken. A range of evidence has been considered. A number of reviews report that cobalt is mutagenic, but the data are conflicting with opposing views also published. A review by the Expert Group on Vitamins and Minerals noted mixed results had been obtained for the genotoxicity of cobalt and recommended a pragmatic guidance intake value from dietary supplements (e.g. vitamins and minerals). A European migration limit into food from food contact materials has also been recommended. Considering the uncertainty and conflicting data on the mutagenicity of cobalt II ions, its presence in food and guidance intake values from authoritative organisations, it has been decided to adopt a proportionate and pragmatic approach in terms of groundwater and to amend the</p>

				determination to 'non-hazardous'.
Cyanide		1	Cyanide shouldn't be classified as non-hazardous, when it has known disruptive effects on human biology, i.e. inhibiting cell energy production	Cyanide was determined as non-hazardous under the revised methodology. Cyanide is of high toxicity and the data included in the determination recognise this. It does not however meet the criteria for persistence, bioaccumulation or mutagenic/'no determinable threshold' so is not determined as hazardous. Inputs of cyanide to groundwater will still be regulated as a result of its determination as non-hazardous.
Dichloromethane		1	This is a favourable position for the water industry, in so much as artificial groundwater recharge schemes, being recharged with potable water will now be seen as a favourable option, despite previous concerns.	N/A Dichloromethane was determined as non-hazardous under the revised methodology.
Lead		1?	Lead as a chemical element is clearly persistent, and potentially toxic concentration of Pb(II) may be present in water under typical pH and redox conditions. It is clearly toxic. However, the data for bioaccumulation show a wide range about the 2000 used for determination. Is it reasonable to pick the highest value for determination purposes, or is a more considered judgement necessary. Although it is stated that there is no 'safe' lead concentration, there is a lead limit for drinking water that is above LoD for lead in water. Thus there is a concentration that is tolerated, as distinct from 'safe'. 'Safe' is seldom a reasonable aspiration.	Lead was determined as hazardous under the revised methodology. All the available evidence was considered to assess lead's potential for accumulation. Available bioconcentration factor (BCF) values are wide ranging, however based on the number of BCF values reported above 2000, along with evidence of accumulation in humans, the weight of evidence suggests lead met the criteria. Both the World Health Organisation (WHO) and European Food Safety Authority (EFSA) have concluded based on the available data that there is no known level of lead that is considered safe. Concern is high due to the effects on children and the fact lead has been found to accumulate in bones and teeth. Evidence shows that accumulated lead can be remobilised into the blood during pregnancy thus exposing the foetus. The drinking water limit is based on technical achievability due to lead from pipes and solder (plumbing) and therefore does not represent the intrinsic properties. Based on these and the fact lead meets the criteria for P, B and T it is determined as hazardous.

Mecoprop	5			The reclassification of mecoprop is sensible, given the relative lack of persistence and its low toxicity. I believe that it is nevertheless still an appropriate organic substance to use as an indicator for more toxic (hazardous) substances in environmental monitoring and risk assessments. This is because it is relatively commonly found and behaves relatively conservatively in risk assessment terms (slow degradation especially in anaerobic conditions, relative mobility).	N/A Mecoprop was determined as non-hazardous under the revised methodology.
Mercury				As for cobalt concerns were raised that: The determinations are based on uncertain or inconclusive evidence The evidence provided for Mercury. This is because no statement has been made regarding whether it is deemed a “no threshold” substance. We believe that this is relevant information and should be a requirement for making an informed determination.	Mercury was determined as hazardous under the revised methodology based on it meeting the criteria for P, B and T. The term 'no determinable threshold' and mutagenicity do not need to be considered since mercury meets the PBT criteria (see section 2.3 in this document) -
Nickel	3			The lack of mobility of metal ions like nickel II, due to their high degree of sorption to aquifer materials, means that they are very unlikely to present a serious issue for groundwater	N/A Nickel was determined as non-hazardous under the revised methodology.
PFOS (Perfluoro-octanesulfonic acid)	1			No comments provided	N/A PFOS was determined as hazardous under the revised methodology.
Propylene Glycol	2			We agree with the assessment. However, again specific risk to groundwater is not assessed.	Propylene glycol was determined as non-hazardous under the revised methodology. See Part 3 for further information on the specific risk to groundwater.

3. Other comments from consultees

Fifteen consultees provided additional comments on the methodology, and these, along with the responses, are summarised in this section.

Removal of 'persistent and very toxic' criterion

One consultee requested examples to illustrate and justify the recommendation for removing the 'persistent and very toxic' criterion. The comment raised was 'If a substance persists in groundwater and has been shown to cause toxic effects to humans through drinking water (that are not necessarily related to mutagenicity) then it should be prevented from entering groundwater. For example, arsenic has been determined to be hazardous, which the consultee agreed is the correct outcome, but the determination is solely based on its mutagenicity. Arsenic also causes chronic health effects by interfering with metabolism (and this is why it has created such problems in SE Asia, not through its mutagenicity). If this was the case for other substances that are not mutagenic, and assuming such a substance was persistent but didn't bioaccumulate, it would be determined as a non-hazardous pollutant under the proposed revised methodology which perhaps might not be appropriately protective.'

Response: Arsenic has been determined as a hazardous substance based on the fact it has been agreed that a threshold can't be determined for its carcinogenic effects and therefore that concentrations should be controlled by being as low as reasonable practicable. Substances that are not PBT or equivalent level of concern are determined as non-hazardous. Inputs of non-hazardous pollutants are also regulated in the UK to protect people and wildlife. 'The "persistent and very toxic" criterion has been removed, as the substances only captured by this criterion are thought not to meet the requirements for hazardous, as they are not bioaccumulative and are not substances for which thresholds cannot be derived. It was felt this criterion should therefore be removed.'

Substances missing from the consultation that were included in previous consultations

One consultee commented that lead, toltrazuril and propylene glycol were missing from the consultation but formed part of the 2013 consultation.

Response: The assessments made were not intended to be a re-run of the 2013 consultation. Assessment for lead and propylene glycol were added to the consultation documents in March 2016. Toltrazuril, a veterinary medicine, can be assessed in subsequent consultation if needed.

Exclusion of volatile substances

One consultee commented that volatile substances in groundwater could present risks via inhalation exposure and should not be excluded from the methodology.

Response: The intention of the methodology is to consider the exposure pathways that are plausible via groundwater so the text in the methodology has been amended to better express that. The text now reads *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 the inhalation, is also relevant to potential exposure).*

Current list of hazardous substances is no longer available on the JAGDAG website

Several consultees commented that the list of hazardous substances is no longer available on the JAGDAG website

Response: The list of hazardous substances has been reinstated on the [JAGDAG website](#) and will be updated to reflect the outcome of the substances considered in the consultation in due course.

Radioactive substances

The approach for radioactive substances was raised by several consultees, noting that it needs reviewing. Consideration should be given to the HSE's tolerability of probability of harm

Response: The proposed revisions do not change to the pre-existing determination methodology for radioactive substances, which follows [Defra's guidance on groundwater activities](#). However, it is recognised that there are continuing concerns on this aspect of the methodology and we will explore those concerns with industry, regulators and administrations. Should any changes need to be made we will consult as required.

Future regulation of substances

Several responses raised questions about the regulation of substances in future, including what standards will apply, guidance on how substances will be regulated and requesting a cost-benefit analysis for the economic impact of any changes.

Response: The regulations and standards that apply to substances are not within the scope of JAGDAG's methodology for the determination of hazardous substances and JAGDAG do not believe the revision to the determination methodology constitutes a regulatory change. However, the UK agencies acknowledge the points raised and will take advice from government on whether the determination methodology requires a cost benefit assessment and impact assessment. They will inform businesses of any changes.

Any regulatory impact should be seen in the light of the risk/impact assessment for groundwater. UKTAG will be advising on regulatory standards in due course and updated proposals for regulation are expected to be published in the near future.

Available evidence for making assessments

Concerns were raised about the lack of available evidence for assessing some substances and that the assessments are 'tick box' in nature. There was a request for a substantive review to be undertaken by subject matter experts and documented in a report that would be available for expert scrutiny and review.

Response: The assessments made by the JAGDAG methodology are based on a review of the available data which is obtained from a wide range of sources, including both national and international reviews and opinions where available. The assessment of each substance is documented in a template. The key data used is documented and referenced in the templates which forms the basis of the proposed determination. If data is limited or there is conflicting evidence it is noted in the template. The proposed determinations are subject to public consultation thereby inviting review of the evidence and an opportunity for further evidence to be submitted, before any determination is finally agreed. In view of the consultation comments received we will review the templates to ensure that decisions recorded are clearly worded prior to final publication.

Metals

Concerns were raised over the application of the P, B and T criteria in the methodology to metals.

Response: The methodology acknowledges that particular consideration is required in assessing metals and inorganics in regard to the criteria for P, B and T. The methodology acknowledges that the criteria are not directly applicable to metals and that this is borne in mind when assessing and applying the available data (see section 2.6). Assessments for metals and inorganics are undertaken on a case by case basis using all the relevant data available for assessment so that substances can be assessed consistently against the criteria. No alternative method of assessment was proposed during the consultation.

Equivalent level of concern

Concerns were raised about the use of 'equivalent level of concern'

Response: The Water Framework Directive defines hazardous substances 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”. Therefore equivalent level of concern has been included in the methodology. The criteria used to define 'equivalent level of concern' have been revised in the review of the methodology which has been consulted upon. The focus of the two remaining criteria used to indicate 'equivalent level of concern' is to capture those substances for which it is difficult to determine a threshold due to their hazardous properties.

Groundwater data

Concern was raised that 'specific risk to groundwater' assessment was not undertaken for substances.

Response: The section on the substance templates titled 'Specific risk to groundwater' has not been completed for any of the substances. For the substances considered in the consultation, sufficient data has been available to make a proposed determination without the need to consider groundwater monitoring data. The methodology has been amended to reflect that groundwater quality monitoring data will not be used on a routine basis but only in those cases where a determination is unclear based on the other criteria.

Breakdown products

One response to the consultation highlighted the need to show hazardous breakdown products more clearly when the original substance is a non-hazardous pollutant.

Response: Where there is information about breakdown products their status is noted on the assessment for the original substance. The template will be amended to more prominently show any breakdown products that are hazardous substances. However where a substance has breakdown products that are hazardous substances, the breakdown products have no bearing on the determination of the original substance. Any breakdown products would be assessed on their own characteristics to determine if they are hazardous substances. The individual agencies would consider and implement an appropriate regulatory approach for substances that are determined as non-hazardous pollutants but where breakdown to hazardous substances.