

EU Chemicals Strategy for Sustainability Conference

October 18th 2023







Regulatory updates



Yvonne Mullooly 18-10-2023



Restrictions Roadmap update



- Deliverable under the CSS as part of the European Green Deal.
- Sets out planned restrictions
- Transparency to stakeholders on the authorities' restriction work and allowing companies to anticipate (potential) upcoming restrictions, e.g. by beginning substitution.
- Published in April 2022
- Rolling list of substances for restriction
- Rolling list of Article 69(2) assessments
 - results published on ECHA website
- Rolling lists undergo regular review



Restrictions Roadmap Progress update

HSA

Subject of restriction proposal	Hazards in scope	Update
Microplastics	Р	Completed
Formaldehyde and formaldehyde releasing substances in articles	С	Completed
Undecafluorohexanoic acid (PFHxA), its salts and related substances	P/vP	At REACH Committee
Per- and polyfluoroalkyl substances (PFAS) in firefighting foams	PBT, vPvB, PMT, R	Opinions adopted
Medium-chain chlorinated paraffins (MCCPs)	PBT, vPvB	Opinions adopted
Substances containing polycyclic aromatic hydrocarbons (PAHs) (including pitch, coal tar, high temp (CTPHT)) used in clay Pigeons	C,M, PBT, vPvB	Opinions adopted
Lead in ammunition and in fishing tackle	R	Opinions adopted
Terphenyl, hydrogenated (substance used as high temperature heat transfer fluids)	PBT/vPvB	Opinions adopted
N,N-dimethylacetamide (DMAC); 1-ethylpyrrolidin-2-one (NEP)	R	Opinions adopted

Restrictions Roadmap Progress update HSA

Subject of restriction proposal	Hazards in scope	Update
Bisphenols with endocrine disrupting properties for the environment and their salts	ED Env	Withdrawn
Creosote and Creosote related substances	C,M	With ECHA Committees
PFAS	PBT, vPvB, PMT, R	With ECHA Committees
1,4-dioxane	С, Р, М	Intention (Rol)
Octocrilene	PBT	Intention (Rol)
Chromium (VI) substances	С, М	Intention (Rol)
Lead in PVC	R	Under revision
Skin sensitizing substances in consumer mixtures	Skin sens	Under development
PVC and its additives	Multiple hazard properties	Under development
CMRs in childcare articles	C, M, R	Report drafting by ECHA

Microplastics restriction Regulation (EU) 2023/2055



- Environmental concern reduce microplastic pollution
- Concerns synthetic polymer microparticles (SPM) below five millimetres that are organic, insoluble and resist degradation
- Restricts SPM on their own or intentionally added to mixtures.
- Applies from 17 October 2023, with some time-limited derogations
- Expected to prevent the release of 500,000 tonnes of microplastics over 20 years.
- Q&A document: <u>https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_4</u> <u>602</u>
- The commission have indicated further guidance on the restriction will be available before the end of the year



Scope and derogations

- Scope (and derogation):
 - Plastic glitter (no derogation)
 - Cosmetics microbeads (no derogation)
 - Cosmetics other uses (4 12 years*)
 - Granular infill material used on artificial sport surfaces (8 years)
 - Certain plant protection products (8 years)
 - Certain fertilisers (5 years)
 - Detergents, waxes, polishes air care products, fabric softeners (5 years)
- Out of Scope
 - Articles
 - Products already regulated by other EU legislation, e.g. medicinal products, certain fertilisers, veterinary medicinal products, food and feed are not in scope
- * depending on the complexity of the product, the need for reformulation and the availability of suitable alternatives.



Microplastics- Glitter

Plastic glitter (loose plastic glitter) is a mixture under REACH and within scope



- Glitter/SPM sold for use at industrial sites (derogated para. 4a)
- **Inorganic Glitter** made of material (e.g. glass, metal), natural, biodegradable or soluble in water (out of scope)
- Glitter if affixed to an article depends on whether glitter is an integral part of the article or if the decorative function is secondary (out of scope) or purely decorative function and not integral
- Beads and sequins intended to be threaded or sewn onto articles (out of scope).
- **Loose plastic glitter used as a cosmetic product**, as well as **cosmetics containing glitter** have specific transitional periods para. 6.
 - 16 October 2027 included, for **rinse-off** cosmetics (paragraph 6b)
 - 16 October 2029 included, for **leave-on** cosmetics (paragraph 6d)
 - 06 October 2035 included, for **make-up, lip and nail cosmetics** (paragraph 6c).
 - Labelling as of 17 October 2031 to 16 October 2035 make-up, lip and nail products need to bear a label re containing microplastics.



Chromium (VI) substances



- The EU Commission has asked ECHA to prepare a restriction proposal on chromium (VI) substances
- Chromium VI is an SVHC and is currently listed in Annex XIV of REACH.
- Main use is in electroplating
- The proposal aims to address the challenges of the workload of ECHA's Committees and the Commission related to the high number of applications for authorisation
- Proposal will contain at least all chromium (VI) substances that are currently in entries 16 and 17 of the REACH Authorisation List (Annex XIV)
- Dossier will also investigate the potential for regrettable substitution
- Expected date for submission October 2024
- Information document for affected companies: <u>http://ec.europa.eu/docsroom/documents/56174</u>

"Global Framework on Chemicals – For a planet free of harm from chemicals and waste."

- Agreed at Fifth International Conference on Chemicals Management (ICCM5), Bonn, Germany 30th Sept 2023
- Comprehensive global framework which sets concrete targets and guidelines for key sectors across the entire lifecycle of chemicals
- 28 targets outlining a roadmap for countries and stakeholders to collaboratively address the lifecycle of chemicals, including products and waste.



Goals of the Global Framework on Chemicals



- Prevention of the illegal trade and trafficking of chemicals and waste,
- Implementation of national legal frameworks,
 - Phase out by 2035 of highly hazardous pesticides in agriculture.
 - Transition to safer and more sustainable chemical alternatives,
 - Responsible management of chemicals in various sectors including industry, agriculture and healthcare
 - Enhancement of transparency and access to information regarding chemicals and their associated risks.
- Participants also adopted the 'Bonn Declaration':
 - Commitment to "prevent exposure to harmful chemicals, and phase out the most harmful ones, where appropriate, and enhance the safe management of such chemicals where they are needed"







Go raibh maith agaibh Thank you



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CIRCULAR ECONOMY Future Challenges

WARREN PHELAN Programme Manager, EPA



ENVIRONMENTAL PROTECTION AGENCY ROLE & MANDATE



Ireland's An Integrated Assessment 2020







Our Purpose

To protect, improve and restore our environment through regulation, scientific knowledge and working with others

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Our Vision

We live sustainably in a healthy environment that is valued and protected by all

Environment

epa





Rialtas na hÉireann Government of Ireland

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NATIONAL POLICIES, PLANS & PROGRAMMES





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THE CIRCULAR ECONOMY IN IRELAND









FURTHER CHANGES COMING...





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CIRCULAR ECONOMY PROGRAMME 2021 - 2027

1. Evidence

Reporting of national statistics, green public procurement and behavioural insights studies

2. Collaboration

Implementation of circular economy (partnerships, funding supports, coordination of actions to address hazardous waste)

3. Regulation

End-of-waste, by-products and waste-sector licensing



OUR PRIORITY AREAS: Plastics Textiles Food, Water Construction & Nutrients & Buildings Electronics **Batteries** & Vehicles



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WASTE CONTINUES TO GROW



Waste Generation CSO Data (Kilotonnes)



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IRELAND'S CIRCULARITY RATE

Material flow diagrams Ireland - year 2021 Million tonnes





Legend

Σ Total



HAZARDOUS WASTE GENERATION



Hazardous Waste Generated in Ireland (2020 data)





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HAZARDOUS WASTE CAPACITY

Hazardous Waste Treatment in the EU (2010, 2018 data) and Ireland (2020 data)





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PLAN OUTPUTS

Rialtas Áitiúil Éireann Local Government Ireland

BEST PRACTICE GUIDANCE FOR **HANDLING ASBESTOS**



ASBESTOS GUIDANCE

Published in July 2023



Legislative context Best practice for handling asbestos



Health Risks



Advice on collection



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PLAN OUTPUTS

LITHIUM ION BATTERIES

Guidance on Safe Storage at Waste Handling facilities:



Will be published in Q4 2023





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END-OF-WASTE & BY-PRODUCTS 101





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PRODUCTION PROCESS





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END-OF-WASTE DECISION LEVELS





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INDIVIDUAL END-OF-WASTE DECISIONS

END-OF-WASTE CRITERIA FOR PULVERISED FUEL ASH & FURNACE BOTTOM ASH



SINGLE CASE DECISION FOR ELECTRICITY SUPPLY BOARD (ESB) This document sets out end-of-waste criteria for pulverised fuel ash (PFA), sometimes referred to as coal fly ash, and furnace bottom ash (FBA) produced during the combustion of coal.



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ESB (ELECTRICITY SUPPLY BOARD)

- Determination in 2019
- Pulverised Fuel Ash & Furnace Bottom Ash can be used in bound applications (e.g. concrete).
- Must comply with End of Waste criteria
- Waste authorisation obligations still apply (e.g. waste collection permit, waste licence, Cert of Registration etc.)













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INDIVIDUAL BY-PRODUCT DECISIONS

JOHNSON & JOHNSON

Determination in 2022

Notified Materials:	Propylene glycol (PG)	
Production Process:	Contact lens manufacture at Johnson & Johnson Vison Care Facility in Limerick	
Further Use:	Aircraft de-icer (antifreeze) & heat transfer fluid	
Defined User:	Within Europe (Sweden)	

PG IS A HIGH DEMAND PRODUCT

Production of PG to increase from 14,000m³ per annum to 24,500m³ in 2025.







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END-OF-WASTE & BY-PRODUCTS

DEVELOPMENT OF NATIONAL CRITERIA:



STRATEGIC STEP CHANGE IN OUR APPROACH:





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CHALLENGES & OPPORTUNITIES



PREVENTIO

- 1. Expanding the use of by-product regulation
- 2. Reducing hazardous substances in production processes

Role of legislation -

Eco-design Regulations

Alignment of hazardous waste definitions in CLP and Reach Regulations



RECYCLING

1. Expanding the use of end of waste regulation

- 2. New treatment technologies are needed
- National collection systems and producer responsibility
 schemes needed for the management of hazardous substances



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THANK YOU

For more information on the **Circular Economy Programme** contact <u>cep@epa.ie</u>





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Updates to the Classification, Labelling and Packaging (CLP) Regulation



Dr. Majella Cosgrave 18th October 2023


Introduction



- CLP a reminder
- Revisions to CLP in place via Delegated Act
- Upcoming revisions to CLP via normal legislative procedure
- Upcoming deadline for PCN
- Guidance and Chemicals Helpdesk

CLP – a Reminder

- Based on United Nations' Globally Harmonised System (GHS)
- Aims to ensure:
 - protection of health and the environment
 - free movement of substances and mixtures
- Requires manufacturers, importers, downstream users to classify, label and package hazardous chemicals before placing them on the market
- A key aim: determine if substance/mixture has properties that lead to hazardous classification
- Identified hazards must be communicated -> Labelling
- Packaging standards to ensure safe supply
- Other elements include harmonised classification and labelling, notification to the C&L inventory and Poison Centre notifications
- Overall, CLP provides basis for action under other EU legislation to address and mitigate risks of hazardous chemicals



Revision of CLP



- CLP has ensured a well-functioning single market for chemicals and a high level of protection for human health and the environment since 2008
- But, Commission's fitness check showed revision required to:
 - Take account of scientific/technological progress/market developments
 Optimise labelling rules
 - Address gaps to ensure more complete information on chemical hazards
 Clarify roles of different parties
- New hazard classes to be introduced



Quotes



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'We are making the rules on marketing chemicals simpler and more transparent, also relying on digital labelling where possible. Consumers and workers – notably in SMEs – will be better informed of chemical hazards included in substances and mixtures. The proposal will enable investments in even safer and more sustainable chemicals in Europe'.

Thierry Breton, Commissioner for Internal Market - 18/12/2022

'This proposal is an essential deliverable of the Chemicals Strategy for Sustainability and of our commitment to move towards a toxic-free environment. will ensure that very dangerous substances are properly identified, labelled and classified. It will strengthen evidence-based policy making and informed citizens' choices and will pave the way for the upcoming revision of the REACH Regulation'.

Virginijus Sinkevičius, Commissioner for Environment, Oceans and Fisheries - 18/12/2022

Delegated Act 2022 – New Hazard Classes

- Commission Delegated Act (DA 2022) introduced new hazard classes and criteria for classifying substances and mixtures into CLP (EiF 20 Apr 2023)
- New hazard classes:
 - Endocrine disruptors for human health or the environment (Cat 1 and Cat 2)
 - Persistent, bioaccumulative and toxic (PBT); very persistent and very bioaccumulative (vPvB)
 - Persistent, mobile and toxic (PMT); very persistent and very mobile (vPvM)
- DA 2022 sets out:
 - Criteria to classify a substance into one of the new hazard classes
 - Label elements (signal words, hazard statements, precautionary statements) and the classification limits for mixtures

Delegated Act 2022– New Hazard Classes

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• Applies to all chemical substances and mixtures placed on the EU market

• As of April 2023:

- Member States can prepare CLH proposals with the new hazard classes
- Manufacturers, importers, downstream users and distributors can selfclassify

• Transition periods:

- The new hazard classes can be applied on a voluntary basis
- At the end of the transitional period, all manufacturers, importers, downstream users and distributors must apply the new hazard classes
- New hazard classes are included in the GHS 2023-2024 biennium
- ECHA guidance expected mid 2024

New Hazard Classes Transition Periods HSA



Obligations for Industry after 20th April 2023 HSA

All manufacturers, importers, distributors and downstream users should:

- Review C&L of substances and mixtures against criteria for new hazard classes
- ✓Note transition periods
- ✓ If part of REACH joint submission, agree on C&L; update registration dossier
- If part of group of manufacturers/importers for C&L notification, agree on C&L; update notification
- ✓ Contact other notifiers for the same substance to agree on the new C&L
- ✓ Revise labels
- ✓ Update Poison Centre notification
- ✓ Consider if new Poison Centre notification required
- ✓ Update SDS with new C&L and relevant new hazard information
- Prepare to provide SDS upon request if mixtures not classified but contain a substance at 0.1% or more of Cat 2 endocrine disruptor not intended for general public

Revision of CLP – ordinary legislative procedure



- Commission proposal to amend CLP published 20 Dec 2022
- Proposal subject to European Parliament and Council approval
- EU Council adopted general approach 30 June
- European Parliament (Committee on the Environment, Public Health and Food Safety) adopted legislative report 11 Sept. Voted in plenary Oct 4
- Next step: Trilogue negotiations between Council, Commission and Parliament

Elements of COM Proposal to revise CLP HSA

- **1.** Identification and Classification of Chemical Hazards
 - New hazard classes introduced by Delegated Act in 2022
 - COM to initiate and fund more harmonised C&L dossiers
 - Changes around the **C&L Inventory**
 - Improve transparency and predictability of **C&L proposals**
 - How to evaluate and classify 'multi-constituent substances'

Elements of COM Proposal to revise CLP HSA

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2. Improving Hazard Communication

- Formatting rules for labels and deadlines for updating labels
- Rules for the **refill sales** of chemicals
- Allow for the voluntary digital labelling of chemicals
- Broader use of fold-out labels
- Derogations for chemicals sold to consumers in bulk and in very small packaging

Elements of COM Proposal to revise CLP HSA

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3. Addressing legal gaps and ambiguities of CLP provisions

- Provisions for distance sales, including **online sales**
- Clarify provisions for notifications to poison centres

EU Council adopted negotiating position 30 June 2023



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Introduced amendments to improve clarity and legal certainty of the proposal:

- Adjusts provisions on label form and design, addressing legibility issues and industry burdens
- Clarifies the concept and rules for digital labelling
- ✓ Strikes a balance between promoting refilling and reducing the risks linked to it
- Further clarifies COM's proposal on issues such as the labelling and information to be provided for chemical products sold at distance (including online)
- Calls on COM to prepare a report 4 years after EiF on the classification provisions for MOCS
- Amends provisions concerning new hazard classes to avoid duplication with ongoing assessments under different legislation

EU Parliament adopted negotiating position 4th Oct 2023

MEPs broadly backed COM's proposal, with some suggested amendments incl:

- An tÚdarás Sláinte agus Sábháilteachta Health and Safety Authority
- ✓ Promotes alternative methods (new approach methodologies) for assessment of hazards
- ✓ Calls for prioritisation of groups of substances in harmonised C&L proposals
- ✓ Maintains COM's proposal for MOCS but:
 - provides for exemption for those of renewable botanical origin that are not chemically or genetically modified, and
 - calls for COM to report on evaluation and classification of these MOCS of renewable botanical origin within 6 years of EiF

 Strengthens provisions related to access to justice for anyone with 'substantiated concern' on classification decisions

✓ Calls for adequate resources and funding for the Agency

CLP Revision and REACH



- REACH and CLP revisions are complementary
- New information requirements under REACH will provide information on the intrinsic properties of substances leading to their classification under new hazard classes
- Harmonised classification of substances for those hazards under CLP will be the basis for increased risk management under REACH

CLP Revision and European Green Deal

• Revision of CLP will:

- Help innovate for safe and sustainable chemicals
- Allow the identification of the most harmful substances
- Enable actions to be taken to restrict the use of harmful substances
- ✓ Increase protection from hazardous chemicals
- ✓ Lead towards a toxic-free environment
- Combined actions will contribute to:
 - Tackling climate change
 - ✓ Reducing pollution
 - Enhancing toxic-free material cycles in the circular economy
- -> all of which are objectives of the European Green Deal

Upcoming Deadline on PCN – 1st Jan 2024

• CLP Annex VIII will EiF for industrial use mixtures on 1st Jan 2024

HSA

- Hazardous mixtures placed on Irish market must be notified to the National Poisons Information Centre (NPIC) in the harmonised format via ECHA PCN portal
- Notifications submitted before 1st Jan 2024 remain valid until 1st Jan 2025, or until changes are made to the product
- If product remains unchanged until 1st Jan 2025, new notification must then be made as no migration of data is planned
- If that unchanged product discontinued before end of 2024, no new submission required
- ECHA website has information on making a notification via the PCN portal
- ECHA webinar 14 November 2023 <u>https://echa.europa.eu/-/poison-centre-notifications-ensuring-compliance-for-industrial-use-mixtures</u>

Guidance and Chemicals Helpdesk

HSA

- CLP Guidance and Q&As on ECHA's website <u>www.echa.europa.eu</u>
- HSA website <u>www.hsa.ie/chemicals</u>
- HSA's Chemicals Helpdesk; <u>chemicals@hsa.ie</u> or 1890 289 389







Go raibh maith agaibh Thank you



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Questions and Answers

CPC Environmental Protection Agency An Environmental Protection Agency