

Consultation Supporting Document - Summary of the main changes to the methodology and the considerations that led to those changes

The following outlines the key changes being proposed to each section of the methodology. The changes are based on comments received after publication of the 2012 version of the methodology. A copy of the 2012 version of this methodology is available on the JAGDAG website for comparison

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

There have been no major changes to this section.

Section 2.2 - Substances self evidently not potential pollutants in groundwater

This is a new section. It includes discussion of an approach for dealing with substances which are considered unlikely to be potential pollutants in groundwater.

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

Revisions have been made to the criteria for toxicity. The revisions relate to the criteria for human toxicity with the amendments bringing the criteria in line with those used in REACH to define toxicity as part of the consideration of Persistence, Bioaccumulation and Toxicity (PBT). The proposed changes are:

- The CLP¹ Category 2 criterion for mutagenicity has been removed. The criteria for Mutagenicity are now Category 1A and 1B.
- The CLP Category 2 criterion for toxicity to reproduction has been added. The toxicity criteria are therefore now Category 1A, 1B and 2 for toxic for reproduction.
- The CLP classifications of Acute Tox 1, 2 or 3 and STOT SE1 have been removed. The chronic toxicity criteria are now the CLP classifications STOT RE1 and RE2.

The revisions to these criteria bring them in line with the REACH criteria for toxicity in relation to PBT assessments. Although the criteria published in the [2012 methodology](#) were based on the REACH criteria, some slight changes were made to take into account the approach used under the previous Groundwater Directive and the need to ensure that the level of protection provided by the new methodology was equivalent to the previous approach. It is now proposed however to amend the toxicity criteria to be in line with those in the REACH PBT guidance (ECHA, 2014).

Section 2.4 - Substances that give rise to an equivalent level of concern

Two of the criteria that were originally included under Equivalent Concern have been removed:

1. Substances that are very acutely toxic to aquatic biota

¹ [CLP regulation \(classification, labelling and packaging of substances and mixtures; EC 1272/2008\)](#)

2. Substances that are persistent and very toxic

The criterion 'Substances that are carcinogenic, mutagenic or toxic for reproduction' has been amended to 'Substances that are mutagenic or have no determinable threshold for adverse effects on human health'.

A brief outline of the reasoning behind the above revisions is noted below.

The "very acutely toxic to aquatic biota" criterion was considered to not be as relevant to groundwater as it was to surface waters. The chronic toxicity criterion included in the PBT assessment is considered to be suitable for the consideration of the toxicity of a substance to aquatic life and be protective of surface water potentially impacted by inputs to groundwater. This criterion has therefore been removed from 'Equivalent Concern' in the proposed methodology.

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.

The "Substances that are carcinogenic, mutagenic or toxic for reproduction (CMR)" criterion was amended to focus on those substances for which a threshold was unable to be proposed based on their CMR properties. The criterion was therefore amended to only include mutagenic substances and those for which a threshold cannot be determined.

Section 2.5 Availability of data to undertake assessment

The wording has been amended to note that where insufficient data is available for a specific substance, use can be made of other recognised approaches such as "read across" and predicted data to obtain information on a substance and its potential impact. In addition, other recognised information sources, such as substance reviews by the European Food Safety Authority (EFSA) and the World Health Organisation (WHO) can be used to supplement CLP classification information.

- The above allows for other information sources including recognized international reviews such as WHO and EFSA to be considered alongside CLP. This approach was used, for example, for the determinations for cadmium and vinyl chloride.
 - The CLP classification indicated cadmium had the classification of "Muta 2". However, as other evidence that was outlined in a WHO review² indicates that cadmium shows mutagenic effects via inhalation rather than oral exposure, it was determined as non-hazardous in groundwater.
 - Vinyl chloride has been determined as hazardous even though it did not meet the CLP criteria. This is because additional evidence that was

² WHO (2011) [Cadmium in drinking-water](#)

outlined in a WHO review³ indicates it is not possible to derive a threshold for this substance as it is a genotoxic carcinogen.

Where other sources of information are used to influence the decision alongside CLP classifications, this will be documented and transparent within the template.

Section 2.6 Metals and other inorganics

The wording in the section on metals has been expanded to:-

- Further clarify that the REACH criteria for PBT are not directly applicable to inorganic substances including metals
- Reflect discussions on essential elements and the decision that such substances are not exempt from assessment
- Note assessments will be undertaken on a specific form of metal or inorganic substance, for example, cobalt (II) ions.

Section 2.7 Mixtures

This section replaces that of 'Substances with Intrinsic Impurities' in the 2012 methodology. It was changed to widen the issue from that of impurities to that of mixtures in general. It reflects that determinations are done on individual substances rather than groups of substances but that in some circumstances, for example dioxins and PCBs, the determination is based on the group as they occur together and have similar structures and properties.

Section 2.8 Breakdown products

No major changes to this section.

³ WHO (2011) [Chemical hazards in drinking-water - vinyl chloride](#)