Information Sheet

Carcinogens, Mutagens, and Reproductive Toxins (CMRs)

1. Introduction

Carcinogens, mutagens and reproductive toxins (CMRs) pose a serious threat to human health so exposure to them must be prevented or strictly controlled. This document contains information on what CMRs are and examples of control measures appropriate for meeting the legal requirements of Control of Substances Hazardous to Health (COSHH) Regulations 2002. The purpose is to promote best practice for work involving the use of carcinogens, mutagens and reproductive toxins.

This document does not include the requirements for the Control of Asbestos Regulations 2012 or the Control of Lead at Work Regulations 2002.

2. Definitions

CMRs: is a collective term for carcinogens, mutagens and reproductive toxins.
Carcinogens: are substances or mixtures which cause cancer or are suspected of causing cancer.
Mutagens: are substances or mixtures that induce heritable mutations in the germ cells of humans or are suspected of inducing heritable mutations in the germ cells of humans.
Reproductive Toxins: are substances or mixtures which cause adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring and effects through lactation.

- This includes teratogens, these substances can cause structural or functional abnormalities, miscarriage, stillbirth, birth defects, or developmental issues in a developing embryo or foetus.

3. Categorising CMRs

CMRs can be identified in Section 2 of the safety data sheet, using the pictogram, signal word, and hazard statements provided (see table 1 below). The category of CMR will also be listed in this section.

Table 1: Categorisation of Carcinogens, mutagens and reproductive toxins

GHS & Signal Word	CLP Hazard Statements	CLP Category & Definition
 Danger	**H350** May cause cancer. or **H350i** May cause cancer by inhalation	***Category 1A carcinogens** Chemicals known to have a carcinogenic potential for humans; based largely on human evidence. ***Category 1B carcinogens** Chemicals – presumed to have a carcinogenic potential for humans; based largely on animal evidence.
 Warning	**H351** Suspected of causing cancer	**Category 2 carcinogens** Suspected human carcinogens – based on human and animal evidence but which is not sufficiently convincing to place chemical in Category 1.
 Danger	**H340** May cause genetic defects	***Category 1A mutagens** - chemicals known to induce heritable mutations in germ cells of humans. Based largely on human evidence. ***Category 1B mutagens** - chemicals which should be regarded as if they induce heritable mutations in germ cells of humans. Based largely on animal evidence.
 Warning	**H341** Suspected of causing genetic defects	**Category 2 mutagens** – chemicals which cause concern for people owing to the possibility that they may induce heritable mutations in germ cells of humans.
 Danger	**H360** May damage the unborn child/impair fertility	***Category 1A reproductive toxins** – chemicals known to be human reproductive toxicant. ***Category 1B reproductive toxins** – chemicals presumed to be human reproductive toxicant.
 Warning	**H361** Suspected of damaging fertility / the unborn child	**Category 2 reproductive toxins** - chemicals suspected to be human reproductive toxicant [where evidence not sufficiently convincing to place in Cat 1]
Reproductive Toxin No GHS	**H362** May cause harm to breast fed children	Reproductive toxicity – effects on or via lactation

***Categories 1A & 1B carcinogens and mutagens** (the shaded rows in the Table 1, above) are subject to specific requirements under COSHH that must be followed. Substance and processes listed in Schedule 1 of COSHH (see Appendix I) are also subject to these mandatory requirements.

EH40/2005 Workplace exposure limits document (HSE) identifies chemicals with workplace exposure limits; these have been set to help protect workers' health. WELs are concentrations of hazardous substances in the air, averaged over a set period of time. They are legal limits that must not be exceeded. EH40 also identifies Category 1 carcinogens and mutagens (see "*Carc"* in the comments column), for these chemicals the workplace exposure limits must not be exceeded, and exposure must be reduced to as low as is reasonably practicable.

Examples of CMRs:

- Benzene
- Formaldehyde
- Ethidium Bromide
- Mercury
- Acetaldehyde
- Aluminium chloride
- Welding Fume

4. Purchasing and Storage

Prior to purchasing a chemical, you must ensure a chemical pre-purchase form has been completed. This will include actions to take in the event of an emergency.

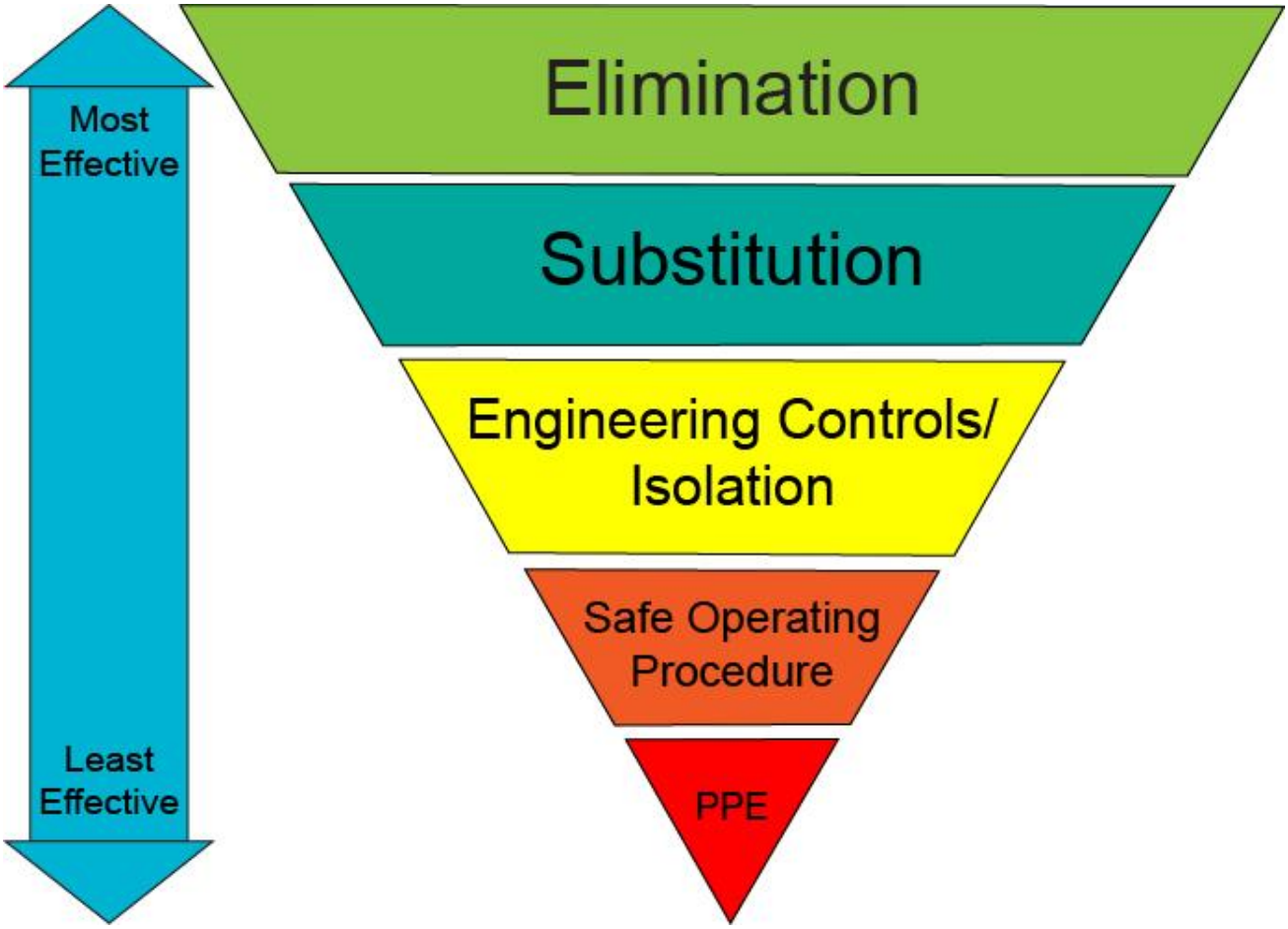
Once the chemical arrives it must be added to the chemical inventory and stored in an appropriately labelled and locked cabinet.

Before use ensure a suitable and sufficient assessment of risk has been carried out for the activity and the controls required can be implemented.

See Staff H&S webpages or PG Hwb for guidance on risk assessment and the storage and labelling of chemicals.

5. Controls for CMRs

As with other hazards when deciding on controls, we must consider the hierarchy of control, see the image below:



Taking into consideration the hierarchy of control for all CMRs our starting point must be preventing exposure by eliminating the use of CMRs. In your work, you should choose methods which:

1. Avoid, if reasonably practicable, the use of CMRs at the start, or as part of any process or activity.
2. Avoid, if reasonably practicable, the formation of by-products, intermediates, wastes or residual contaminants consisting of, or containing, CMRs.

Category 1A and 1B carcinogens and mutagens should not be used if a suitable non-hazardous or less hazardous substance or process can be used.

If a CMR is substituted for a less hazardous substance, you will still need to consider the other properties of the substitute chemical, such as toxicity.

If it is not reasonably practicable to prevent exposure to CMRs by elimination or substitution, then adequate controls must be put in place; the principles of good control practice must always be followed and Workplace Exposure Limits (WELs) must not be exceeded.

Mandatory control requirements for Category 1A and 1B carcinogens and mutagens, and substances and processes that are listed in Schedule 1 of COSHH (Appendix 1):

1. Exposure must be reduced to as low a level as reasonably practicable; this means improving control until the cost of further reduction in exposure becomes grossly disproportionate when weighed against the benefit gained.
2. Totally enclose the process and handling systems, unless this is not reasonably practicable, (e.g. use an isolator/glove box or Class III microbiological safety cabinet). Where it is not reasonably practicable to enclose the process, robust reasons for this decision must be recorded in your risk assessment.
3. Prohibit eating, drinking and smoking in areas that may be contaminated by carcinogens or mutagens.
4. Clean floors, walls and other surfaces (e.g. tools, equipment and PPE) at regular intervals and whenever necessary.
5. Clearly identify the areas and installations that may be contaminated by carcinogens and mutagens and use suitable and sufficient warning signs; takes measures to prevent the spread of contamination within and beyond these areas.
6. The number of people likely to be exposed to carcinogenic or mutagenic substances and the duration of their exposure must be kept to the minimum necessary for the work. Non-essential personnel must be excluded.
7. Store, handle and dispose of CMRs safely, using closed and clearly labelled containers.

For other CMRs, a precautionary approach is good practice; therefore, many of these controls are recommended and should be considered as part of the risk assessment; *but limit the use of the warning signs in designated areas to Category 1A and 1B carcinogens and mutagens only*.

Additional controls to reduce the risk of exposure to all CMRs:

1. Reduce, to the minimum required for the work
   - The number of employees subject to exposure; Exclude non-essential personnel.
   - The level and duration of exposure.
   - The quantity of CMRs present at the workplace.
2. Use an adequate ventilation system to remove contaminants at source:
   - These chemicals must not be handled on an open bench.
   - Use a ducted fume cupboard. Containment testing is recommended.
   - Handling CMRs in recirculating fume cupboards or Class I and Class II microbiological safety cabinets is not recommended. Do not use these cabinets for work with CMRs without confirming their performance and suitability.
   - Recirculating local exhaust ventilation systems with suitable filtration may be used for the control of welding fume, solder fume and wood dust.
   - For further information refer to university guidance document: Laboratory Equipment – Containment and Extraction.
3. Develop and adopt safe systems of work, e.g.
   - Ensure that equipment others may use is not contaminated with CMRs, ensure good cleaning measures are in place.

- Obtain agents in pre-weighed vials or 'isovac' containers to remove need for dispensing [even if this is more expensive]. Appendix 2 identifies a model procedure for weighing solid CMR and other toxic compounds.
- The use of sharps in procedures involving CMRs should be avoided where possible. Do not re-sheath needles.
- Contaminated glassware, spatulas and other non-disposal items must **not** be placed in communal washing-up containers. They must be decontaminated and rendered safe by the user (as much as reasonably practicable) before sending for washing. This should take place within the glove box / fume cupboard and any washings, including solvent, carefully stored and labelled as hazardous waste.
- Dispose of CMR or CMR contaminated waste correctly (see Appendix 3)
- Provide appropriate hygiene measures, including adequate washing facilities.

4. Use suitable Personal Protective Equipment (PPE). Consider the use of disposable PPE where appropriate. Ensure that gloves are chemically compatible with the substance and provide adequate protection for the task. PPE must be removed carefully to avoid spreading contamination and disposed of safely where it cannot be decontaminated and reused.
5. Respiratory protective equipment (RPE) such as respirators, should only be worn as a secondary means of protection, in addition to working in a fume cupboard, or in the event of a spill outside primary containment. Care must be taken when selecting RPE to ensure that it is right for the job. Depending on type selected, users may require face-fit testing. The wearer must receive suitable training in the correct use of the RPE. A regime of cleaning and maintenance must be in place.
6. Ensure sufficient information, instruction, training and supervision has been provided and understood to ensure that the work can be carried out safely. The training must include the hazards and risks from the substances they work with, the use of control measures developed to minimise the risks and the steps to take in the event of an emergency.
7. Maintenance of controls. Ensure that all controls are maintained and working, e.g. checks on fume cupboards.
8. When working with CMRs, action must be taken to avoid risk to the health and safety of a pregnant or breast-feeding individual and their baby. Before carrying out any further work with CMRs the individual should inform their line manager / supervisor, they must carry out a Pregnant Persons - New & Breastfeeding Parent Risk Assessment. For further information refer to the Pregnant Persons – New & Breastfeeding Parent Policy Arrangements. Workers undergoing fertility treatment or trying to conceive are encouraged to seek advice from their GP or from Occupational Health.
9. Young people (under 18) and children (under the minimum school leaving age) are prohibited from handling all carcinogens, mutagens and reproductive toxins. There is an exemption for young people, who are not children, where
    - it is necessary for their training
    - where the young person will be supervised by a competent person; and
    - where any risk will be reduced to the lowest level that is reasonably practicable.

6. Transport of CMRs

On campus:
CMRs, including wastes, may be removed from the laboratory or moved to another suitable laboratory only if:

- The outside of the vessel is clean.
- The vessel is transported in a chemically resistant container.
- The vessel is clearly labelled, with appropriate hazard information

Between campuses and off campus locations:
Staff must not transport CMRs in private vehicles or on public transport.

If you need to move any chemical from one campus to another or to an off-campus location, please contact the Health Safety and Resilience team. They will be able to assist you in moving it safely.

You may invalidate insurance and break the law if you decide to transport CMRs using your own vehicle.

Transporting hazardous chemicals via public transport is illegal.

7. Health Surveillance

Principal Investigators (PIs)/ line managers are responsible for ensuring that the risks associated with work with CMRs are assessed. They must ensure that the risk assessment identifies whether health surveillance or individual health records are required. Occupational Health or the HS&R Team should be consulted where necessary. Where health surveillance or individual health records are required, the PI/ line manager is responsible for communicating this to Occupational Health.

Health surveillance is required if there is:
(1) an identifiable disease or adverse health effect linked to exposure,
(2) a likelihood of hazardous exposure occurring and
(3) a valid technique is available to detect early signs of exposure.

The Higher Education Occupational Physicians/Practitioners (HEOP) guidance, 'Guidance on Carcinogens within UK Universities', provides information on typical laboratory activities involving carcinogens and mutagens and can assist in determining if health surveillance is appropriate.

Many occupational cancers have a long latency period, often spanning decades, between exposure to a carcinogen and the development of detectable disease. For most carcinogens there are no effective screening tests that can reliably detect cancer at the time of exposure. Where hazardous exposure can occur a health record should be maintained in lieu of active monitoring for the effects of exposure. The risk assessment must therefore consider the need for appropriate health surveillance and the maintenance of individual health records, in accordance with COSHH requirements.

Where known or suspected carcinogens or mutagens are stored or used, they must be included in the chemical inventory.

Faculties/ PSU must maintain an appropriate register for the use of known or suspected carcinogens and mutagens. This register must include:

- The name of the carcinogen or mutagen
- The title of the project
- Name of the Principal Investigator (PI) / line manager
- Location(s) of use e.g. laboratory and location within it
- Name of authorised users
- Dates that users started and finished work with the substance
- If Health Surveillance is required

Within the University, Occupational Health is responsible for coordinating health surveillance arrangements, maintaining relevant health records, and liaising with the Health, Safety, Resilience and Sustainability (HSR&S) Team in accordance with COSHH and University's procedures.

COSHH health surveillance and health records must be kept for at least 40 years from the date of the last entry.

8. Adverse Events

Where an incident occurs, that results in the potential or actual exposure of any individual to a CMR, even if there is no apparent health effect, it must be reported as an adverse event and the HS&R Team must be immediately informed. The HSR&S Team may be required to report this as a dangerous occurrence to the Health and Safety Executive.

A copy of the adverse event report will be forwarded to Occupational Health who will review the circumstances of the exposure and ensure an appropriate entry is made on the individual's health record. If deemed necessary, they will invite the individual to attend an appointment. Where no surveillance was instituted for the work, a health record should be set up for the person(s) involved in the exposure incident.

Work related ill-health: Cases of cancer attributed to occupational exposure to a known human carcinogen or mutagen must be reported as an adverse event.

Examples include:

- mesothelioma or lung cancer in a person who is occupationally exposed to asbestos fibres
- cancer of the nasal cavity or sinuses in a person who is occupationally exposed to wood dust.

The HSR&S Team may be required to report this to the Health and Safety Executive.

9. Available Training

- Introduction to Health, Safety and Sustainability in Laboratories (available on canvas)
- Laboratory Chemical Risk Assessment (available via HSR&S Team)
- Chemical First Aid (available via HSR&S Team)
- Spill Training (available via HSR&S Team)

See Staff H&S webpages or PG Hwb for details of the training and how to book a place on the courses.

10. Key Legislation

- Control of Substances Hazardous to Health Regulations (COSHH) 2002
- Classification Labelling and Packaging (CLP) regulation (EC No 1272/2008)
- Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009
- The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013

11. Appendices

Appendix 1

Schedule 1. Other substances and processes to which the definition of “carcinogen” relates:

- Aflatoxins.
- Arsenic.
- Auramine manufacture.
- Calcining, sintering or smelting of nickel copper matte or acid leaching or electrorefining of roasted matte.
- Coal soots, coal tar, pitch and coal tar fumes.
- Hardwood dusts.
- Isopropyl alcohol manufacture (strong acid process).
- Leather dust in boot and shoe manufacture, arising during preparation and finishing.
- Magenta manufacture.
- Mustard gas (ß, ß’ -dichlorodiethyl sulphide).
- Rubber manufacturing and processing giving rise to rubber process dust and rubber fume.
- Used engine oils.

The following polychlorodibenzodioxins:

- 2,3,7,8-TCDD
- 1,2,3,7,8-PeCDD
- 1,2,3,4,7,8-HxCDD
- 1,2,3,6,7,8-HxCDD
- 1,2,3,7,8,9-HxCDD
- 1,2,3,4,6,7,8-HpCDD OCDD,

The following polychlorodibenzofurans:

- 2,3,7,8-TCDF
- 2,3,4,7,8-PeCDF
- 1,2,3,7,8-PeCDF
- 1,2,3,4,7,8-HxCDF
- 1,2,3,7,8,9-HxCDF
- 1,2,3,6,7,8-HxCDF
- 2,3,4,6,7,8-HxCDF
- 1,2,3,4,6,7,8-HpCDF
- 1,2,3,4,7,8,9-HpCDF
- OCDF

Where T=tetra, Pe=penta, Hx=hexa, Hp=hepta and O=octa.

Appendix 2

Model procedure for weighing solid CMRs and other toxic compounds

Considerations before handling:

- Has the process in which the compound is to be used, been subject to a suitable and sufficient COSHH Risk assessment? If not, do not proceed – consult your supervisor.
- Could you substitute a less harmful compound? If yes do so.
- Is the compound available in pre-weighed iso-vac containers? If yes, order it in that form.
- Have you been trained in how to carry out the procedure safely and assessed as being competent? If not, do not proceed – consult your supervisor**.**
- Decontamination, spillage and disposal procedures must have been determined by the risk assessment. Ensure you are aware of these and have appropriate PPE and materials in hand *before* you start the procedure.

Choice of equipment:

- Precision balances are sensitive to air movement and therefore will not perform optimally if placed in a fume cupboard (FC). In schools/departments where there is a need to weigh carcinogens regularly, a balance should be sited adjacent to the FC, preferably just to one side of the sash opening.
- Very fine lyophilised powders may fly about within the FC if the fans are on. In this case it would be wise to consider a totally enclosed system such as a suitable glove box.
- Glass screw cap vials should be used in preference to plastic as the latter are more prone to static charge.

Procedure:

- Rehearse procedures by practicing with a non-hazardous compound of similar form and make sure you know what to do in the event of a spillage.
- Ensure you are wearing a lab coat [fastened] and PPE Category 3; and suitable chemical resistant gloves. Reduce static charge on gloves by rinsing hands in water and patting dry.
- Ensure the fume cupboard is operating efficiently and there is a good draw of air through the front aperture. Position the sash as low as possible.
- Place all items, including the substance, on a shallow tray within the fume cupboard, at least 150mm back from the opening.
- Switch on balance adjacent to the FC. When it has stabilised, zero the display and place empty, capped weighing vessel onto to pan, close doors and when reading has stabilised ‘tare’ to set display to zero.
- Return vessel to tray in FC, remove cap and dispense powder into vessel, recap and wipe exterior with damp tissue soaked in deactivation fluid.
- Re-weigh vial and repeat until approximately the desired weight of compound is achieved. Calculate amount of diluent required to give desired concentration and add this within the fume cupboard and recap the vial.
- Ensure that the spatula is placed in decontamination solution. Wipe down the tray and all surfaces with deactivation fluid.
- Comply with any local recording procedures that are in place.

Appendix 3 - Disposal of CMRs

Follow the standard university disposal route, via the Chemical Waste Store.

- Waste solid/liquid material must be treated as Hazardous Waste.
- Disposable or contaminated lab materials such as weighing boats, filter papers, blue roll, wipes, disposable protective wear etc. should be discarded into a red bag and clearly labelled as hazardous waste.
- Disposable sharps contaminated with CMRs, such as needles, pipettes, plastic tubes/vials and broken glass etc. must be disposed of directly into a sharps bin.

Where CMRs have been diluted, refer to Table 2, to correctly classify the chemical. Chemicals over the threshold limit must be classified as the applicable hazardous property for the disposal of waste.

Table 2: Waste classification technical guidance WM3

Waste classification technical guidance WM3			
Carcinogens, mutagens and reproductive toxins are considered hazardous waste under the Hazardous Waste (England and Wales) Regulations 2005 where the total concentration exceeds the threshold limits shown.	**Hazard statement**	**Hazardous property**	**Threshold limit** (*used for waste*)
Carcinogen Cat 1A & 1B	H 350/350i	HP7 Carcinogen	>0.1%
Carcinogen Cat 2	H 351	HP7 Carcinogen	>1%
Mutagen Cat 1A & 1B	H340	HP11 Mutagen	>0.1%
Mutagen Cat 2	H341	HP11 Mutagen	>1%
Reproductive toxin Cat 1A & 1B	H360	HP10 Toxic for reproduction	> 0.3%
Reproductive toxin Cat 2	H361	HP10 Toxic for reproduction	>3%
Additional category for effects on or via lactation	H362		N/A

For further information see WMGN20 - Chemical waste, classification and storage.

Further advice can also be sought from the Sustainability Team: sustainability@swansea.ac.uk