Classification and Labelling of Active Substances in Plant Protection and Biocidal Products in the European Union: Changes in Procedures and Increased Importance

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The Classification, Labelling and Packaging (CLP) Regulation published in 2008, which replaced the classification, packaging and labelling of Dangerous Substances Directive (DSD) published in 1967, incorporated the internationally agreed Globally Harmonised System of Classification and Labelling of Chemicals (GHS) into Community law and did not only place all existing EU harmonised classifications listed under the DSD in a table in an annex to the CLP Regulation, but also converted all existing classifications into GHS classifications using the GHS criteria and placed them in another table in the annex. Under the CLP Regulation, a chemical Active Substance (AS) of a Plant Protection Product (PPP) or Biocidal Product (BP) is normally subjected to Harmonised Classifications and Labelling (CLH). In this article, the provisions introduced by the CLP Regulation, the changes on the procedures for setting/revising CLH, increased importance of CLH in the evaluation processes for active substances in PPPs and BPs, *etc*. are summarised.

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Introduction

Since the days of the European Economic Community (EEC), the European Union (EU) has recognised that the differences between the national provisions of the Member States (MSs) on classification and labelling can help to create barriers to trade.

To achieve the free movement of chemical substances within the European Community (hereinafter, the "Community"), the first Dangerous Substances Directive (DSD or DS Directive) relating to the classification, packaging and labelling of dangerous substances was published in 1967.

However, under the DSD, EU Harmonised Classifications and Labelling (CLH) had not been set to all approved chemical Active Substances (ASs) of Plant Protection Products (PPPs) or Biocidal Products (BPs) in the EU. For chemical ASs for which no CLH had been established, self-classifications carried out by the manufacturers or importers had been continuously used.

The DSD was replaced by the Classification, Labelling and Packaging (CLP) Regulation published in 2008. The CLP Regulation incorporated the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) into Community law.

All the existing EU harmonised classifications listed in the DSD were not only placed unchanged in an annex to the CLP Regulation but also converted into GHS classifications using the GHS criteria and listed separately in the annex to the Regulation.

Under the CLP Regulation, ASs of PPPs or BPs are normally subject to CLH. Under the CLP Regulation, the European Chemicals Agency (ECHA) is involved in the evaluation for setting/revising CLH.

Though CLH can influence the decision on approval/renewal of approval of ASs of PPPs or BPs, in some cases an opinion proposing CLH setting/revising of an AS of PPPs or BPs was adopted later than the adoption

of the conclusion or the opinion for the AS, and consequently, the decision on approval/renewal of approval was delayed. To solve this problem, measures to facilitate earlier adoption of CLH proposals were introduced.

To improve the efficiency of chemical substance evaluation and promote harmonisation, there also have been recent movements towards a "one substance - one assessment" approach in Europe and OECD activities towards harmonisation of international classification of chemical substances.

Sumika Technoservice Corporation has long investigated information on regulations regarding approval/renewal of approval of active substances in plant protection products and biocidal products in the EU and also provided support for intelligence investigations on CLH setting/revisions that influence evaluations for approval/renewal of approval of AS. Based on our accumulated experience in such investigations, this article provides an overview of the past DSD established for setting/revising CLH for chemical substances, as well as the CLP Regulation which replaced the DSD, and summarises the evaluation procedures for CLH setting/revising under the CLP Regulation, the importance of CLH in approval/renewal of approval of ASs of plant protection products or biocidal products, and recent movements in the evaluation for classification and labelling.

Evaluation for the classification and labelling of chemical substances in the EU

1. DSD and evaluation for the classification and labelling under the DSD

(1) Structure of the DSD

DSD 67/548/EEC[1)], the first Directive for classification, labelling and packaging of dangerous substances, was published in the EU Official Journal (OJ) on August 16, 1967. Member States should apply the measures by January 1, 1970, at the latest. At that time, hazard classification provided were based on limited physical and chemical properties and general toxicity, and did not include carcinogenicity, mutagenicity and reproductive toxicity.

DSD 67/548/EEC consisted of Annexes I to IV as listed in **Table 1**.

DSD 67/548/EEC originally contained provisions on classification, labelling and packaging, but has been amended many times over the years to include measures for evaluation of chemical substances and EU test methods.

Table 1 Annexes to Directive 67/548/EEC

Annex	Title
Annex I	LIST OF SUBSTANCES CLASSIFIED
Annex II	DANGER SYMBOLS AND INDICATIONS OF DANGER
Annex III	NATURE OF THE SPECIAL RISKS ATTACHING TO DANGEROUS SUBSTANCES
Annex IV	SAFETY ADVICE CONCERNING DANGEROUS CHEMICAL SUBSTANCES

Table 2 Annexes to Directive 67/548/EEC as amended by Directive 79/831/EEC

Annex		Title
Annex I		LIST OF SUBSTANCES CLASSIFIED
Annex II		DANGER SYMBOLS AND INDICATIONS OF DANGER
Annex III		NATURE OF THE SPECIAL RISKS ATTACHING TO DANGEROUS SUBSTANCES
Annex IV		SAFETY ADVICE CONCERNING DANGEROUS CHEMICAL SUBSTANCES
Annex V		
	Part A	Methods for the determination of physico-chemical properties
	Part B	Methods for the determination of toxicity
	Part C	Methods for the determination of ecotoxicity
Annex VI		GENERAL CLASSIFICATION AND LABELLING REQUIREMENTS FOR DANGEROUS SUBSTANCES
Annex VII		INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ('BASE SET') REFERRED TO IN ARTICLE 6 (1)
Annex VIII		ADDITIONAL INFORMATION AND TESTS REQUIRED UNDER ARTICLE 6 (5)
Annex IX		
	Part A	Provisions relating to child-resistant fastenings
	Part B	Provisions relating to tactile warnings of danger

According to the Amendment Directive 73/146/EEC[2], Annex V was inserted. Test methods were specified in Annex V.

According to the 6th Amendment Directive 79/831/EEC[3], the articles of the DSD were substantially changed. Articles 1 to 8 were replaced by new Articles 1 to 23, and original Articles 9, 10 and 11 became Articles 24, 25 and 26, respectively.

Following the introduction of new articles, danger for the environment, carcinogenicity, mutagenicity and teratogenicity were added as hazards subject to classification and labelling.

Annexes VI to IX were added, and the DSD as amended by the 6th Amendment Directive consisted of Annexes I to IX as listed in **Table 2**.

According to the 7th Amendment Directive 92/32/EEC[4], the articles of the DSD were substantially changed again. Articles 1 to 23 were replaced by new Articles 1 to 32, and original Articles 24, 25 and 27 became Articles 33, 34 and 35, respectively. In Annex II, a symbol indicating danger for the environment was added, and Annex VI Part I.A, Annexes VII and VIII were replaced with new ones.

As a result of many amendments, the DSD not only contained provisions relating to classification, labelling and packaging contained in the CLP Regulation but also contained provisions on chemical substance evaluation conducted under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation 1907/2006[5] and EU test methods contained in Test Methods Regulation 440/2008[6].

According to the Amendment Directive 2006/121/EC[7] published together with the REACH Regulation in the OJ on December 30, 2006, deletion of Annexes VIIA, VIIB, VIIC, VIID and VIII related to the provisions incorporated in the REACH Regulation, and Annex V containing EU test methods was applied from June 1, 2008. The EU test methods laid down in Annex V were incorporated into the Test Methods Regulation 440/2008.

The DSD, which still contained provisions relating to classification and labelling, was finally replaced by CLP Regulation 1272/2008[8] published in the OJ on December 31, 2008.

(2) Evaluation for classification and labelling under the DSD

The first DSD 67/548/EEC, was intended to promote harmonised classification and labelling for specific hazards in the EU. Later on, annexes specifying EU test methods and data requirements were added, enabling the addition of hazards subject to classification and labelling and evaluation for classification and labelling.

According to the "European Chemicals Bureau: an overview of 15 years experience in EU chemicals legislation, 2008"[9], until the ECHA came to be involved in evaluation for classification and labelling under CLP Regulation 1272/2008, the European Chemicals Bureau (ECB) created in 1993 as a unit within the European Commission's Joint Research Centre (JRC) had provided scientific and technical support for the classification and labelling of dangerous substances.

The ECB was responsible for the scientific and technical preparation of the European Commission's proposals to update the annexes to the DSD. The ECB was also responsible for preparing Annex I, which contained the list of dangerous substances for which CLH had been agreed at Community level in accordance with the criteria and procedures laid down in the DSD.

To prepare the proposals for the classification and labelling of substances, as well as updating of the classification criteria, the ECB coordinated and chaired the Technical Committee for Classification and Labelling (TC C&L). The TC C&L was an expert committee with nominees from government authorities, industry and Non-Governmental Organisations (NGOs). Since 1994, the ECB had held the TC C&L meetings. The ECB organised specialised expert meetings in the fields of reproductive toxicity, carcinogenicity and mutagenicity. The ECB coordinated the development of guidance documents on various classification and labelling topics and also prepared and published the "Working routines for the Technical Committee on Classification and Labelling of Dangerous Substances"[10].

In the TC C&L meeting, chemical substances to which the Member States had made classification proposals were discussed. Substances on the meeting agenda would be prioritised as:

1) Substances with concern for carcinogenic, mutagenic and reproductive toxicity (CMR) endpoints or respiratory sensitisation
2) Classification and labelling of other substances of concern that would give rise to additional risk management, as justified by the proposing Member State
3) Substances for which the classification should be updated

4) Substances of the following special concern, as justified by the proposing Member State:
   a) Substances for which the classification and labelling is not consistent amongst companies
   b) Existing pesticides that are not yet presented in Annex I to the DSD
5) Other substances

The system established by the ECB for classification and labelling was handed over to the ECHA.

2. CLP Regulation and evaluation for classification and labelling under the CLP Regulation

(1) Structure of CLP Regulation 1272/2008

CLP Regulation 1272/2008 was published in the OJ on December 31, 2008 and came into force on January 20, 2009.

The CLP Regulation consists of Titles and Chapters listed in **Table 3** and Annexes listed in **Table 4**.

Table 3 Titles and Chapters provided in Regulation 1272/2008

Title	Chapter		Articles
Title I	GENERAL ISSUES		1–4
Title II	HAZARD CLASSIFICATION		
	Chapter 1	Identification and examination of information	5–8
	Chapter 2	Evaluation of hazard information and decision on classification	9–16
Title III	HAZARD COMMUNICATION IN THE FORM OF LABELLING		
	Chapter 1	Content of the label	17–30
	Chapter 2	Application of labels	31–34
Title IV	PACKAGING		35
Title V	HARMONISATION OF CLASSIFICATION AND LABELLING OF SUBSTANCES AND THE CLASSIFICATION AND LABELLING INVENTORY		
	Chapter 1	Establishing harmonised classification and labelling of substances	36–38
	Chapter 2	Classification and labelling inventory	39–42
Title VI	COMPETENT AUTHORITIES AND ENFORCEMENT		43–47
Title VII	COMMON AND FINAL PROVISIONS		48–62

Table 4 Annexes to Regulation 1272/2008

Annex		Title (first established by)
Annex I		CLASSIFICATION AND LABELLING REQUIREMENTS FOR HAZARDOUS SUBSTANCES AND MIXTURES
Annex II		SPECIAL RULES FOR LABELLING AND PACKAGING OF CERTAIN SUBSTANCES AND MIXTURES
Annex III		LIST OF HAZARD STATEMENTS, SUPPLEMENTAL HAZARD INFORMATION AND SUPPLEMENTAL LABEL ELEMENTS
	Part 1	Hazard statements
	Part 2	Supplemental hazard information
	Part 3	Supplemental label elements/information on certain substances and mixtures
Annex IV		LIST OF PRECAUTIONARY STATEMENTS
	Part 1	Criteria for the selection of precautionary statements
	Part 2	Precautionary statements
Annex V		HAZARD PICTOGRAMS
Annex VI		HARMONISED CLASSIFICATION AND LABELLING FOR CERTAIN HAZARDOUS SUBSTANCES
	Part 1	Introduction to the list of harmonised classifications and labelling
	Part 2	Dossiers for harmonised classification and labelling
	Part 3	Harmonised classification and labelling tables*
Annex VII		TRANSLATION TABLE FROM CLASSIFICATION UNDER DIRECTIVE 67/548/EEC TO CLASSIFICATION UNDER THIS REGULATION

*: Initially the following two tables were provided
- Table 3.1: List of harmonised classification and labelling of hazardous substances
- Table 3.2: The list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC

According to Article 1 (2) of Amendment Regulation 2016/1179, Table 3.2 was deleted (this deletion was applied on 1 June 2017)
According to Article 2 (2) of Amendment Regulation 2017/776, the title of Table 3.1 was replaced by the following (this replacement was applied on 1 June 2017)
Table 3 List of harmonised classification and labelling of hazardous substances

Title II "Hazard classification", Title III "Hazard communication in the form of labelling" and Title IV "Packaging" applied in respect of substances from December 1, 2010, and in respect of mixtures from June 1, 2015.

Annex I, Annex III Part 1 and Annexes IV and V incorporate the GHS criteria. Annex I contains classification and labelling requirements for hazardous substances and mixtures. Annex III Part 1 titled "Hazard statements" lists hazard statements written in each official EU language. Annex IV titled "List of precautionary statements" Part 1 contains criteria for the selection of precautionary statements, and Part 2 lists precautionary statements written in each official EU language. Annex V contains hazard pictograms (GHS pictograms).

Annex II contains special rules for labelling and packaging of certain substances and mixtures. Supplemental information on the label referred to in Annex II is Community hazard classes not yet part of the GHS, and uses "EUH" for EU hazard statement instead of the letter "H" for hazard statement in the codification of hazard statements. Annex II Part 4 titled "special rules for labelling of plant protection products" mentions Article 16 and Annex V in PPP Directive 91/414/EEC[11], and indicates the hazard statement code "EUH401" and the wording "To avoid risks to human health and the environment, comply with the instructions for use".

Annex III Part 2 referred to as supplemental hazard information, contains lists of EU hazard statement codes related to physical properties, health properties and environmental properties and corresponding hazard statements written in each official EU language. The list of hazard statement code "EUH401" for plant protection products and corresponding hazard statements is included in Part 3 referred to as supplemental label elements/information on certain substance and mixtures.

Annex VI contains the general principles and lists related to CLH. Part 1 provides an introduction to the list of CLH, Part 2 lays down general principles for preparing dossiers to propose CLH, and Part 3 lists hazardous substances for which CLH has been established at Community level as Tables 3.1 and 3.2. Table 3.2 is the list of CLH from Annex I to DSD 67/548/EEC. Table 3.1 is the list of CLH whose GHS classification arise from translation of the classifications from Annex I to DSD 67/548/EEC contained in Table 3.2 according to the classification translation table in Annex VII, and whose labelling corresponds to the GHS criteria.

Under the CLP Regulation, substances that fulfil the criteria for hazard classes referred to in Article 36 (1) and ASs of PPPs or BPs [Article 36 (2) of Regulation 1272/2008] are normally subject to CLH. If a substance that is not an AS of a PPP or BP fulfils the criteria for hazard classes other than those referred to in Article 36 (1), CLH may be set on a case-by-case basis in accordance with the provisions on evaluation procedure, if justification is provided demonstrating the need for such action at Community level [Article 36 (3) of Regulation 1272/2008].

Table 5 lists the number of chemicals to which CLH was set/revised by the CLP Amendment Regulations published in the OJ between 2012 and 2020. This table shows that the sum of ASs of PPPs or BPs account for more than half of all these chemicals. This is because CLH shall normally be set to chemical ASs in PPPs or

Table 5 Number of chemicals to which CLH was set/revised*1 by Amendment Regulations published in the OJ from 2012–2020

	Set (Inserted in Annex VI Table 3)					Revised (Replaced)				
	PPP	BP	PPP/BP*2	Other	Total	PPP	BP	PPP/BP*2	Other	Total
Regulation 618/2012 (OJ 2012.07.11)	3	1	(1)	8	11	1	0	(0)	4	5
Regulation 944/2013 (OJ 2013.10.03)	6	4	(2)	14	22	3	4	(0)	10	17
Regulation 605/2014 (OJ 2014.06.06)	7	2	(0)	5	14	3	1	(0)	5	9
Regulation 2015/1221 (OJ 2015.07.25)	15	2	(0)	3	20	7	1	(0)	4	12
Regulation 2016/1179 (OJ 2016.07.20)	12	9	(4)	9	26	10	10	(6)	8	22
Regulation 2017/776 (OJ 2017.05.05)	9	8	(0)	7	24	4	5	(1)	5	13
Regulation 2018/1480 (OJ 2018.10.05)	7	5	(0)	4	16	6	4	(1)	9	18
Regulation 2020/217 (OJ 2020.02.18)	5	1	(0)	11	17	3	1	(0)	7	11
Regulation 2020/1182 (OJ 2020.08.11)	13	12	(1)	13	37	8	4	(0)	9	21
Total	77	44	(8)	74	187	45	30	(8)	61	128

*1: CLH set/revised according to RAC Opinion adopted from 2010.01 to 2019.01
*2: The number of ASs is the double-counted one, because the ASs are both PPP and BP

BPs, but CLH may not be set to other substances than ASs of PPPs or BP.

(2) CLH evaluation under CLP Regulation 1272/2008

CLH evaluation under CLP Regulation 1272/2008 is set out in Article 37 "Procedure for harmonisation of classification and labelling of substances", Chapter 1 "Establishing CLH of substances", under Title V "Harmonisation of Classification and Labelling of Substances and the Classification and Labelling Inventory". This provision came into force on January 20, 2009, the date when the CLP Regulation came into force.

A proposal for CLH of substances may be submitted by a competent authority of a Member State [Article 37 (1) of Regulation 1272/2008] or a manufacturer, importer or downstream user of a substance [Article 37 (2) of Regulation 1272/2008]. For ASs of PPPs or BPs, however, the Dossier Submitter (DS) should be the Member State [the Rapporteur Member State (RMS) for ASs of PPPs] or the competent authority of the Member State [the Evaluating Competent Authority (eCA) for ASs of BPs] in charge of AS evaluation. The Member State prepares a CLH dossier using data/information contained in the AS approval/renewal of approval application dossier and submits it together with a CLH proposal.

The parties concerned are given the opportunity to comment on the submitted CLH proposal. After the deadline for commenting, the DS provides a Response to the Comments (RCOM). The CLH proposal, the comments received and the RCOM are forwarded to the Committee for Risk Assessment (RAC), and a RAC member appointed as a Rapporteur drafts a RAC Opinion. The RAC shall adopt a RAC Opinion within 18 months of receipt of the CLH proposal, and the ECHA shall forward the RAC Opinion and the background documents, the CLH proposal and the comments received, to the European Commission [Article 37 (4) of Regulation 1272/2008].

Where the European Commission finds that the harmonisation of classification and labelling of the substance concerned is appropriate, the European Commission shall submit a draft decision concerning the inclusion of that substance together with the relevant classification and labelling elements in Table 3.1 of Part 3 of Annex VI to the CLP Regulation [Article 37 (5) of Regulation 1272/2008]. Until May 31, 2015, a corresponding CLH had been included in Table 3.2 also. According to Amendment Regulation 2016/1179[12], deletion of Table 3.2 was applied from June 1, 2017 [Articles 1 (2) and 2 (2) of Regulation 2016/1179]. Following the deletion of Table 3.2, the table number of the title of Table 3.1 was replaced by Table 3, which was applied from June 1, 2017 according to Amendment Regulation 2017/776[13] [Article 2 (2) and Annex (3) (c) of Regulation 2017/776].

Before adopting the draft Amendment Regulation, the European Commission shall consult with experts designated by each Member State [Article 53a (4) of Regulation 1272/2008]. As soon as the draft Amendment Regulation is adopted, the European Commission shall notify it simultaneously to the European Parliament and to the European Council [Article 53a (5) of Regulation 1272/2008]. The draft Amendment Regulation shall enter into force, only if no objection has been expressed either by the European Parliament or by the European Council within a period of two months of notification of the draft Amendment Regulation or if, before the expiry of that period, the European Parliament and the European Council have both informed the European Commission that they will not object [Article 53a (6) of Regulation 1272/2008].

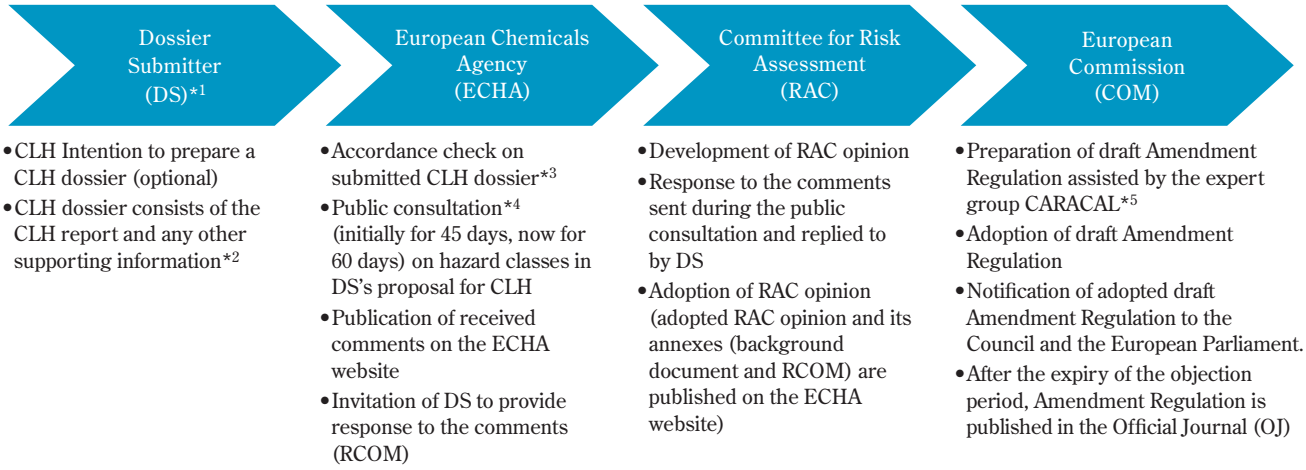
Fig. 1 shows a simplified outline of the scheme of the procedure.

The CLP Regulation requires any manufacturer or importer to notify to the ECHA the classification and labelling for any registered or hazardous substances placed on the market even if they are chemical substances with no existing CLH under either the DSD or the CLP Regulation [Article 40 (1) of Regulation 1272/2008], and the notified classification and labelling shall be included in the classification and labelling inventory (Article 42 of Regulation 1272/2008). Consequently, information on the classification and labelling set by the manufacturers or importers is published, even for chemical substances with no existing CLH.

Impact of CLH on the decision on approval/renewal of approval of ASs of PPPs/BPs

1. Cut-off criteria for approval of ASs of PPPs and exclusion criteria for approval of ASs of BPs

PPP Directive 91/414/EEC was replaced by PPP Regulation 1107/2009[14], and BP Directive 98/8/EC[15] was replaced by BP Regulation 528/2012[16]. These new Regulations set out so-called cut-off criteria for ASs of PPPs or exclusion criteria for ASs of BPs, on which non-approval/non-renewal of approval of ASs may be



*1: In case of PPP AS, the DS is normally a Rapporteur Member State (RMS). In case of BP AS, the DS is normally an Evaluating Competent Authority (eCA).
*2: In case of ASs of PPP or BP, the CLH report is compiled from Draft (Renewal) Assessment Reports (DARs/RARs) or Competent Authority Reports (CARs). Templates to be used for DARs/RARs and proposals for CLH, and the template to be used for both the proposal for CLH (CLH report) and CAR are provided by the COM DG SANTE website and ECHA website, respectively.
*3: If the dossier is found to be in accordance, the ECHA will start the public consultation of the proposed CLH as presented in the CLH report on its website. Otherwise, the DS is asked to bring the dossier in accordance and to resubmit it.
*4: If needed, targeted consultations (length of the commenting period is determined on a case-by-case basis and is normally shorter than the usual public consultation on a CLH proposal) for a CLH proposal are launched on a particular hazard class, or if comments are sought on (*e.g.* a specific additional document), and publication of received comments on the ECHA website.
*5: The Competent Authorities for the REACH and CLP Regulations

Fig. 1 Scheme of procedures for setting and revising CLHs

decided based solely on the results of hazard evaluation.

Annex II to PPP Regulation 1107/2009 contains criteria for the approval of ASs. Article 4 (1) of the PPP Regulation set out the provision that the assessment of AS shall first establish whether particular criteria are satisfied. If the evaluation of an AS concludes that it meets the criteria to be classified as a certain hazard classification related to these particular criteria, which means that it meets cut-off criteria, non-approval/non-renewal of approval of the AS may be decided. Most of the cut-off criteria are related to CLH, namely category 1A or 1B of the hazard classification regarding carcinogenicity, mutagenicity or reproductive toxicity.

Some cut-off criteria are subject to application of derogation and ASs may be approved if all the conditions laid down in Article 4 (7) are met.

Most of the cut-off criteria subject to application of derogation laid down in Article 4 (7) are related to CLH. However, the derogation shall not apply to ASs classified as mutagenicity category 1A or 1B, carcinogenicity category 1A or 1B without a threshold, or toxic for reproduction category 1A. A cut-off criterion that is subject to application of derogation, and which is not related to CLH, is that ASs are considered as having endocrine disrupting properties that may cause adverse effects. Until Amendment Regulation 2018/605[17] setting out scientific criteria for the determination of endocrine disrupting properties applied from November 10, 2018, the criteria for endocrine disrupting properties related to human health were provisionally set out and applied to ASs classified as carcinogenic category 2 and toxic for reproduction category 2, or substances classified as toxic for reproduction category 2 and which have with toxic effects on endocrine organs (Annex II 3.6.5 to Regulation 1107/2009 before being amended by Amendment Regulation 2018/605).

Article 5 (1) of BP Regulation 528/2012 sets out exclusion criteria for the approval of ASs. If a certain AS meets any of the exclusion criteria, non-approval/non-renewal of approval of the AS may be decided. Similar to ASs of PPPs, most of the exclusion criteria are related to CLH. Unlike ASs of PPPs, an AS that meets at least one of the conditions laid down in Article 5 (2) approval/renewal of approval as a candidate for substitution may be decided.

Exclusion criteria that are not related to CLH categories include having endocrine disrupting properties that may cause adverse effects. Until Amendment Regulation 2017/2100[18] setting out scientific criteria for

the determination of endocrine disrupting properties applied from June 7, 2018, the criteria for endocrine disrupting properties related to human health were provisionally set out and applied to ASs classified carcinogen category 2 and toxic for reproduction category 2, or substances classified toxic for reproduction category 2 and that have toxic effects on endocrine organs [Article 5 (3) of Regulation 528/2012 before being amended by Amendment Regulation 2017/2100].

As shown in **Table 6**, the same CLH-related criteria exist in both the cut-off criteria and the exclusion criteria.

2. Criteria for low-risk ASs of PPPs and criteria for ASs included in Annex I to BP Regulation 528/2012

Contrary to the cut-off criteria or exclusion criteria, there are criteria for low-risk ASs for ASs of PPPs, and criteria for ASs included in Annex I to BP Regulation 528/2012 (BPs containing only ASs included in Annex I are eligible for application for authorisation under the simplified authorisation procedure as laid down in Article 25) for ASs of BPs, and the condition that ASs shall not be classified as any particular CLH is included in those criteria.

Article 22 of PPP Regulation 1107/2009 sets out provisions of low-risk ASs, which shall be approved for a period not exceeding 15 years, though first approval is normally for a period not exceeding 10 years. The criteria for low-risk ASs are specified in Point 5 of Annex II. The criteria include the condition that ASs shall not be classified as any particular CLH.

Annex I to BP Regulation 528/2012 contains a list of ASs that contained in BPs eligible for the simplified authorisation procedure laid down in Article 25. These ASs included in Annex I are ASs that do not give rise to concern for which criteria is specified in Article 28 (2) of Regulation 528/2012. The criteria include the condition that ASs shall not be classified as any particular CLH.

Table 6 Similarities between PPP Cut-off criteria and BP Exclusion criteria for CLH

PPP Cut-off criteria (Regulation 1107/2009 Article 4 (1) and Annex II)		BP Exclusion criteria (Regulation 528/2012 Article 5 (1))
Annex II 3.6.2	Criterion regarding mutagenicity (Muta. 1A, 1B)	(b) Criterion regarding mutagenicity (Muta. 1A, 1B)
Annex II 3.6.3	Criterion regarding carcinogenicity (Carc. 1A, 1B)	(a) Criterion regarding carcinogenicity (Carc. 1A, 1B)
Annex II 3.6.4	Criterion regarding reproductive toxicity (Repr. 1A, 1B)	(c) Criterion regarding reproductive toxicity (Repr. 1A, 1B)
Annex II 3.7.2	Criterion regarding persistent, bioaccumulative and toxic (PBT) substances	(e) Criterion regarding persistent, bioaccumulative and toxic (PBT) substances or very persistent and very bioaccumulative (vPvB) substances
Annex II 3.7.3	Criterion regarding very persistent and very bioaccumulative (vPvB) substances	

Table 7 Similarities between PPP Low-risk criteria and BP Annex I listing criteria for CLH

Regulation 1107/2009 Annex II (5) as amended by Regulation 2017/1432	Regulation 528/2012
Annex II 5 Low-risk active substances	Art. 28 Amendment of Annex I
5.1. Active substances other than micro-organisms	(2) Active substances give rise to concern where:
5.1.1. An active substance, other than a micro-organism, shall not be considered as being of low-risk where it corresponds to any of the following:	
(a) it is or has to be classified in accordance with Regulation (EC) No 1272/2008 as any of the following:	(a) they meet the criteria for classification according to Regulation (EC) No 1272/2008 as:
- explosive,	- explosive/highly flammable,
- skin corrosive, category 1A, 1B or 1C,	- corrosive of category 1A, 1B or 1C,
- skin sensitiser category 1,	- skin sensitiser,
- Carc. 1A, 1B or 2,	- Carc. 1 or 2,
- Muta. 1A, 1B or 2,	- Muta. 1 or 2,
- Repr. 1A, 1B or 2,	- Repr. 1 or 2 or with effects on or via lactation,
- STOT 1 or 2,	- STOT SE 1 or RE 1,
- Acute Tox. 1, 2 or 3,	- Acute Tox. 1, 2 or 3,
- respiratory sensitiser category 1,	- respiratory sensitiser,
- Aquatic acute 1 and Aquatic chronic 1,	- Aquatic acute 1
- serious damage to eye category 1	

As shown in **Table 7**, many of the same CLH-related criteria exist in both the criteria for approval as low-risk ASs and the criteria for ASs included in Annex I.

Provisions introduced in Regulations related to the PPP Regulation and provisions introduced in BP guidance documents in order to accelerate the adoption of CLH proposals

In an effort to ensure that CLH proposals can be submitted at the time of submission of the Draft Assessment Report (DAR) or the draft Renewal Assessment Report (RAR) prepared by the RMS or the Competent Authority Report (CAR) prepared by the eCA for ASs of PPPs or BPs, the templates of these assessment reports were revised to align the structure and content of the assessment report with the report for proposed CLH.

For ASs of PPPs, the previous assessment report templates were revised into a combined template to be used for assessment reports and proposals for CLH[19], which was agreed on October 6, 2017 and it should be used for ASs for which applications for approval/renewal of approval submitted as from the date of agreement. For ASs of BPs, the first version of the combined CAR and CLH template[20] (the version dated March 19, 2020 is currently the latest version) was published on March 13, 2018 and used by the Member States from the date of its publication.

Evaluation for renewal of approval of ASs of PPPs or BPs must be completed before the expiry date of approval.

PPP Regulation 1107/2009 set out a provision that allows the extension of the approval period where the approval is likely expire before the decision has been taken (Article 17 of Regulation 1107/2009), and BP Regulation 528/2012 also set out a similar provision [Article 14 (5) of Regulation 528/2012]. However, repeated extension of approval period has become a problem.

One of the causes of the prolonged evaluation for renewal of approval of ASs of PPPs is CLH related to cut-off criteria which exist in existing CLH or proposals for CLH setting/revising. For this reason, a proposal from a DS for CLH setting/revising needs to be finalised at adoption of an opinion by the RAC earlier than the decision on renewal of approval of the AS.

Amendment Regulation 2020/103[22] to Renewal Regulation 844/2012[21] as regards the CLH of ASs, set detailed rules of procedure regarding the submission of CLH proposals to the ECHA in accordance with Article 37 (1) of CLP Regulation 1272/2008 by the RMS during evaluation for renewal of approval of ASs. An adopted RAC Opinion is needed to confirm whether CLH relevant for the cut-off criteria or the criteria for not considered as a low-risk AS is allocated. Thus, "a suggestion for the classification or reclassification", which should be included in the RAR prepared by the RMS, was replaced with "a suggestion for the classification, or its confirmation, where applicable, or reclassification" [Article 11 (2) (e) of Regulation 844/2012], and a provision stating that the RMS shall at latest at the time of the RAR submit a CLH proposal to obtain an opinion on CLH (RAC Opinion) of the AS at least particular hazard class, or for the hazard classes, which are already covered by an existing RAC Opinion, it is sufficient that the RMS duly justifies in its submission to the ECHA that the existing opinion remains valid as regards the particular hazard classes[Article 11 (9) of Regulation 844/2012] was added. A provision requiring that the RAC shall endeavour to adopt the opinion within 13 months (18 months under the CLP Regulation) from the submission of a CLH proposal was also added. The previous provision stating that an EFSA conclusion for renewal of approval of an AS should be adopted within five months from the expiry of the period from the date the RAR is made available to public for the submission of written comments was changed to require that such an EFSA conclusion should be adopted within the existing deadline or within two weeks from the adoption of the RAC Opinion, if any adopted, whichever occurs later [Article 13 (1) of Regulation 844/2012]. As documents to be taken into account in a renewal report prepared by the European Commission and a draft Regulation for renewal of approval, the RAR prepared by the RMS, submitted comments to the RAR, and the EFSA conclusion were previously specified, and the RAC Opinion, if any, was added as another document to be taken into account [Article 14 (1) of Regulation 844/2012].

The amendments as regards to CLH of ASs that were incorporated into Renewal Regulation 844/2012 by Amendment Regulation 2020/103 have been incorporated in the new Renewal Regulation 2020/1740[23], which replaces Renewal Regulation 844/2012.

Concerning renewal of approval of ASs of BPs, no particular Amendment Regulation to BP Regulation 528/2012 as regards the CLH of ASs is prepared at present, but the "Guidance on the data requirements

and assessment of applications for renewal of approval of active substances under BPR, 2020.11" prepared by the ECHA[24] states that a combined CAR and CLH report template should be used for draft Risk Assessment Report-Renewal Assessment Report (hereinafter referred to as "BP-RAR" so as not to confuse it with the RAR for PPPs). It also states that in case the eCA identifies any need to revise CLH, especially on the exclusion criteria, it should prepare the CLH dossier submission in advance of the BP-RAR, in order to be able to take into account the RAC Opinion on CLH in the final BP-RAR.

"One substance - one assessment", the chemicals strategy for sustainability

Under the CLP Regulation, evaluation procedure for setting/revising CLH of ASs either of PPPs or BPs is almost the same as that for industrial chemicals evaluated under the REACH Regulation. For chemical substances that are ASs of both PPPs and BPs, if no CLH has been set or if there is new data on the chemical substance that was not available at the time of previous setting/revising and supporting the proposal for revision of the existing CLH, the evaluation for approval/renewal of approval of ASs will be normally conducted in parallel with the evaluation for CLH setting/revision.

"Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment"[25] published on October 14, 2020 presents an action plan in which there are proposals, such as establishment of 'One substance, one assessment' process to coordinate the hazard/risk assessment on chemicals across chemical legislation through an expert group and a Commission coordination mechanism, amendment of CLP Regulation 1272/2008, removal of legislative obstacles for re-use of data and streamlining the data flow across legislation, and extension of the open data and transparency principles from the food safety sector to other pieces of chemical legislation. The implementation of these proposals is expected to introduce changes in the evaluation procedure for CLH setting/revising.

The International Uniform Chemical Information Database (IUCLID) software package, was specified for submissions of applications for approval/renewal of approval of ASs to the ECHA under the BP Regulation (Article 79 of Regulation 528/2012). Concerning PPPs, Regulation 2021/428 adopting a standard data formats for the submission of applications for the approval or the amendment to the conditions of approval of ASs[26] and Renewal Regulation 2020/1740 specified the use of IUCLID software package for the submission of such applications [Articles 1 and 2 of Regulation 2021/428 and Article 7 (3) in Regulation 2020/1740]. The IUCLID software package is also used in the evaluation of chemical substances under the REACH Regulation, and a platform for "one substance - one assessment" is being developed.

OECD activities toward harmonisation of international classification of chemical substances

Along with harmonised classification in the EU, the OECD is also working to develop harmonised classification among OECD Member Countries. Upon invitation from the UN Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals (UNSCEGHS), the OECD Task Force on Hazard Assessment (TFHA) and the Joint Meeting (JM) of the Chemicals Committee/Working Party on Chemicals, Pesticides and Biotechnology agreed to provide a coordination role for a pilot classification project in 2014. The process of the pilot project is presented in the Report on the Joint Pilot Project of the OECD and the UNSCEGHS (OECD Series on Testing & Assessment No. 246)[27]. Accompanying the report, three case study reports on chemical substances (OECD Series on Testing & Assessment No. 247[28], 248[29], and 249[30]) were also prepared. The Report on the Pilot Project states that the results of the pilot project will be submitted to the UNSCEGHS for consideration on the potential development of a global list of classified chemicals.

Conclusion

The current EU practices on CLH setting/revising have been formulated by trial and error. Considering the problems occurred at the time of decision on approval/renewal of approval of ASs of plant protection products or biocidal products due to absence of CLH or non-compliance with the GHS criteria, provisions and system have been established to allow CLH setting/revising proposals to be adopted before the adoption of conclusions or opinions for approval/renewal of approval of ASs, so that evaluation for approval/renewal of approval of ASs can proceed efficiently. As a result,

in cases where the existing CLH may meet cut-off criteria for approval for ASs of plant protection products or the exclusion criteria for ASs of biocidal products, non-submission of applications for approval or renewal of approval was decided after examining whether it could be approved by the application of derogation.

For the approval/renewal of approval of ASs of plant protection products or biocidal products, it is necessary to understand the possible impact of CLH on the evaluation for approval/renewal of approval of ASs, and if it is foreseeable that ASs meet any of the cut-off criteria or exclusion criteria, it is necessary to gather information for application of the derogation, if necessary, as early as possible. We would be pleased if this article is of assistance in dealing with such work. In the section 'Reference', the links to the referenced documents are also provided, as far as they are currently available, so that the details can be confirmed with the contents of the source document.

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