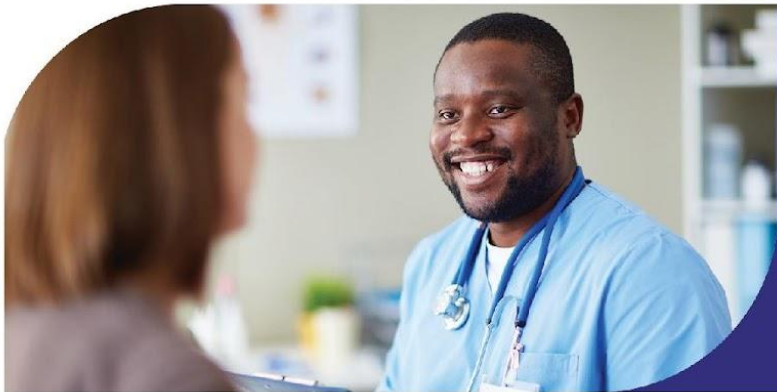




HSA

An tÚdarás Sláinte agus Sábháilteachta
Health and Safety Authority

CMRS & COP



Michelle McDermott
OHSI Ireland 2025

Updates

- Safety, Health and Welfare at Work (Carcinogens, Mutagens and Reprotoxic Substances) Regulations 2024 (CMRS)
- 2024 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations (2001-2021) & the Safety, Health and Welfare at Work (Carcinogens, Mutagens and Reprotoxic Substances) Regulations (2024). (COP)
- Resources to assist compliance

CMRS Regulations

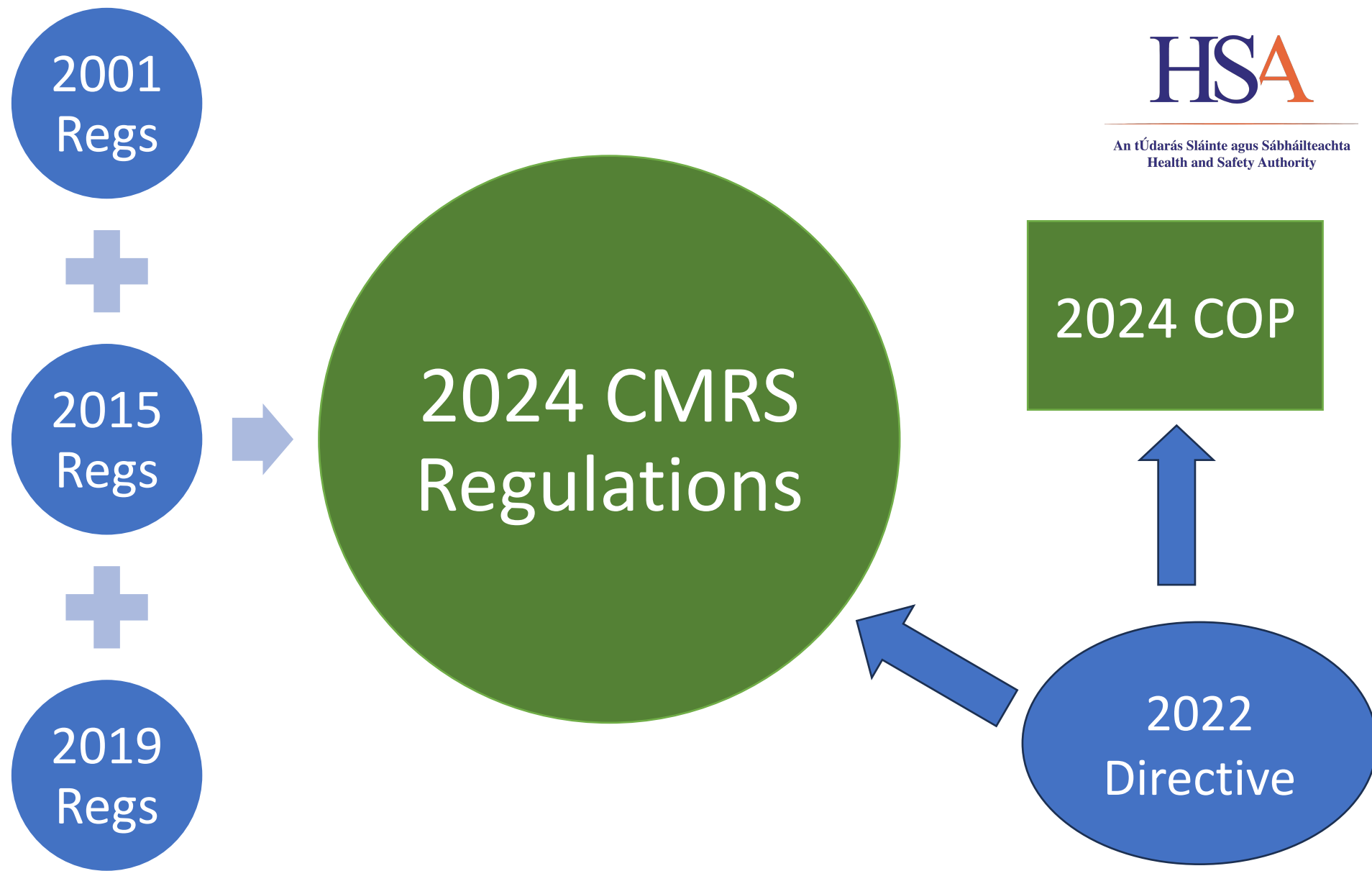
- *Safety, Health and Welfare at Work (Carcinogens, Mutagens and Reprotoxic Substances) Regulations 2024*, Download [here](#) .

CMRS (CMR)

- Carcinogen
- Mutagen
- Reprotoxic Substance



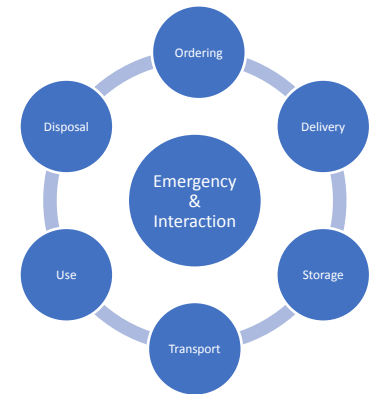
Apply in addition to Chemical Agents Regulations



Existing Requirements – reminder

- **Risk Assessment**

- A competent person to assess any risk to the health or safety of employees
- The risk assessment shall:
 - take account of the nature, degree & duration of exposure
 - be renewed regularly & whenever any change
 - take account of all other routes of exposure including skin
 - give particular attention concerning employees at particular risk (*e.g. pregnancy*)
- *Meet Regulation 4 of Chemical Agents Regs*



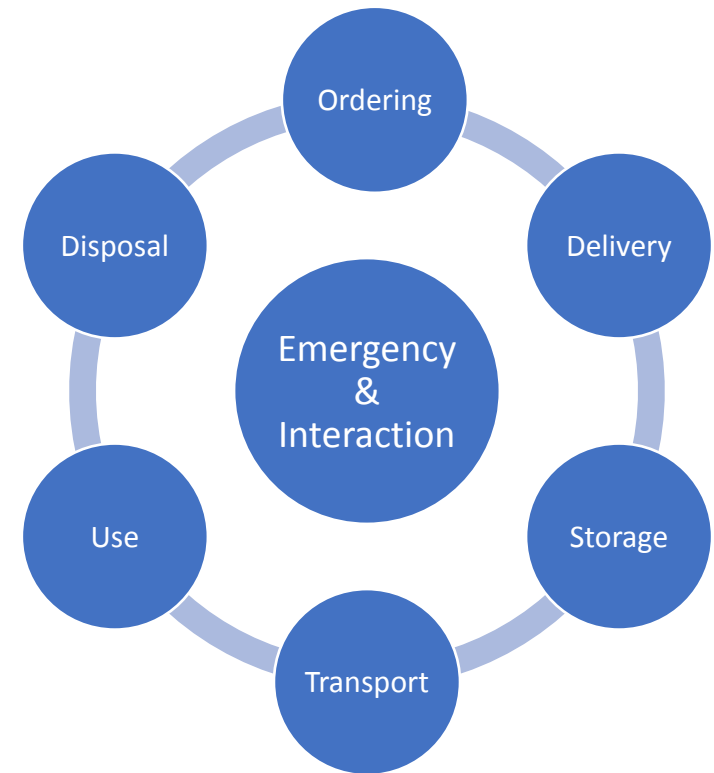
Existing Requirements – reminder

- Applied to
 - Carcinogenic (category 1A or 1B)
 - Mutagenic (category 1A or 1B)

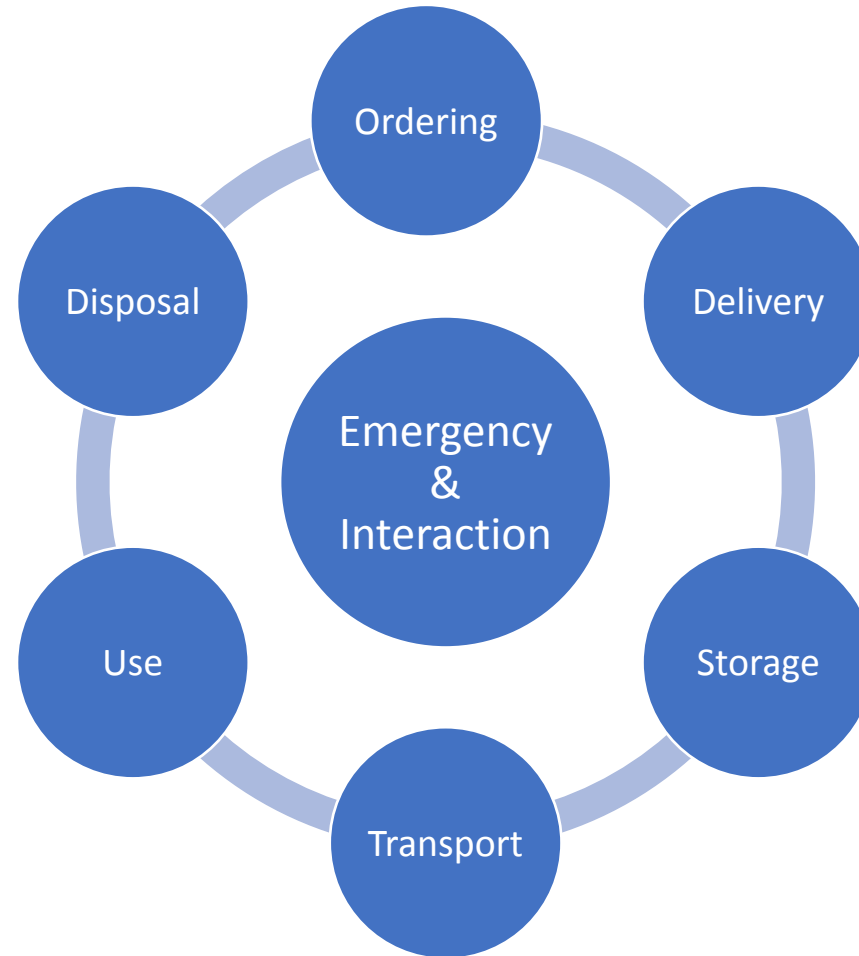
Duty of Care (in so far as is technically possible)

- Substitution
- Closed System
- Reduce level of exposure
- Limit quantity
- Limit number of employees
- Avoid release
- Extraction at source

Also Training, Health Surveillance, Exposure Records, Information to Authority



Existing Requirements – reminder



- Apply in addition to Chemical Agents Regulations
- e.g. arrangements for safety drills to be performed at regular intervals

Existing Requirements - reminder

- Carcinogenic
- Mutagenic



List of Carcinogenic Substances, Mixtures and Processes

1. Manufacture of auramine.
2. PAH - polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch.
3. Work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes.
4. Strong acid process in the manufacture of isopropyl alcohol.
5. hardwood dusts.
6. respirable crystalline silica (RCS)
7. dermal exposure to mineral oils
8. diesel engine exhaust emissions (DEE)

Existing Requirements – Schedule 4 of COP

List of Carcinogenic Substances, Mixtures and Processes

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2. Work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch.
3. Work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes.
4. Strong acid process in the manufacture of isopropyl alcohol.
5. Work involving exposure to hardwood dusts.
6. Work involving exposure to respirable crystalline silica dust generated by a work process.
7. Work involving dermal exposure to mineral oils that have been used before in internal combustion engines to lubricate and cool moving parts within the engine.
8. Work involving exposure to diesel engine exhaust emissions

New Requirements - CMRS Regs

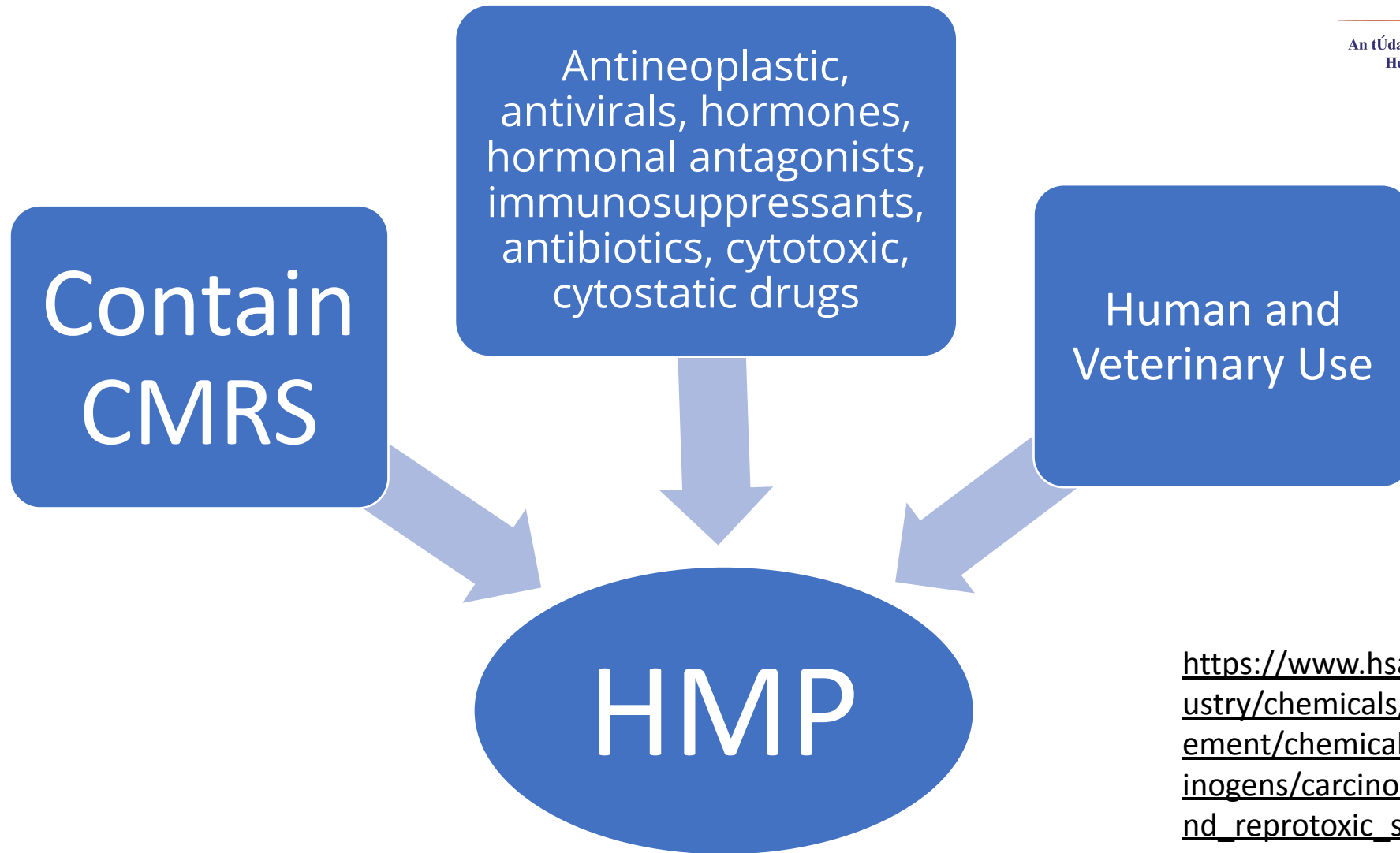
- Reprotoxic Substances have been added (stricter requirements)



- Introduction of Hazardous Medicinal Products (HMP)



Hazardous Medicinal Products



https://www.hsa.ie/eng/your_industry/chemicals/legislation_enforcement/chemical_agents_and_carcinogens/carcinogens_mutagens_and_reprotoxic_substances/hazardous_medicinal_products_hmps/

Hazardous medicinal products

are defined as medicinal products that contain one or more substances that meet the criteria for classification as:

- Carcinogenic (category 1A or 1B)
- Mutagenic (category 1A or 1B)
- Toxic for reproduction (category 1A or 1B)

in accordance with Regulation (EC) No 1272/2008 (CLP Regulation)

Medicinal products

Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;

or

Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action

or

to making a medical diagnosis. ’

Hazardous medicinal products

Information from

- ECHA database on hazardous substances
- EMA database on medicinal product
- [NIOSH List of Hazardous Drugs in Healthcare Settings, 2024 | NIOSH | CDC](#)
- European Trade Union Institute (ETUI)
<https://www.etui.org/publications/etuis-list-hazardous-medicinal-products-hmps>

Hazardous Medicinal Products

Identify

- EU Commission [EUR-Lex - 52025XC01150 - EN - EUR-Lex](#) – Annexes
- SDS (if available) or SPC's
- Labelling
- Communication with supply chain
(SPC's - Summary of Product Characteristics)



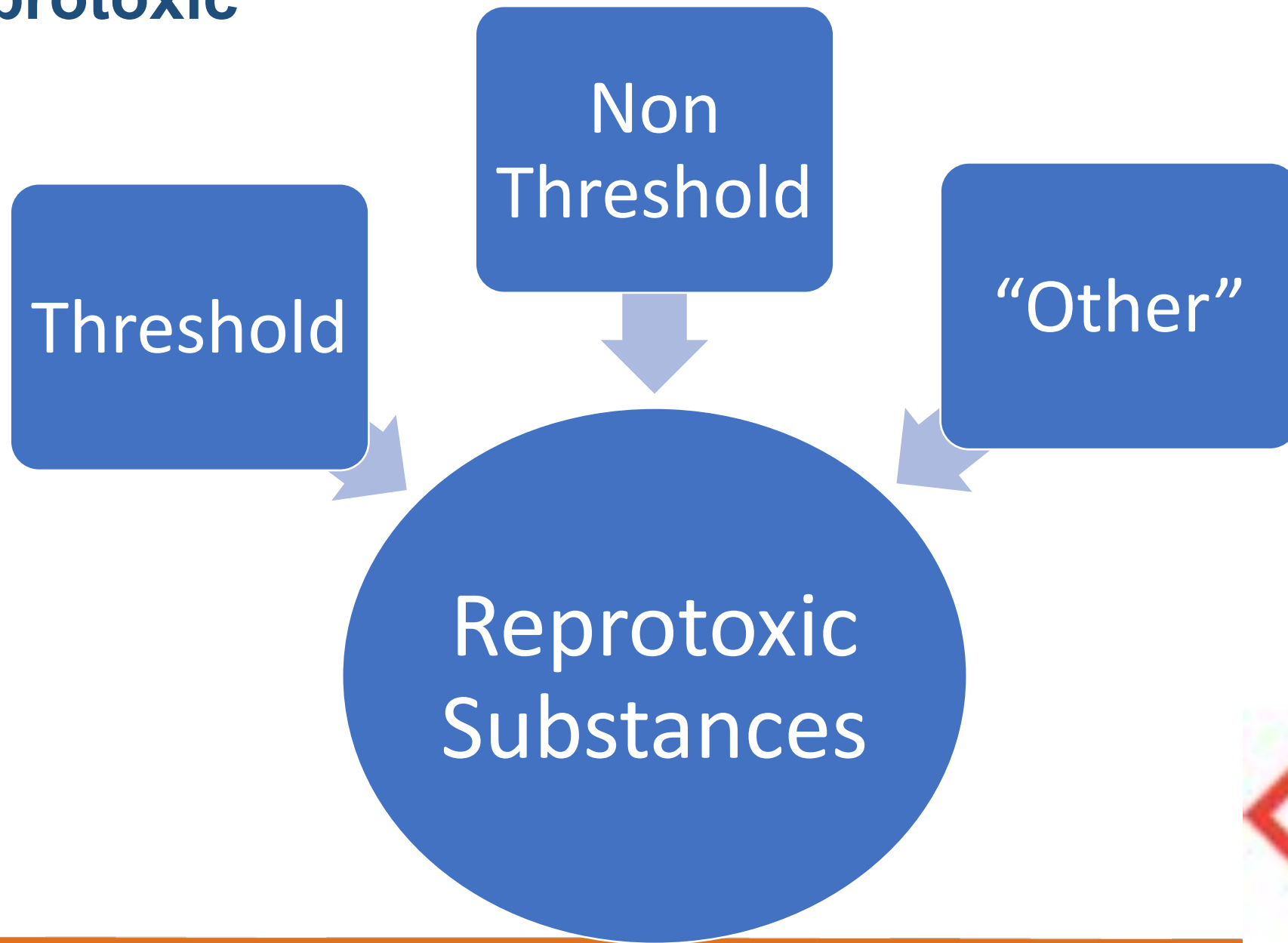


New Requirements - Reprotoxic



- Reprotoxic Substances
 - Toxic for reproduction (category 1A or 1B)
 - See label and Safety Data Sheet
 - H360 -May damage fertility or the unborn child.
- Reproductive toxicity includes
 - adverse effects on sexual function in adult males and females
 - adverse effects on fertility in adult males and females
 - development toxicity in the offspring

Reprotoxic



New Requirements - Reprotoxic



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Under CMRS these can be subdivided

- (a) “non-threshold reprotoxic substances” - no safe level of exposure
- (b) “threshold reprotoxic substances” a safe level of exposure exists below which there is no risk to employees’ health

Many substances classified as reprotoxic substances are not yet subdivided into either of these categories.

These will be identified in the Code of Practice. *(Currently only Pb)*

Training Requirements – HMP included

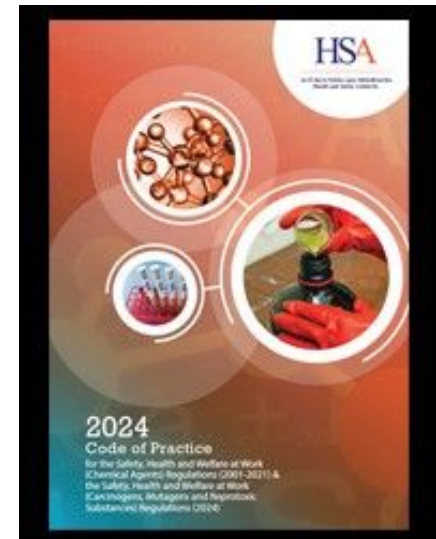
- workers must be given specific training to prevent risks of adverse effects on their health.
- should cover the potential risk to health,
- the precautions to prevent exposure,
- the hygiene requirements,
- the wearing and use of personal protective equipment,
- the steps to be taken in the event of an incident,
- significance of the labelling, warning and hazard signs in relation to installations and containers containing CMRS.
- take into account any new or changed risk.
- provided on a regular basis when workers are likely to be exposed to CMRs including those contained in hazardous medicinal products.

2024 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations (2001-2021) & the Safety, Health and Welfare at Work (Carcinogens, Mutagens and Reprotoxic Substances) Regulations (2024).



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- Schedule 1: list of all EU Commission derived occupational exposures limit values (OELVs). Updated
- Schedule 2: Advisory OELVs derived from non-EU sources – no change
- Schedule 3: lists intended changes and those substances under review (non exhaustive)
- Schedule 4 lists carcinogenic substances, mixtures and processes – no change
- Schedule 5 contains information on Health Surveillance and Biological Limit Values. Change of location



New OEL's in 2024 Code

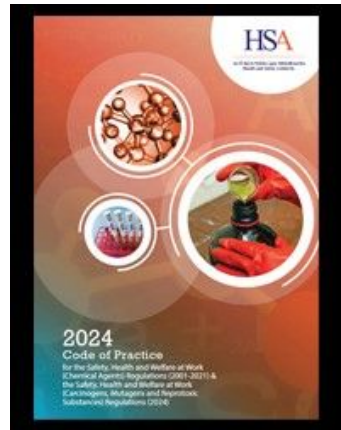
COP	Substances	ppm	mg/m3	Notes
2021 COP	Benzene	1	3.25	Until April 2024
2024 COP	Benzene	0.5	1.65	Until April 2026
2024 COP	Benzene	0.2	0.66	From 5th April 2026
2021 COP	Acrylonitrile	2	4.5	Schedule 2 and 3
2024 COP	Acrylonitrile	0.45	1	From 5th April 2026.
2021 COP	Nickel compounds		0.1-1	Schedule 1 and 3
2024 COP	Nickel compounds		0.1	Until 18th January 2025
2024 COP	Nickel compounds		0.01-0.05	from 18th January 2025

Notations

Substances	Notation	
Benzene	Skin	Substantial contribution to the total body burden via dermal exposure possible
Acrylonitrile	Skin Dermal sensitisation	Substantial contribution to the total body burden via dermal exposure possible The substance can cause sensitisation of the skin.
Nickel compounds	Dermal and respiratory sensitisation	The substance can cause sensitisation of the skin and of the respiratory tract.

Compliance - reminder

- A competent person such as an occupational hygienist should determine a suitable monitoring strategy.
- The actual OEL value is only 1 aspect of OEL compliance.
- OEL compliance is just one aspect of compliance Irish Legislation.
- OEL does not take dermal exposure into account
 - E.g. 0.1% constituent – air monitoring carried out ????
- EU work on residual risk communication



New Location- COP- Lead

Biological Limit Values for lead are now in the in the 2024 COP.

Biological monitoring must measure blood-lead level (PbB)

Binding biological limit value is: 70 μg Pb/100 ml blood.

Health surveillance is carried out if:

- a. exposure to a concentration of lead in air is greater than 0.075 mg/m³, (TWA 40 hr week), or
 - b. a blood-lead level greater than 40 μg Pb/100 ml blood is measured in individual employees.
- Health surveillance – mandatory as BLV



HSA – Regulations changing 2025/2026



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CMRS

- update to Mutagens definition to include Schedule 4 List of carcinogenic and Mutagenic processes

Chemical Agents Regulations

- Removal of Lead limits
- Consolidation ?

2025 or 2026 COP for CMRS and CA Regulations

- Removal of Asbestos
- new Lead OEL and BLV
- new Diisocyanates Limits
- Review of ACGIH TLV 2025.
- Other?

Lead (Pb) – further amendments

Directive (EU) [2024/869](#) as regards the limit values for lead and its inorganic compounds has been adopted.

The adopted directive contains the following provisions for **lead**:

- Reduction of occupational exposure limit
- Reduction of biological limit value
- Notation of lead as a non-threshold reprotoxic substance
- Medical surveillance requirements updated

We have until 9 April 2026 to implement these via an update to COP

https://www.hsa.ie/eng/your_industry/chemicals/legislation_enforcement/chemical_agents_and_carcinogens/chemical_agents/latest_news/

Disocyanates further amendments

Directive (EU) [2024/869](#) regarding the limit values for diisocyanates

- NEW Binding Occupational Exposure Limit Values (BOELV)
 - limit value of 10µg NCO/m³ (8hr), 20µg NCO/m³ (STEL) until 31 Dec 28
 - limit value of 6µg NCO/m³ (8hr), 10µg NCO/m³ (STEL) from 1 Jan 29
- Notations
 - “Skin” (Substantial contribution to the total body burden via dermal exposure possible)
 - “Dermal & respiratory sensitisation” The substance can cause sensitisation of the skin & respiratory tract

The “NCO” - isocyanate functional groups of the diisocyanate compounds.

Isocyanates further amendments

The 2024 COP has advisory limit values for several diisocyanates. These will be replaced with the BOELVs as per the Directive. We have until 9 April 2026 to implement the BOELVs via an update to our Code of Practice.

The HSA are aware of the current difficulties associated with air monitoring for diisocyanates.

See [Diisocyanates - Health Surveillance and Monitoring - Health and Safety Authority \(hsa.ie\)](https://hsa.ie/Diisocyanates-Health-Surveillance-and-Monitoring).

The actual OEL value is only 1 aspect of OEL compliance.

In addition, OEL compliance is just one aspect of compliance with Irish Legislation.

It is the duty of every employer, so far as is reasonably practicable, to reduce risks / exposure to a minimum.

The Future



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CMR - 6th amendment of CMRs Directive –

- Plan to have proposal accepted first half 2025
- Welding fume to be added to Annex 1
 - only welding fume that containing CMRs such as nickel and chromium.
 - Raise awareness of duty holders to check composition of their welding fumes.
- PAH, isoprene, 1,4-dioxane, Cobalt & and inorganic cobalt
 - OELV
 - Notations
 - [ACSH Adopted opinion Welding fumes 22.09.23-EN \(1\).pdf](#) - [ACSH Adopted opinion PAHs 22.09.23 -EN.pdf](#) – [ACSH Adopted opinion Isoprene 22.09.23-EN \(1\).pdf](#) - [ACSH Adopted opinion Cobalt and inorganic compounds 22.09.23-EN \(2\).pdf](#) - [ACSH Adopted opinion 1_4-dioxane 22.09.23-EN \(1\).pdf](#).

CMR 7th amendment of CMRs Directive

- call for tender for external study January 25 & finalising the bids
- 1,2-Dichloropropane;
- 1,2,3-Trichloropropane;
- 2-Chloro-1,3-butadiene (Chloroprene);
- 2,3-Epoxypropyl methacrylate (glycidyl methacrylate);
- Nitrosamines
- Respirable Crystalline Silica,
- Chromium VI compounds
- initiative to revise CMRD needs to be validated by the Commission, including its scope, covered substances and timeline

2026-2028

Biomonitoring

- EUOSHA - guide on Health Surveillance & biomonitoring by April 2026
- Consult with SLIC Chemex

Combined Exposure

- Guidelines on combined exposure based on scientific assessment by ECHA and RAC
- ECHA Guidance 2028 (Tripartite group and EUOSHA).

Endocrine Disruptors

- Commission to initiate process to evaluate if need to include these in the CMRs
- Scientific assessment by ECHA and RAC (2026-2028)

General Comments

- Exposure Risk Relationship - ERR of a carcinogenic hazardous substance refers to the relationship between the substance concentration (inhalation) and the statistical probability of developing cancer (additional risk beyond the background incidence)

Methodology establishing risk-based limit values for non-threshold carcinogens, for the purposes of Article 1 (18a) of Directive 2004/37/EC – See

<https://ec.europa.eu/social/BlobServlet?docId=27151&langId=en#:~:text=If%20non%2Dthreshold%20applies%2C%20DECOS,the%20government%20and%20social%20partners.>

How to communicate to end users

- Dermal Exposure
- BLV & BGV e.g. acrylonitrile BLV of 60 µg CEV/L blood (erythrocyte fraction of whole blood) 6 (sampling time: after at least 3 months of exposure)
- Medical Surveillance

ECHA – what’s possibly coming next???

Check status of substance <https://echa.europa.eu/information-on-chemicals>

Consultations on Classifications –
<https://echa.europa.eu/harmonised-classification-and-labelling-consultation>

The table <https://echa.europa.eu/oels-activity-list> provides up-to-date information on the activities planned, ongoing or completed by ECHA in relation to its work on occupational exposure limits.



Resources

- Roadmap on Carcinogens
<https://stopcarcinogensatwork.eu/>
- Has IARC carcinogens – CMRS do not apply



**S.T.O.P.
CARCINOGENS
AT WORK**

Resources

HSA Website



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Health and Safety Authority

- https://www.hsa.ie/eng/your_industry/chemicals/legislation_enforcement/chemical_agents_and_carcinogens/
- <https://hsa.newsweaver.co.uk/newsletter/1gj1mbq8m4b-1f235na4uk?email=true&lang=en&a=1&p=62718235&t=24949895>
- [a short guide to health surveillance in the workplace.pdf](#)
- Occupational Hygiene Society of Ireland
<https://www.breathefreely.ie/>



To Do.....

- Do you have a Chemical Inventory?
- Have you checked Schedule 4 of the COP?
- Are there CMRs or HMPs?
- Do you have a life cycle risk assessment?
- Controls – in so far as technically feasible?
- Does your Training meet the requirements
- Implications of changes

- *In offering this advice the Health and Safety Authority wish to make it clear that:*
- *only the Courts can interpret statutory legislation with any authority;*
- *this advice is based on information to hand and is subject to revision in the light of further information, and;*
- *the advice is not intended to be a definitive guide to, or substitute for, the relevant law. Independent legal advice should be sought where appropriate.*
- *The above are a non-exhaustive list of issues which may require attention*



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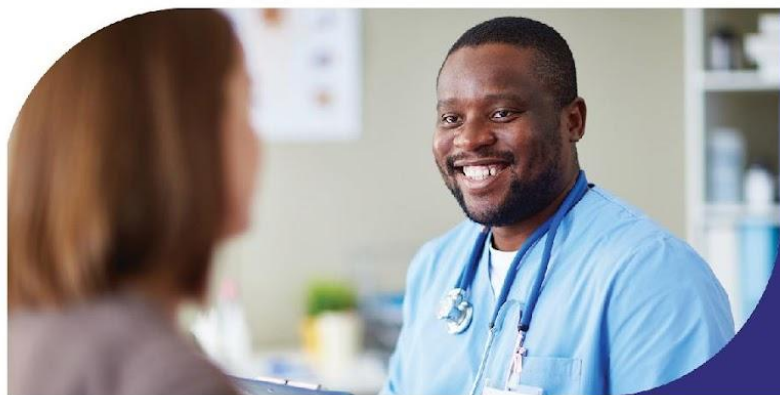
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Health and Safety Authority

Go raibh maith agaibh
Thank you

T: 0818 289 389

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W: www.hsa.ie



Questions.....



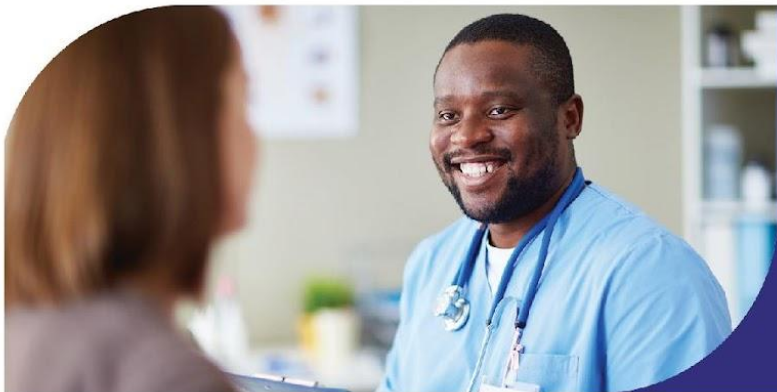
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Thank you



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