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EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on the Application of the CLP Criteria

Guidance Series Overview (Incl. notes on usage)

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

Version 1.0
Nov 2024

LEGAL NOTICE

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Guidance on the Application of CLP Criteria

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DOCUMENT HISTORY

Version	Comment	Date
Version 1.0	First Edition	November 2024

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1. THE NEW GUIDANCE ON THE APPLICATION OF THE CLP CRITERIA SERIES CONTENTS AND USAGE NOTES

This new guidance series re-presents the 'Parts' of the Guidance on the Application of the CLP by presenting them as a series of separate documents for ease of use. Besides this overview document, this new CLP Guidance series contains as separate guidance documents:

Part 1: General Principles for Classification and Labelling
(Including Annex I: Collection of Internet links for the users of the Guidance)

Part 2: Physical Hazards
(Including Annex I: Relation between Transport and CLP classification regarding Physical Hazards)

Part 3: Health Hazards
(Including Annex I: Background document to the guidance for setting specific concentration limits for substances classified for reproductive toxicity according to Regulation (EC) No 1272/2008)

Part 4: Environmental Hazards and Part 5: Additional Hazards
(Including Annexes:

I. Aquatic Toxicity
II. Rapid Degradation
III. Bioacumulation
IV. Metals and Inorganic Metal Compounds

Note: Although split into separate parts, these guidance series documents together constitute a single Guidance on the Application of the CLP Criteria. As such, users of the CLP Guidance series should take care to carefully consult Part 1: General Principles for Classification and Labelling before progressing to any of the subsequent parts.

For a full explanation and details of the reorganisation, including explanations of the revised annex and version numbers, please see sections 2 and 3 below.

2. INTRODUCTION TO THE DOCUMENTS IN THE GUIDANCE ON THE APPLICATION OF THE CLP CRITERIA SERIES

2.1. OVERVIEW

Sections 2 and 3 provide a more detailed overview of Parts contained within the Guidance on the Application of the CLP Criteria series. Note that prior to November 2024 all Guidance on the Application of the CLP Criteria was contained within one document. However, due to the increasing size of this single document, it became necessary to reorganise the guidance by splitting it into its constituent 'Parts' for ease of use.

For details on the CLP Guidance document history and revised version numbers, please see section 3 of this document.

2.2. PARTS AND ANNEXES OF THE GUIDANCE ON THE APPLICATION OF THE CLP CRITERIA

The Guidance on the Application of the CLP Criteria (v6.0 Jan 2024) consisted of the following parts and annexes:

Part 1: General Principles for Classification and Labelling

Part 2: Physical Hazards

Part 3: Health Hazards

Part 4: Environmental Hazards

Part 5: Additional Hazards

Annex I: Aquatic Toxicity

Annex II: Rapid Degradation

Annex III: Bioaccumulation

Annex IV: Metals and Inorganic Metal Compounds

Annex V: Collection of Internet links for the users of the Guidance

Annex VI: Background document to the guidance for setting specific concentration limits for substances classified for reproductive toxicity according to Regulation (EC) No 1272/2008

Annex VII: Relation between Transport and CLP classification regarding Physical Hazards

2.3. DOCUMENTS IN THE NEW GUIDANCE ON THE APPLICATION OF THE CLP CRITERIA SERIES

In order to promote user friendliness and practicality, the parts and Annexes have been reorganised into the following single documents and published separately (Annex numbers V, VI, and VII have been altered as indicated below to respect their position in a new document and to avoid confusion):

Part 1: General Principles for Classification and Labelling
(Including Annex I, formerly Annex V)

Part 2: Physical Hazards
(Including Annex I, formerly Annex VII)

Part 3: Health Hazards
(Including Annex I, formerly Annex VI)

Part 4: Environmental Hazards and Part 5: Additional Hazards
(Including Annexes I-IV)

3. GUIDANCE UPDATE HISTORY UNTIL NOV 2024

3.1. PREFACE (FROM V6.0 JAN 2024)

This document is the Guidance on the Application of the CLP Criteria. It is a comprehensive technical and scientific document on the application of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP), which replaced the Dangerous Substances Directive 67/548/EEC (DSD) and the Dangerous Preparations Directive 1999/45/EC (DPD) in a staggered way. CLP is based on the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and is implementing the provisions of the GHS within the EU. The objective of this document is to provide detailed guidance on the application of the CLP criteria for physical, health and environmental hazards. The guidance is developed to

primarily assist manufacturers, importers and downstream users in applying the classification and labelling criteria, and it also includes practical examples. It is also assumed to be the guidance on classification and labelling for Competent Authorities in the Member States (MS CA), for the Commission services and the European Chemicals Agency (ECHA).

In certain chapters, like for example the ones on carcinogenicity, mutagenicity and reproductive toxicity, the guidance includes to a larger extent scientific advice on how to interpret different data used for classification. This additional guidance is based on experience gained within the EU during the application of the classification criteria under Directive 67/548/EEC, and is written for the experts within the respective fields.

This guidance document was developed as a REACH Implementation Project (RIP 3.6) at the Institute for Health and Consumer Products (IHCP) of the Joint Research Centre in Ispra, with support from working groups consisting of experts on classification and labelling from EU Member States and Industry. The project started in September 2007 and the different working groups had meetings and continuous discussions to discuss and develop the guidance text until spring 2009. Finally all texts were consolidated and edited at the IHCP. RIP 3.6 was financially supported with an administrative arrangement made with Directorate-General Enterprise and Industry (currently DG Growth). The guidance was handed over to ECHA in summer 2009.

After that the guidance has been revised twice – version 2.0 in April 2012 on the long-term aquatic hazard and version 3.0 in November 2012 in relation to the guidance chapters on setting of specific concentration limits (SCLs) for health hazards.

During 2012/2013, further drafting work was done in close collaboration with European experts, to take account of a range of guidance aspects (for example further guidance on the criteria for respiratory and skin sensitisation, and other health related points, as well as guidance on the criteria for chemically unstable gases and aerosols and other physical hazards related changes) following the 2nd and/or the 4th Adaptation to Technical Progress (ATP) to the CLP (Commission Regulation (EU) No 286/2011 and No 487/2013[1]). This work resulted in publication of version 4.0 in November 2013 and the subsequent corrigendum version 4.1 June 2015 to update the text following the transitional period for the 4th ATP.

In relation to labelling and packaging, a new stand-alone guidance document was prepared (*'Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008'*), warranting the deletion of Part 5 and of Annex V of the Guidance on the Application of the CLP Criteria. The Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 is published on ECHA's guidance website, under http://guidance.echa.europa.eu/guidance_en.htm.

Both guidance documents were further updated in 2016 to address the changes due to the 8th ATP (e.g. new alternative methods to classify oxidising solids, changes in the classification for skin corrosion/irritation, serious eye damage/irritation and aerosols, as well as changes in precautionary statements).

Therefore, the current version of the Guidance reflects the changes made by the 8th ATP (Regulation 2016/918) in Annex I to CLP. These changes apply from 1 February 2018.

However:

- The 8th ATP may already be applied on a voluntary basis before that date.

[1] Commission Regulation (EU) No 286/2011 of 10 March 2011 and Commission Regulation (EU) No 487/2013 of 8 May 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

- Substances and mixtures placed on the market before 1 February 2018 shall not be required to be relabelled and repackaged in accordance with the 8th ATP during a period of two years, i.e. before 1 February 2020.

Between 2019 and 2023, the part 4 of the guidance (hazards to the aquatic environment) and annexes I – IV were updated to provide guidance on new OECD TGs, provide clarity on a number of areas, and correct a number of errors/typos. More substantial matters were updated by consulting a PEG established for the purpose, RAC, and Member States/COM via CARACAL. Matters editorial in nature (spelling and typos) were update following a fast-track procedure involving only CARACAL. This update represents the 6th update of the CLP guidance (v 6.0).

Note that Version 6.0 represented the last version of the Guidance on the Application of the CLP Criteria contained within one single document.

3.2. PREFACE (FROM NOV 2024)

In November 2024 the guidance was re-presented split in its component 'Parts' as a guidance series (see section 2.3). This re-presentation follows updates and the introduction of new guidance as follows:

- Part 2: Physical Hazards - Substantial update of all hazard classes (sections 2.1 – 2.16) to account for:
    - CLP ATP 12 · Updates to test guidelines
    - Developments in science
    - Clarifications on comparability between EU and UN methods
    - Removal of references to DSD
    - Addition of section 2.17 on desensitised explosives.

- Part 3: Health Hazards - Addition of section 3.11 on Endocrine Disruption (HH)
- Part 4: Environmental Hazards and Additional Hazards - Addition of sections 4.2 on Endocrine Disruption (Env) and 4.3 on PBT/vPvB and PMT/vPvM.

ECHA would like to acknowledge the contribution of colleagues from European Food Safety Agency (EFSA) for the drafting of the guidance on endocrine disruptors in sections 3.11 and 4.2 and the significant role they played in producing the guidance in these sections.

3.3. DOCUMENT HISTORY

The below table shows the history of the single document for Guidance on the Application of the CLP Criteria from its introduction in 2009 (Version 1.0) until 2024 (Version 6.0), when the document is split in its various parts. Following the split, the individual documents have a version number which reflects the number of updates the individual 'Parts' and relevant 'Annexes' have received since 2009. Details of these updates can be found in each Part's document history table.

Table 2.1: Document History for Guidance on the Application of the CLP Criteria, 2009 – 2024.

Version	Comment	Date
n.a.	First edition	August 2009
n.a.	Please note that change between the version published in August 2009 and that of April 2011 are not recorded in this document history.	April 2011
Version 2.0	Revision of the Guidance addressing content in relation to the environmental criteria chapters and Annexes following the 2nd Adaptation to Technical Progress to the CLP Regulation (Commission Regulation (EU) No 286/2011). The ECHA Secretariat revised the Guidance *Part 4 – Environmental hazards* and *Annexes* of the guidance document referring to the revised criteria for the long-term aquatic hazard for substances and mixtures and added new *Part 5 – Additional hazards* referring to the hazard class 'hazardous to the ozone layer'. As well, a number of examples have been included in the respective Parts and Annexes to illustrate the revisions performed. Further to this, a range of editorial corrections were proposed for *Part 1 – General principles for classification and labelling*. The update includes the following: • Revision of Part 1, by eliminating and amending out of date information and restructuring the text in order to reflect the Guidance update. • All green boxes in Part 4 that are impacted by the 2nd ATP were updated. As the CLP legal text uses commas instead of dots to define numbers smaller than 1, the green boxes now show commas as well. • Revision of Part 4, by providing guidance on the application of the new long-term aquatic hazard criteria for substances and mixtures. • Section 4.1.3 Classification of substances hazardous to the aquatic environment and section 4.1.4 Classification of mixtures hazardous to the aquatic environment were substantially revised, for example by addition of new references, as well as the new/revised examples to illustrate relevant topics in the Part 4. • New Part 5 – Additional hazards was added (please note that Part 5: Labelling was deleted from the Guidance in previous non-recorded versions and covered via a new	April 2012

	Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 published in April 2011). • Most of the I.3 sub-sections in Annex I – Aquatic toxicity were revised. • In Annex II – Rapid degradation the terminology was modified. • Most of the Annex IV – Metals and Inorganic Metal Compounds was substantially modified and revised, as well as in sub-section IV.7 new examples were added.	
Version 3.0	Revision of Guidance Part 3 Health Hazards, relating to specific concentration limits (SCLs) for 4 hazard classes and the inclusion of a new Annex. The update includes the following: • Revision of Part 3, by providing guidance on the setting of lower and higher SCLs for 4 health hazard classes in section 3.2.2.5 Skin Corrosion/Irritation; section 3.3.2.5 Serious Eye Damage/Eye Irritation; section 3.7.2.5 Reproductive Toxicity and section 3.8.2.6 STOT-SE, in accordance with CLP Article 10(7); • Inclusion of a new Annex (Annex VI) providing guidance on setting SCLs for the reproductive toxicity hazard class based on potency considerations.	November 2012
Version 4.0	(i) Revision of the CLP Guidance addressing content in relation to the Part 2: Physical hazards, Part 3: Health hazards and Annex VI following the 2nd and the 4th Adaptation to Technical Progress to the CLP Regulation (Commission Regulation (EU) No 286/2011 of 10 March 2011 and Commission Regulation (EU) No 487/2013 of 8 May 2013). The revision includes: • Numbering of chapters within CLP Guidance, Parts 2 & 3 were synchronised with corresponding chapter numbering of CLP, Annex I. • Changes in the legal text due the 2nd and 4th ATPs. • Changes in the legal text due to the 4th ATP were highlighted in orange within all relevant green boxes. All changes are preceded by a note highlighting the changes. (To note: a corrigendum will change the colour of relative legal text boxes from orange to green when the 4th ATP applies). In addition, the revisions to Part 2: Physical hazards include the following: • Chapters 'Pyrophoric liquids and solids' and 'Oxidising liquids and solids' were divided into four chapters: 'Pyrophoric liquids', 'Pyrophoric solids', 'Oxidising liquids' and 'Oxidising solids' respectively.	November 2013

- Based on the 4th ATP the CLP Guidance Chapter 2.2 Flammable gases was extended to take into account the scope of CLP, Annex I, section 2.2 to include chemically unstable gases.
- Further, the 4th ATP amended the criteria in CLP Annex I, Section 2.3 Flammable aerosols and renamed it into 2.3 Aerosols. Hence, the CLP Guidance was amended accordingly.
- All chapters were rechecked and redundant and/or outdated information were deleted, reorganised and/or revised. For example, 'Introduction' chapters were significantly shortened, however several "examples" sections (i.e. 'Example for classification…') were further elaborated.
- Where missing, a new sub-chapter 'Relation to other physical hazards' was added.
- Sub-chapter 2.0.4 'Physical state' was extended with additional information about substance/mixture form and some examples.
- In sub-chapter 2.1.5.2 'Additional labelling provisions' within chapter 2.1 'Explosives' further guidance about hazard communication was provided.
- In sub-chapter 2.5.6.1 a new recommendation for shot hazard codes to identify the classification of gasses under pressure was added.
- Footnotes with references to endorsed or on-going revisions of the GHS which have not yet been implemented into the CLP via a respective ATP were included in relevant sub-chapters of this guidance for information only.

In addition, the major revisions to Part 3: Health hazards include the following:

- All sections: revisions to legal text for the 4th ATP, including revisions to Precautionary Statements in the Tables with labelling information.
- Section 3.1: the introduction of new guidance for the 4th ATP in section 3.1.4.1.
- Sections 3.2.2.5 and 3.3.2.5: clarification to the recently published text (Version 3.0) for the setting of SCLs.
- Section 3.4 (sensitisation) has been significantly re-organised to present all the information on respiratory sensitisation together, followed by the information on skin sensitisation. This is in line with how the sections are presented in the CLP Regulation and in GHS documents.
- Section 3.4: integration of subcategories for respiratory and skin sensitisation based on potency of a substance; clarification of semi-quantitative terms like 'low to moderate sensitisation rate' and 'high or low exposure';

	elaboration of evaluation of human data for skin sensitisation and the addition of new examples. • Section 3.7: the introduction of new guidance for the 4th ATP in section3.7.4.1 and section 3.7.5.1. (ii) Corrigendum of Part 1: General principles for classification and labelling and Part 4: Environmental hazards and its related Annexes I-V. The corrigendum includes the following: • The list of abbreviations was updated. • Update or deletion of outdated references to Guidance on information requirements and chemical safety assessment, Endpoint specific guidance (Chapter R.7a) within Annexes I-V. • A footnote informing the reader that with effect from 1 September 2013, Directive 98/8/EC had been repealed by Biocidal Products Regulation (EU) No 528/2012 was added. • In Part 1, Part 4 and Annexes modal verbs 'shall' were replaced with 'must' where appropriate. • A footnote related to respiratory sensitisation and skin sensitisation in Table 1.1 was removed. • A correction to Example D, sub-chapter 4.1.4.7.5 was applied, namely a reference to CLP, Annex I, point (b) (ii) of Table 4.1.0 was introduced. In addition, the result of a summation method calculation was corrected.	
Version 4.1	Corrigendum to take account of the end of the transition period of the 4th ATP (as foreseen in version 4.0 above): • change the colour of relative legal text boxes from orange to green; • in Part 2, to delete section 2.2.1 Flammable gases and section 2.3.1 Flammable Aerosols (outdated text) and renumber sections 2.2.2 Flammable gases (including chemically unstable gases) and 2.3.2 Aerosols accordingly; • in Part 3, to delete the "outdated text" in sections 3.7.4.1 and 3.7.5.1 in Reproductive Toxicity. In addition, minor editorial errors were corrected and minor reformatting was made.	June 2015
Version 5.0	Partial revision of the Guidance to update the content mainly following the 8th Adaptation to Technical Progress to the CLP Regulation (Commission Regulation (EU) No 286/2011). Revision of few specific additional topics. The update includes the following: (i) Throughout the document: • Revision of legal references and legal text quotations.	July 2017

- Renumbering of some sections.
- Deletion of sections regarding the reclassification of substances and mixtures previously classified in accordance with the DSD or DPD.

(ii) Revision of Part 1:

- Deletion of reference to pre-CLP legislation and transitional period.
- Addition of reference to read-across and grouping in the context of bioavailability.
- Removal of quotation of Article 31(3) of REACH.
- Clarification about applicability of additivity principle.
- Clarification about the application of mixture rules to substances with CMR constituents.
- Reduction of section 1.2.3.1 on physical hazards to avoid redundancy with section 2.0.4.
- Revision of section 1.7 and removal of unnecessary information. Table on additional information using transport classification moved to a new Annex VII.

(iii) Revision of the following sections of Part 2:

- 2.1 (Explosives): replacement of new figure 2.1.3; update of label elements; addition new note 2 to table 2.1.2 on requirement for SDSs.
- 2.3 (Aerosols): update of text on classification criteria; update of decision logic 2.3.1-a; update of section 2.3.6 on the relation to transport classification.
- 2.14 (Oxidising solids): addition of criteria using test 0.3; update of labelling elements.

(iv) Minor changes to the following sections in Part 2:

- 2.8 (Self-reactive): update of label elements.
- 2.12 (Emitting flammable gases): update of label elements.
- 2.15 (Organic peroxides): update of decision logic.2.15.1; update of label elements.

(v) Revision of following sections in Part 3:

- 3.1 (Acute toxicity): Reference to new *in-vitro* test. Indication that harmonised ATE values will be included in Annex VI to CLP. Deletion of reference to the concept of relating the conditions of an acute inhalation test to real life. Indication that not-classified components may influence ATE and, in general, clarification about components to be considered for mixture classification according to the case. Indication to avoid under classification for oral toxicity. Addition of a new example (13) on the application of additivity methods for mixtures with components in different physical forms.

	• 3.2 (Skin corrosion): Subsection on non-testing methods updated and clarified the need to assess the relevance. Update of classification criteria. Inclusion of new figure illustrating the tiered evaluation approach. Inclusion of a new figure illustrating the relative weight of different available pieces of information to be considered when weight of Evidence (WoE) is applied. Replacement of the decision logic chart with separate decision logics for substances and mixtures, based on the chart from GHS. Clarification about classification of mixture as Category 1 without subcategory. • 3.3 (Serious eye damage/irritation): Clarification of the need for further data when considerations about alkaline/acid reserve suggest no risk added. Interpretation of non-testing methods results enhanced. Mentioned the use of LVET data. Inclusion of new figure illustrating the tiered evaluation approach. Inclusion of reference to new figure on hierarchy of information added in section 3.2. Replacement of the decision logic chart with separate decision logics for substances and mixtures, based on the chart from GHS. • 3.4 (Respiratory or skin sensitisation): Deletion of the relationship between skin and respiratory sensitisation potential. Identification of non-human data brought in line with REACH guidance. Introduction of available non-testing systems. Clarification of the test sample to be used in human diagnostic patch testing. • 3.5 (Germ cell mutagenicity): Reference to OECD TG 488 added. New section on classification of substances containing CMR constituents, additives or impurities included. (iv) Minor changes to the following sections in Part 3: • 3.6 (Carcinogenicity): Removal of reference to supporting evidence for classification under DSD. Update of label elements. New section included on classification of substances containing CMR constituents, additives or impurities. • 3.7 (Reproductive toxicity): New section included on classification of substances containing CMR constituents, additives or impurities. • 3.8 (STOT-SE): Editorial corrections to the examples. (vi) Minor changes to Part 4 to update the terminology when referring to short-term (acute) and long-term (chronic) studies.	
Version 6.0	Part 4 has been updated to provide clarifications, correct errors, delete information considered irrelevant, and add text on new OECD TGs. The update includes the following: • Section 4.1.3.3.1: The paragraph referring to the absence of chronic data has been amended to reflect general data availability and established practice;	January 2024

- Section 4.1.3.3.1; Additional text was added to clarify cases where data on a degradation product may need to be considered;
- Section 4.1.3.3.1: A reference to a topic the guidance annexes do not directly comment on was deleted;
- At the end of section 4.1.3.3.2: Some text was added to further define instances where Category Chronic 4 may apply;
- Section 4.1.3.3.3: Text was added on the fact that M-factors are considered part of the classification;
- Section 4.1.4.5: Clarification on deriving classification when using toxicity values calculated from the additivity formula was added;
- Section 4.1.4.7.5: Correction to Example D and explanation added;
- Section 4.1.7 was deleted as any reference to reclassification from DSD is out of date;
- Annex I.2: General statements on most commonly occurring issues during aquatic toxicity testing have been added;
- Annex I.2.1.1: General considerations on OECD TG 236 were added;
- Annex I.2.1.2: General considerations regarding various relevant OECD TGs added;
- Annex I.2.2.1: A more recent change in the respective OECD TG (202) is reflected;
- Annex I.2.2.1: Clarifications on invertebrate data beyond *Daphnia Magna* were added;
- Annex I.2.2.2: A more recent change in the respective OECD TG protocol (202 part II) is reflected;
- Annex I.2.2.2: Clarifications on invertebrate data beyond *Daphnia Magna* were added;
- Annex I.2.3.2: Clarifications on aquatic macrophyte data were added;
- Annex I.2.3.2: CLP preference on algae as the preferred test species deleted;
- Annex I.3.2: Clarification on use of surrogate approach for chronic classification added;
- Annex I.4: Clarification on use of data for difficult to test substances added;
- Annex II.2: Two first sentences of the paragraph have been deleted as they were vague and did not offer any added value;
- Annex II.2.3.6: An additional statement that soil degradation data can be used under certain conditions in the absence of aquatic degradation data has been added;
- Annex II.2.3.7: Clarification on the use of anaerobic degradation data has been added;
- Annex II.3.1: Clarification on the general guidance for

	complex substances has been added (also change in I.4.5); • Annex II.3.5: Clarification text on presence of both positive and negative ready biodegradability tests has been added; • Annex III.2.1: Footnote 29 has been deleted as it is out of date; • Annex III.2.1.2: Clarification text on radio-labelled substances has been added; • Annex III.2.2.2, Table III.1 has been deleted; • Annex III.2.2.2, Guidance on (Q)SAR BCFs and their use has been added; • Annex III.5: Text added to emphasise that a conclusion on bioaccumulation is required under CLP and that a conclusion as "inconclusive" is still possible, albeit not preferred; • Annex III.5: More explicit wording added on the conclusion on bioaccumulation, based on the available data; • Annex IV.3: Rapid removal footnote amended to reflect CARACAL decision on rapid removal; • Annex IV.5.4: Correction of error regarding loading rates used to determine chronic M-factors; • Annex IV.5.6: Correction of how alloys are considered under CLP to remove reference to 'special preparations' and accurately reflect CLP Art. 2(27); • Table IV.1: Correction of criteria error on determining M-factors for readily soluble metal compounds; Besides these changes, typos, spelling errors and other formatting issues, such as homogenisation of referencing (both within the document and to external sources), have been addressed. Note, such changes are not substantial and do not alter the content.	
Document deleted	Single document for Guidance on the Application of the CLP Criteria reorganised and re-presented in constituent parts.	November 2024

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