Global GHS: (EU and GB)

Dean Winder
Regulatory Consultant
CIRS Europe
Dean.winder@cirs-reach.com

CONTENT

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- Over 350+ employees in 5 different countries;
- Has branch offices in Dublin(Ireland), London (UK), Arlington(US), Seoul(Korea), Nanjing(China), Beijing(China), Hangzhou(China);
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Add: 11/F., Bldg 1, Dongguan Hi-Tech Park, 288 Qiuyi Rd, Binjiang District, Hangzhou, China

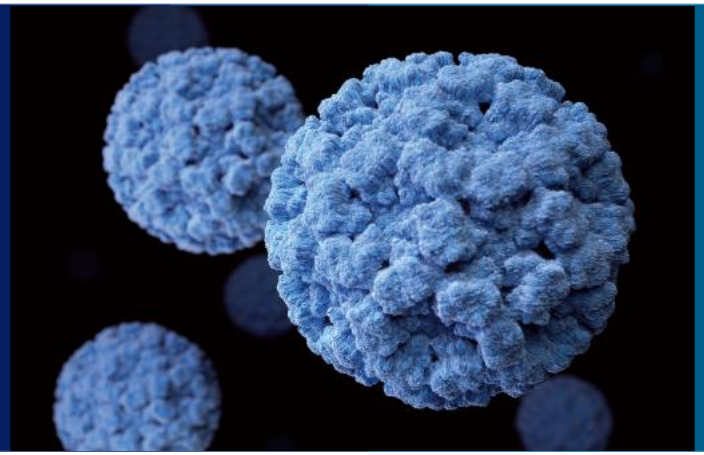
CIRS Europe
Add: CIRS, Regus Harcourt Centre D02 HW77, Dublin, Ireland

CIRS US
Add: #200-092, 3100 Clarendon Blvd., Arlington, VA 22201

CIRS Korea
Add: B-2310, 583, Yangcheon-ro, Gangseo-gu, Seoul, Republic of Korea

CIRS UK
Studio 310, Pill Box, 115 Coventry Road, London, E2 6GG

Introduction



01

The Northern Ireland Protocol

- The Northern Ireland Agreement makes EU Law applicable in NI
- The EU CLP is still the requirement in NI
- Therefore, the GB CLP Regulations only apply to Scotland England and Wales

The Base of EU and GB CLP Regulation

REGULATION (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures

1. Classification
2. Labelling
3. SDS
4. C&L notification

GHS: hazard classifications

Physical Hazards	• Explosives; Flammable Gases; Chemically Unstable Gas; Aerosols; Oxidizing Gases; Gases Under Pressure; Flammable Liquids; Flammable Solids; Self-reactive Substances; Pyrophoric Liquids; Pyrophoric Solids; Self-heating Substances; Substances, Which In Contact With Water, Emit Flammable Gases; Oxidizing Liquids; Oxidizing Solids; Organic Peroxides; Corrosive To Metals; Desensitized Explosives
Health Hazards	• Acute Toxicity; Skin Corrosion / Irritation; Serious Eye Damage / Eye Irritation; Respiratory Sensitization; Skin Sensitization; Germ Cell Mutagenicity; Carcinogenicity; Toxic To Reproduction; Effects On Or Via Lactation; Specific Target Organ Systemic Toxicity (Single Exposure); Specific Target Organ Systemic Toxicity (Repeated Exposure); Aspiration Hazard
Environmental Hazards	• Aquatic Toxicity (Acute, Chronic); Hazardous For The Ozone Layer

EU CLP Annex VI

Annex VI of CLP gives a list of harmonized classification and labelling for hazardous substances.

For listed substances, the Annex VI classifications are mandatory.

Summary of Classification and Labelling

Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

General Information

Index Number	EC / List no.	CAS Number	International Chemical Identification
603-002-00-5	200-578-6	64-17-5	ethanol ethyl alcohol

ATP Inserted / Updated: CLP00

CLP Classification (Table 3)

Classification		Labelling			Specific Concentration limits, M-Factors, Acute Toxicity Estimates (ATE)	Notes
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)		
Flam. Liq. 2	H225	H225		GHS02 Dgr		

https://echa.europa.eu/brief-profile/-/briefprofile/100.000.526

https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/49769

Harmonized Classification and Labelling Decisions (CLH)

Step 1

A national competent authority or a manufacturer /importer submits a proposal to ECHA.

Step 2

ECHA's Risk Assessment Committee (RAC) issues an opinion within 18 months of receipt of the proposal, considering comments received.

Step 3

The European Commission adopts the classification decision through a delegated act.

GB Mandatory Classification List (MCL)

Mandatory classification is a classification that is equivalent to the 'harmonised classifications' that exist under EU CLP.

Where a substance has an MCL for some or all hazard classes, suppliers to the GB market must apply it

The GB mandatory classification and labelling system will be hosted, managed and operated by HSE (as the GB CLP Agency)

Self-classification is where the supplier gathers and evaluates all the available information, then compares it to the classification criteria

Substances which do have a mandatory classification must be self-classified for any hazard classes not covered by that mandatory classification

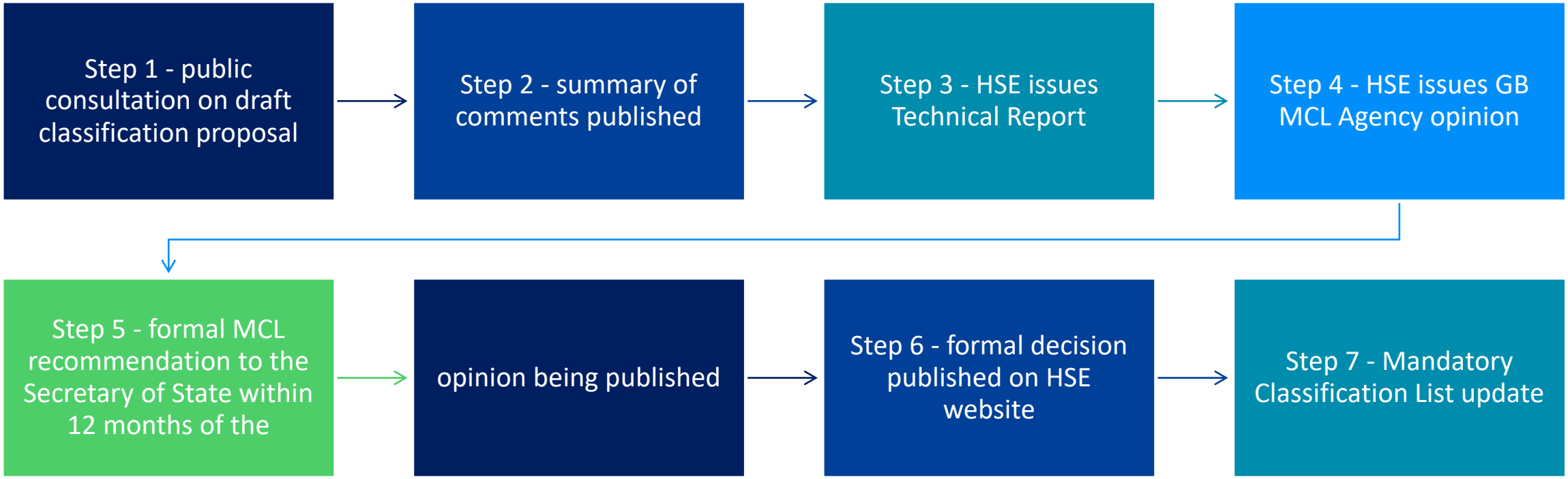
MCL - Responsibility of GB-based businesses

GB-based manufacturers, importers and downstream users of substances have a legal duty to inform HSE and MUST make a GB MCL proposal when:

There is evidence of a change in the classification of a priority hazard class:	Carcinogenicity - Category 1A, 1B or 2	Germ cell mutagenicity - Category 1A, 1B or 2	Reproductive toxicity - Category 1A, 1B or 2	Respiratory sensitisation - Category 1	Evidence of new scientific data or information that may lead to new or revised GB MCL, must submit a GB MCL proposal to HSE (as the GB CLP Agency)

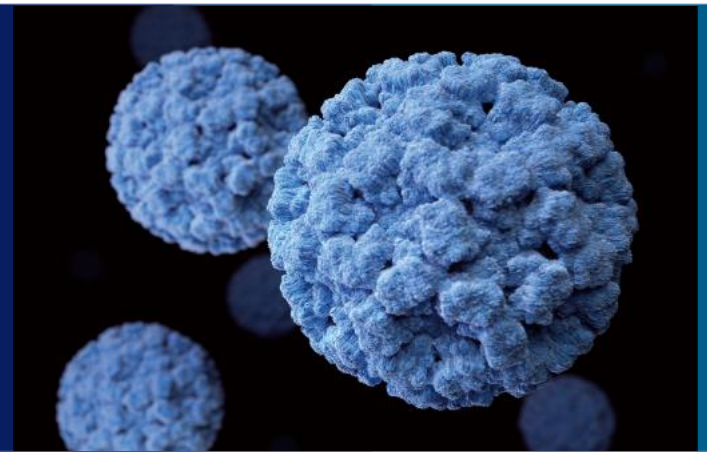
For other hazard classes, GB-based manufacturers, importers and downstream users may submit proposals, if they have access to the scientific data and evidence.

MCL Update Procedure



MCL Available here: https://www.hse.gov.uk/chemical-classification/classification/harmonisedclassification-self-classification.htm

SDS and Label Requirements



02

GHS: SDS

1. Identification of the substance/mixture and of the company/undertaking	9. Physical and chemical properties
2. Hazard identification	10. Stability and reactivity
3. Composition/information on ingredients	11. Toxicological information
4. First-aid measures	12. Ecological information
5. Fire-fighting measures	13. Disposal consideration
6. Accidental release measures	14. Transport information
7. Handling and storage	15. Regulatory information
8. Exposure controls/personal protection	16. Other information

Language requirements

ECHA
EUROPEAN CHEMICALS AGENCY

Languages required for labels and safety data sheets

Country	Language 1	Language 2	Language 3
Austria	German		
Belgium [1)]	French	Dutch	German
Bulgaria	Bulgarian		
Croatia	Croatian		
Cyprus	Greek		
Czech Republic	Czech		
Denmark	Danish		
Estonia	Estonian		
Finland	Finnish	Swedish	
France	French		
Germany	German		
Greece	Greek		

Information required for SDS authoring

Company Info – name, address, contact, emergency contact.

Destination (standard, language); For CLP SDS, indicate the OR of the substance or any substance in the product.

Product info – product name, usage, component (CAS number and concentration/ concentration range)

Physical info – physical state, color, odor, etc.

Transportation information (if available) – UN number, proper shipping name

Any other implementation – SDS, registration number, toxic/eco-toxic data, etc

Precautionary Statement Guidance

- The P-statements should be selected based on the rules in CLP Article 28 and Part 1 of Annex IV to CLP
- The selection of P-statements should take into account the underlying hazards and identified or foreseen uses of the substance
- If the content of two P-statements are the same, choose the most relevant statement
- The P-statements assignment follows a “traffic light” system. They are “highly recommended”, “recommended”, “optional” and “not to be used” for the hazard label
- A particular recommendation should be seen in the light of the original CLP conditions for use specified under the relevant precautionary statement in the selection tables
- Two target groups under the CLP Regulations. Where there is no explicit mention of the target group, the conditions for use apply to both the general public and industrial/professional users
- Where the use of a particular precautionary statement is (highly) recommended but some exemptions are indicated (“unless” condition), it should not be used where the conditions specified in the “unless” clause apply:

GHS: label element

- 1. Pictograms

- 2. Signal words

Danger or Warning

- 3. Hazard statements

May damage fertility or the unborn child; Very toxic to aquatic life with long lasting effects.

- 4. Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection;
Avoid release to the environment;
If exposed or concerned: Get medical advise/attention;

The 9 Standard Pictograms

Oxidizers

Flammables, Self Reactives, Pyrophorics, Self-Heating, Emits Flammable Gas, Organic Peroxides

Explosives, Self Reactives, Organic Peroxides

Acutely Toxic (severe)

Burns Skin, Damages Eyes, Corrosive to Metals

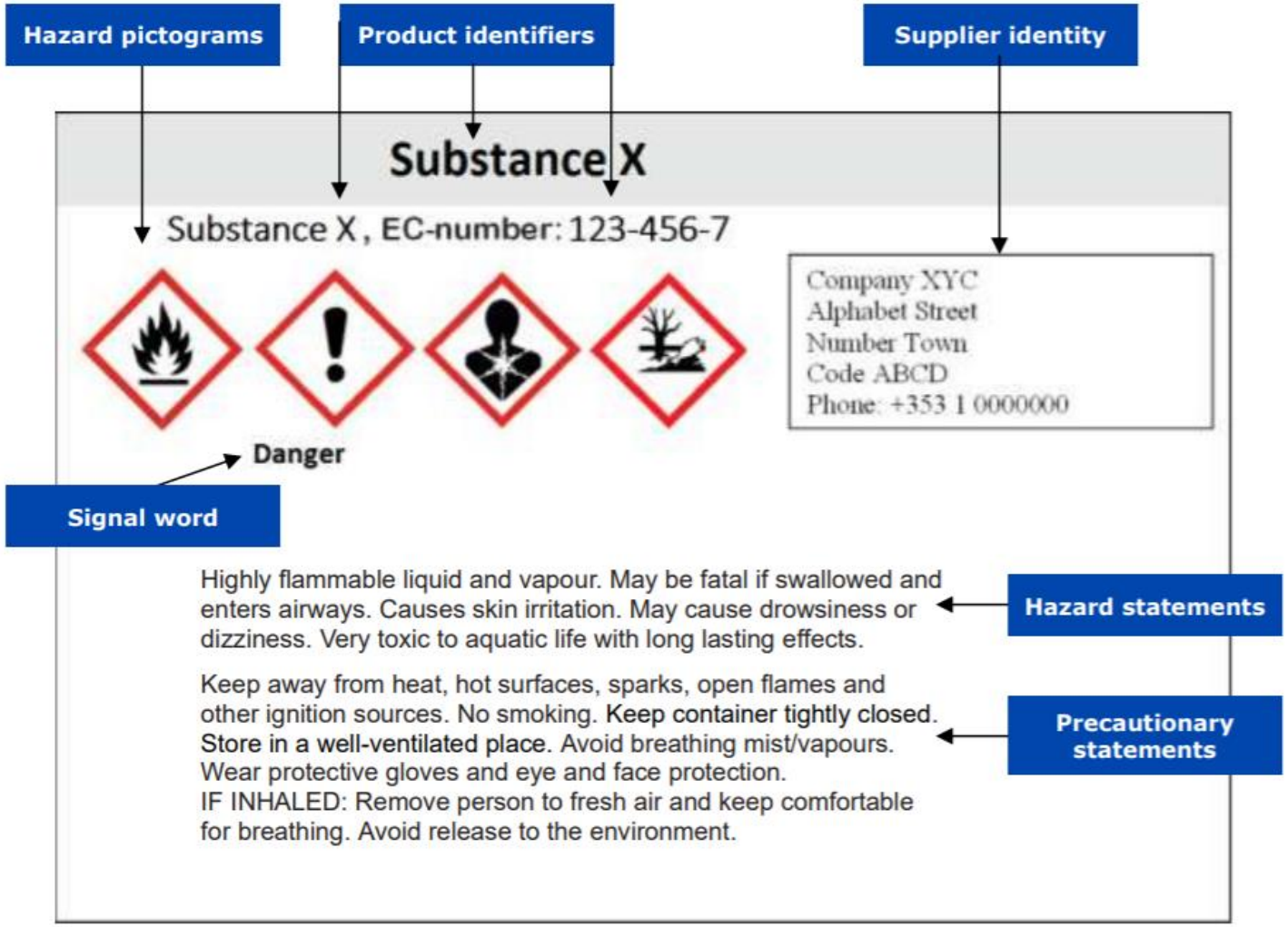
Gases Under Pressure

Carcinogen, Respiratory Sensitizer, Reproductive Toxicity, Target Organ Toxicity, Mutagenicity Aspiration Toxicity

Toxic to aquatic environment

Acutely toxic(harmful), Irritant to skin, eyes or respiratory tract, Skin sensitizer, Hazardous to the Ozone layer.

Label Example



The Current and Future Differences

03

Update to the EU CLP

CLP Update	Noteworthy Points
The update to the REACH annex II applies from beginning 2021.	• Nanoforms information must be included in the SDS. • If available, the specific concentration limits, the multiplying factors and acute toxicity estimates set in accordance with CLP should be provided in the SDS. • The unique formulation identifier (UFI) is indicated in the SDS only regarding dangerous mixtures
The 14th ATP has applied since October 1st 2021.	• The label of liquid mixtures containing 1% or more of titanium dioxide particles with aerodynamic diameter equal to or below 10 µm will bear the EUH211 statement: "Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist." • The label of solid mixtures containing 1 % or more of titanium dioxide will bear the EUH212 statement: "Warning! Hazardous respirable dust may be formed when used. Do not breathe dust." • Note V: If the substance is to be placed on the market as fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1) or particles of the substance fulfilling the WHO fibre criteria or as particles with modified surface chemistry, their hazardous properties must be evaluated in accordance with Title II of this Regulation, to assess whether a higher category (Carc. 1B or 1A) and/or additional routes of exposure (oral or dermal) should be applied." • "Note W: It has been observed that the carcinogenic hazard of this substance arises when respirable dust is inhaled in quantities leading to significant impairment of particle clearance mechanisms in the lung." • "Note 10: The classification as a carcinogen by inhalation applies only to mixtures in powder form containing 1 % or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10 µm."

Update to the EU CLP

CLP Update	Noteworthy Points
The 15th ATP has applied since March 2022 (update to Annex VI)	• The substance lead (CAS number 7439-92-1 and index numbers 082-013-00-1 (lead powder; [particle diameter < 1 mm];) and 082-014-00-7 (lead massive; [particle diameter ≥ 1 mm];)) • The environmental classification for the massive form will not be included in Annex VI • With regard to the substance 2-butoxyethanol; ethylene glycol monobutyl ether; (CAS number 111-76-2 • The hazard class 'acute toxicity (inhalation) this hazard class should not be modified in Annex VI
The 16th ATP has applied since February 2021 (update to Annex VI)	• This relates to the updates to information surrounding carcinogen and mutagens. • Substances that have been updated include, benzene, 1,3- butadiene, dimethyl sulphoxide extract, benzo[a]-pyren.
The 17th ATP applies from December 2022 (update to Annex VI)	• Updates to the Acute Toxicity Estimates (ATE) • ATE values have been derived by the Agency for dicopper oxide, dicopper chloride trihydroxide, tetracopper hexahydroxide sulphate and tetracopper hexahydroxide sulphate hydrate, copper flakes (coated with aliphatic acid), copper(II) carbonate–copper(II) hydroxide (1:1), copper dihydroxide; copper(II) hydroxide, bordeaux mixture; reaction products of copper sulphate with calcium dihydroxide and copper sulphate pentahydrate.

Future EU CLP Updates

The REACH Annex II updated from 2015/830 to 2020/878.

The formats of the EU SDS should be updated before the end of 2022.

The plan is for the EU CLP to be updated again before 2024

The Commission will propose hazard classes and criteria to address environmental toxicity, persistency, mobility and bioaccumulation, terrestrial toxicity

Adding endocrine disruptors, PBTs, vPvBs and PMT/vPvM

Assessing the need for specific criteria for immunotoxicity and neurotoxicity (potential amendment to current “STOT” and “REPR”criteria)

Terrestrial toxicity

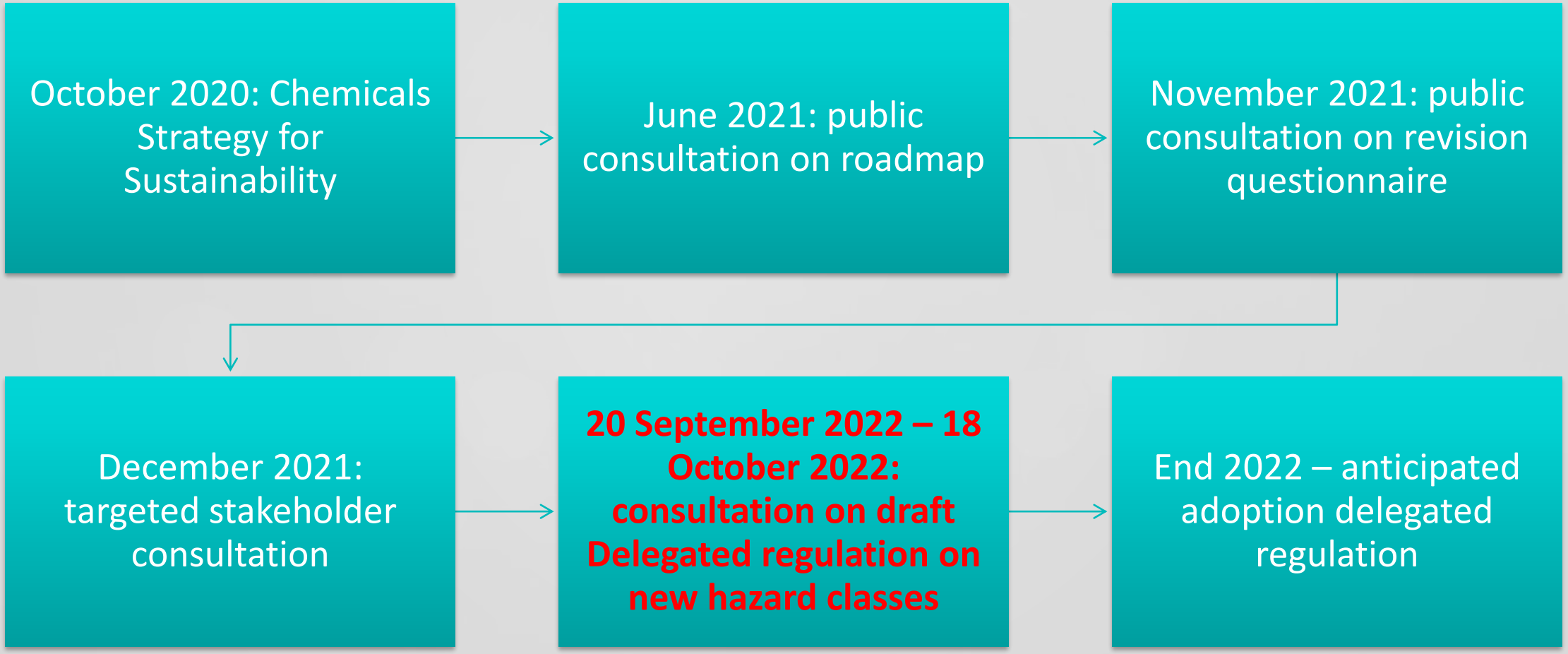
Update to the EU CLP

CLP Update	Noteworthy Points
Update due to Commission Delegated Regulation 2020/1677 and Commission Delegated Regulation 2020/1676 March 2021	• Added in section 3.1.1.4 reference to articles with integral substance or mixture intended to be released. • Added in section 3.3 clarification about the borderline between mixture and substance. • Added new section 3.3.1.3.1 to address the exemption for bespoke paints. • Added in section 3.4 a clarification about mixture with end use not subject to notification requirements. • Added in section 4.1 an introduction on the new workability solutions. • Added in section 4.2.1 a clarification of the UFI concept applied to Interchangeable Component Groups, Standard Formulas and Fuels. • Added in section 4.2.7 clarification about the need to update the UFI in the case of notifications concerning Standard Formulas, fuels or containing Interchangeable Component Groups. • Added new section 4.2.8.3 to provide details on the labelling requirements for bespoke paints. • Added in section 5.3.1 clarification about the extended exemption to the obligation not to notify components which are not present. • Added in section 5.3.2 a recommendation to report the presence of microorganisms in the mixture when relevant. • Clarified in section 5.3.3 the identification requirements for mixtures in mixture. • Added new section 5.5 on the Interchangeable Component Group solution. • Added new section 5.6 on the special provisions for ready-mixed concrete, gypsum and cement products (Standard Formulas solution). • Added new section 5.7 on the special provisions for certain fuels. • Added in section 7.3.1 clarification about security of submitted information. • Added new section 7.4.2.3 clarification about update rules applying to submissions made referring to Standard Formulas. • Added new section 7.4.2.4 clarification about update rules applying to submissions for fuels made referring to the safety data sheet.

Update to the EU CLP

CLP Update	Noteworthy Points
Guidance on harmonised information relating to emergency health response – Annex VIII to CLP (April 2022)	• Update via fast-track procedure to further clarify and complete existing interpretations or make corrections following practical implementation and release of new features in the submission portal. In particular: • Clarified in sections 3.1.1.1 and 4.2.5 obligations and options for importers and non-EU suppliers. • Clarified in sections 3.1.1.2 and 4.2.4 obligations and options in case of toll formulation. • Revised in section 3.5.2 interpretation of obligations during the transitional period to align with revised ECHA Q&A; clarification of obligations in case of Annex VIII notification made before relevant compliance date. • Removal in section 4.2.3.1 of information on MiM's identification which is to be provided in section 5.3.3. Example moved to section 5.3.3. • Clarified in section 4.2.7 obligations to change UFI in case of GCIs. • Clarified in section 5.3.3 use of GCIs; example 21 revised. • Addition in section 5.5 of new footnote to address grouping of fully known MiMs in ICGs; addition of clarification about maximum concentration of a ICG in final mixture. • Addition in section 7.4.2 of reference to changes in mixture resulting in mixture being non-classified. • Clarified in section 7.4.5 obligations in case of splitting existing GCIs. • Clarified in section 7.4.6 update rules in case of group submissions. • Other minor corrections and clarifications throughout the document.
Guidance on Labelling and Packaging March 2021	• Update to implement the amendment of the legal text due to • Commission Delegated Regulation 2020/1677 and Commission • Delegated Regulation 2020/1676 of 31 August 2020 (the • "workability amendments") and limited to: • Clarification of exemption from labelling requirements for • Bespoke paints (new section 5.3.3); • New example of application of the labelling requirements • for a Bespoke paint (new section 6.3); • Minor changes and clarification in the rest of the document.

EU CLP revision – Timeline



Summary

All updates to the EU CLP in force before January 1st, 2021, applied to the GB CLP

There have been several updates to the EU CLP that have not applied to the GB CLP

Companies should be aware of the Mandatory Classifications under both systems and how they may differ for the same product

Continuously monitor updates from ECHA and the HAS

Products sold in the EU and GB require a separate SDS and label

Be aware of the expected update to the EU CLP for SDS format next year

CIRS Services

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EU & GB CLP – MSDS and label Translation Service

PCN Submission Service (EU Importers)

Voluntary PCN Submission Service (non-EU Suppliers)

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Chemical Inspection & Regulation Service Limited

CIRS, Regus Harcourt Centre, Dublin, Ireland, D02 HW77

T +353 1 477 3710 E service@cirs-group.com