

General aspects

CARCINOGENS AT WORK: Know to prevent

What is cancer?

The World Health Organization (WHO) defines cancer as “a large group of diseases that can affect any part of the body [...]. One defining feature of cancer is the rapid creation of abnormal cells that grow beyond their usual boundaries, and which can then invade adjoining parts of the body and spread to other organs; the latter process is referred to as metastasis.”

According to the WHO, cancer is the second leading cause of death worldwide, after cardiovascular diseases, with almost 10 million deaths in 2020. In the European Union, 2.7 million people were diagnosed with cancer that year.

According to the Spanish Society of Medical Oncology, in Spain it is estimated that cancer mortality will increase from 113,000 cases in 2020 to more than 160,000 in 2040.

The probability of developing cancer begins to increase significantly from the age of 45-50, the age range in which people are in working age.

It is estimated that cancer is responsible for 52% of all work-related deaths in the European Union. As a result of exposure to carcinogens at work, each year some 120,000 people develop cancer and almost 80,000 lose their lives.

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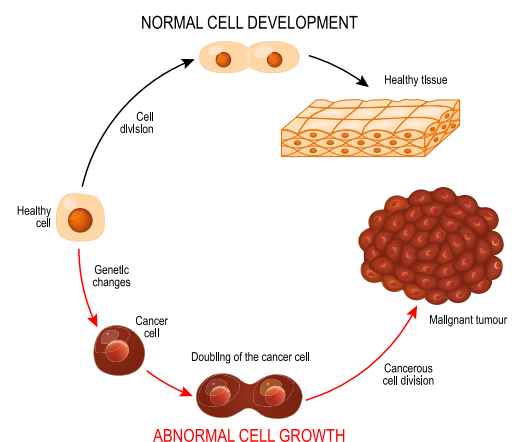
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What are carcinogens or mutagens?

A carcinogen or carcinogenic agent is a chemical, physical or biological agent, or even some other working condition, that has the potential to cause cancer or increase its incidence.

A mutagen or mutagenic agent is an agent that increases the frequency of mutations, that is, permanent changes in the amount or structure of the genetic material in a cell. When these mutations affect germ cells (eggs or sperm), they can be transmitted to the progeny.

As with carcinogenic agents, mutagenic agents may be physical in origin, such as exposure to ionising radiation or ultraviolet radiation; of chemical origin, due to exposure to substances such as benzene or formaldehyde; or of biological origin, caused by infection with certain biological agents (viruses, bacteria and parasites).



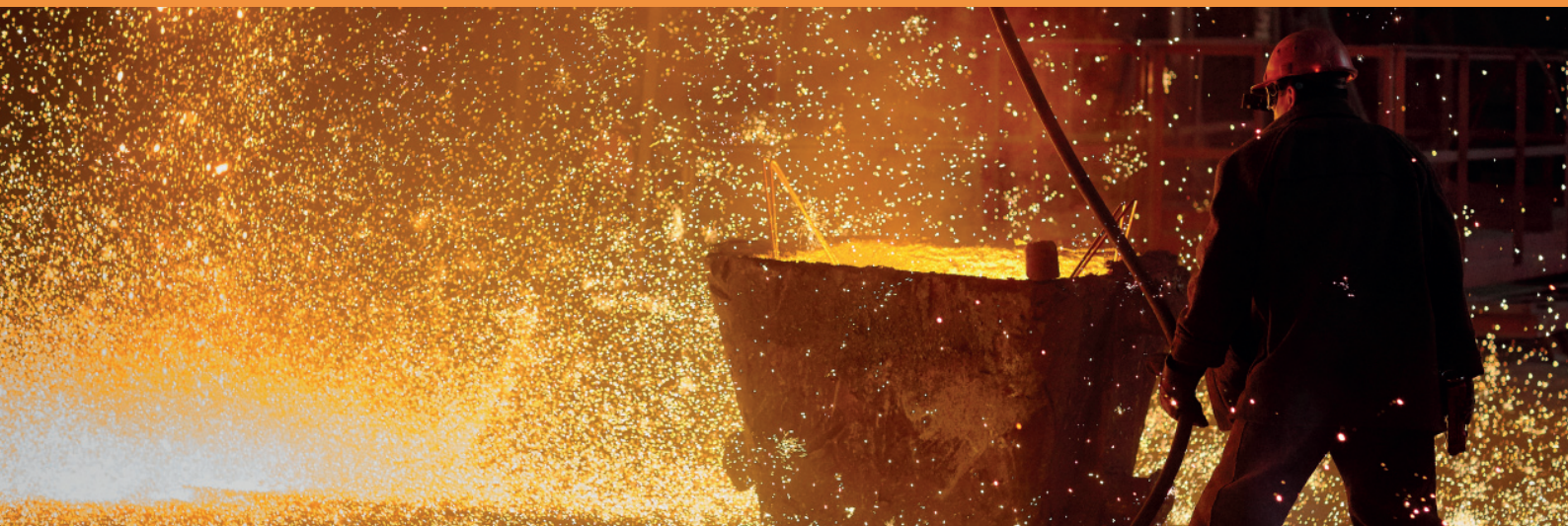
How to identify carcinogenic or mutagenic chemical agents

Classification

There is no single classification for carcinogens or mutagens; different organizations and bodies have their own classification, although most of these institutions use similar criteria based on data from epidemiological studies and animal experiments.

For example, the International Agency for Research on Cancer (IARC), as an autonomous agency of the WHO and an institution of internationally recognised prestige and leadership in cancer research, classifies agents





into four categories taking into account epidemiological studies of cancer in humans exposed to the agent, experimental studies in laboratory animals and studies on the mechanisms of carcinogenicity of the agents (table 1).

The IARC (iarc.who.int) is an autonomous agency of the World Health Organization of the United Nations. It seeks to promote international collaboration in cancer research. It runs studies that are widely recognised for their quality and independence.

At European Union level, Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) classifies carcinogens based on evidence from reliable studies in both humans and animals, plus additional data as appropriate. It thus identifies two distinct categories of hazard:

Category 1 comprises known or presumed human carcinogens. It is further subdivided into two categories:

- Category 1A, which includes substances known to have carcinogenic potential for humans, based on human evidence.
- Category 1B, which includes substances presumed to have carcinogenic potential for humans, based on animal evidence.

Category 2 includes substances suspected human carcinogens on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or 1B.

Regarding mutagens, the CLP Regulation also classifies them into two categories:

Category 1 substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans. It is further subdivided into two categories:

- Category 1A, which includes substances known to induce heritable mutations in the germ cells of humans.
- Category 1B, which includes substances to be regarded as if they induce heritable mutations in the germ cells of humans.

Table 1
Agents classified in the IARC
Monographs, Volumes 1 to 130

Group 1	Carcinogenic to humans	121 agents
Group 2A	Probably carcinogenic to humans	90 agents
Group 2B	Possibly carcinogenic to humans	322 agents
Group 3	Unclassifiable as to carcinogenicity in humans	498 agents



Category 2 covers substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans.

For the purposes of Royal Decree 665/1997 on the protection of workers from the risks related to exposure to carcinogens at work, the term carcinogenic or mutagenic agent is understood to mean:

- A substance or mixture which meets the criteria for classification as a category 1A or 1B germ cells carcinogen or mutagen set out in Annex I to CLP Regulation.
- A substance, mixture or process referred to in Annex I of Royal Decree 665/1997 as well as a substance or mixture release by one of those processes:
 1. Manufacture of auramine.
 2. Work involving exposure to polycyclic aromatic hydrocarbons in coal soot, coal tar or coal pitch.
 3. Work involving exposure to dusts, fumes or sprays produced during the roasting and electro-refining of 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 the moving parts within the engine.
 8. Work involving exposure to engine exhaust emissions.

Identification

The CLP Regulation establishes two tools for reporting the properties of substances and mixtures: the label and the safety data sheet, the latter implemented in Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Regulatory references

The prevention regulation covering carcinogens in Spain is *Royal Decree 665/1997 on the protection of workers from the risks related to exposure to carcinogens at work*. These regulations set out minimum requirements for activities in which workers are or may be exposed to carcinogens or mutagens as a result of their work.

For further information, see the [Technical Guide for the evaluation and prevention of risks related to carcinogenic or mutagenic agents present in the workplace.](#)



The label

The label is a valuable tool for companies and workers to obtain detailed information about substances and mixtures.

The CLP Regulation applies the hazard pictograms, signal words, hazard statements and precautionary statements of the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The GHS sets out harmonised criteria for classifying substances and mixtures by their physical, health and environmental hazards.

The following shall appear on the label of a substance or mixture meeting the criteria for classification as a carcinogen:

- The health hazard pictogram: a graphic composition conveying specific information about the hazard concerned.
- Signal words: a word indicating the relative level of severity of hazards to alert the reader to the existence of a potential hazard. It may be: **Danger**, in the case of a category 1A or 1B carcinogenic agent and **Warning**, in the case of a category 2 agent.
- Hazard statement: is a phrase which is assigned to a hazard class or category and describes the nature of the hazards of a hazardous substance or mixture. For carcinogens these phrases are:
 - H350 "May cause cancer".
 - H350i "May cause cancer by inhalation".
 - H351 "Suspected of causing cancer".
- Precautionary statements: phrases describing the recommended measure(s) to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use or disposal. In the case of carcinogenic substances, the following may be identified:
 - P201 "Obtain special instructions before use".
 - P202 "Do not handle the substance until all safety instructions have been read and understood".
 - P281 "Use personal protective equipment as required".







- P308 + P313 "If exposed or concerned: Get medical advice/attention".
- P405 "Store locked up".
- P501 "Dispose of contents/container to...".



Table 2
Elements that must appear on the label of a substance or mixture classified as carcinogenic



Classification	Category 1A or Category 1B	Category 2
Hazard pictograms		
Signal word	Danger	Warning
Hazard statement	H350: May cause cancer	H351: Suspected of causing cancer
Precautionary statement - Prevention	P201 P202 P281	P201 P202 P281
Precautionary statement - Response	P308 + P313	P308 + P313
Precautionary statement - Storage	P405	P405
Precautionary statement - Disposal	P501	P501

A substance or mixture meeting the criteria for classification as mutagenic must be labelled:

- The hazard pictogram and signal words are the same for carcinogens: **Danger** for category 1A or 1B mutagenic agent and **Warning**, for category 2 agents.
- For mutagenic agents, the hazard statements are H340 "May cause genetic defects" and H341 "Suspected of causing genetic defects".
- The same precautionary advice as for carcinogenic substances can also be found.



Table 3
Elements that must appear on the label of a substance or mixture classified as mutagenic

Classification	Category 1A or Category 1B	Category 2
Hazard pictograms		
Signal word	Danger	Warning
Hazard statement	H340: May cause genetic defects	H341: Suspected of causing genetic defects
Precautionary statement - Prevention	P201 P202 P281	P201 P202 P281
Precautionary statement - Response	P308 + P313	P308 + P313
Precautionary statement - Storage	P405	P405
Precautionary statement - Disposal	P501	P501



The Safety Data Sheet (SDS)

The SDS is the essential tool for giving users of chemical substances and mixtures information about their hazardous properties, risks of using them, as well as the measures to be taken to ensure that the risks arising from using them are controlled.

The information contained in the SDS is regulated in the REACH Regulation, specifically in its Annex II, which specifies the requirements to be met by the SDS.

Their contents must be known, inter alia, to the workers who use these substances or mixtures or those who may be exposed to them in the course of their work.

The safety data sheet consists of 16 sections and an annex (if exposure scenarios are listed).



Carcinogenic or mutagenic substances may be specifically identified in some of the sections of the SDS, such as hazard identification (section 2), composition/information on ingredients (section 3), exposure controls (section 8), toxicological information (section 11) and regulatory information (section 15).

Preventive measures at work involving exposure to carcinogenic or mutagenic agents

When carcinogens or mutagens are present at workplace, exposure prevention, reduction and control measures must be prioritised according to their effectiveness (see Figure 1). The first option must always be to avoid the use of carcinogens or mutagens at work, in particular by replacing it, by a substance, mixture or process which is not dangerous or is less dangerous; where substitution is not technically possible, the possibility of working in a closed system should be considered; where this is not possible, it is necessary level of exposure of workers is reduced to as low a level as is technically possible by applying all the necessary measures listed in article 5.5 of Royal Decree 665/1997. Finally, where the above measures are not sufficient, personal protective equipment (PPE) must be used.

Substitution

It must be the priority measure and is mandatory whenever technically possible. It consists of replacing by another agent or process which is not dangerous or is less dangerous. There are two ways of doing this:

- Total change of one agent for another without affecting the process.
- Elimination or modification of the process to avoid using the agent.

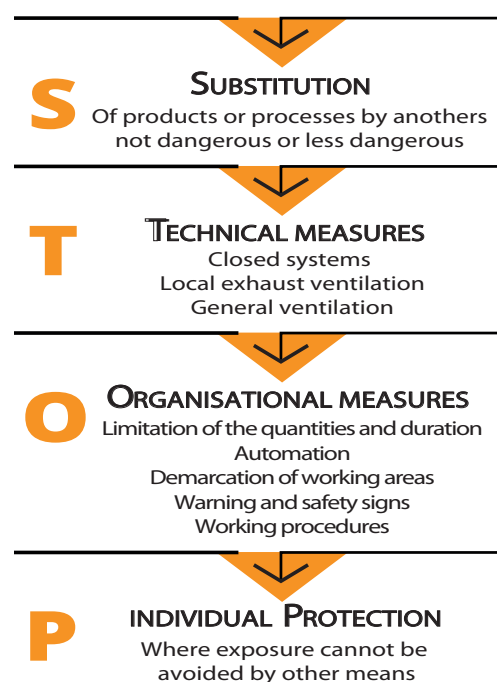


Figure 1. Hierarchy of exposure prevention and control measures.



This measure is the most difficult to implement, especially when a production process is already in place, and many variables must be taken into account, but it must be planned and it is necessary to keep up to date with technological advances in each sector.

The benefits are significant, both for the worker's health and for the company, which can reduce the costs of control measures, protective equipment and can make it easier to comply with legislation.

Technical and organizational measures

Where substitution of the carcinogen or mutagen is not technically possible, the company must ensure that the carcinogen or mutagen is produced and used in a closed system.

Where the application of a closed system is not technically possible, the company must ensure that the workers' level of exposure is reduced to as low a level as is technically possible using other technical measures, such as local exhaust ventilation system to remove the agent at source or, where this is not technically possible, general ventilation, and shall apply the hygiene measures laid down in legislation.

Personal protective equipment (PPE)

Where substitution is not possible and collective and organizational protective measures are not sufficient to avoid exposure, individual protection measures must be applied.

The company must provide workers with the necessary and appropriate individual protection measures, as determined by the risk assessment, as well as training and information for proper use and maintenance of it. PPE must be appropriate to the individual's anatomy and a suitable storage area must be provided.

Resources for substitution

More practical experiences of risk substitution or elimination can be found in the following links:

- Solutions, examples of substitution and good practice for carcinogens, from the Roadmap on carcinogens initiative.

<https://roadmaponcarcinogens.eu/solutions/good-practices/>

- SUBSPORT Substitution Support Portal.

<https://www.subsportplus.eu/>

- OECD Substitution Toolkit Portal.

<http://www.oecdsatoolbox.org/>

- INRS Substitution Fact Sheets.

<http://www.inrs.fr/actualites/nouvelles-far-fas.html>





Carcinogens at work: know to prevent

The INSST publishes a new technical collection called Carcinogens Agents at Work: Know to prevent, with the aim of disseminating information about the main carcinogenic agents present in the workplace to facilitate and promote risk prevention due to exposure to these agents in companies and organisations. The collection consists of a series of information leaflets about the main carcinogenic chemical agents to which workers may be exposed and posters or infographics with more summarised information and recommendations for workers. Each leaflet and poster deals with a specific carcinogen.

In this new collection, you can find the following information about each agent:

1. Information about the substance and where it can be found

It provides general information about the agent, its chemical composition, characteristics and properties. It analyses the places or products where the agent is commonly used or may be present not only in terms of occupational health, but also from a public health and product safety point of view.

2. Health effects

It summarises the main evidence about how the agent acts in our body, which organs or systems it may act as a carcinogen and other health effects it may cause. For example, Figure 2 shows the tumour sites of some of the chemical carcinogens or mutagens that can be found in the work environment.

3. Where the exposure can take place

Collect basic data about occupations or industrial sectors where exposure may occur. Data on average exposure levels are also given where studies are available.

New technical collection

The INSST has published a new technical collection entitled "Carcinogens at work: know to prevent", in order to provide information about the main carcinogenic chemical agents present in the workplace to facilitate and promote risk prevention due to exposure to these agents in companies and organisations.

The first agents to be published are:

- Respirable crystalline silica.
- Diesel engine exhaust emissions.
- Mineral oils used in engines.
- Formaldehyde.
- Hardwood dusts.
- Benzene.

New chemical carcinogenic agents are expected to be added to the collection.



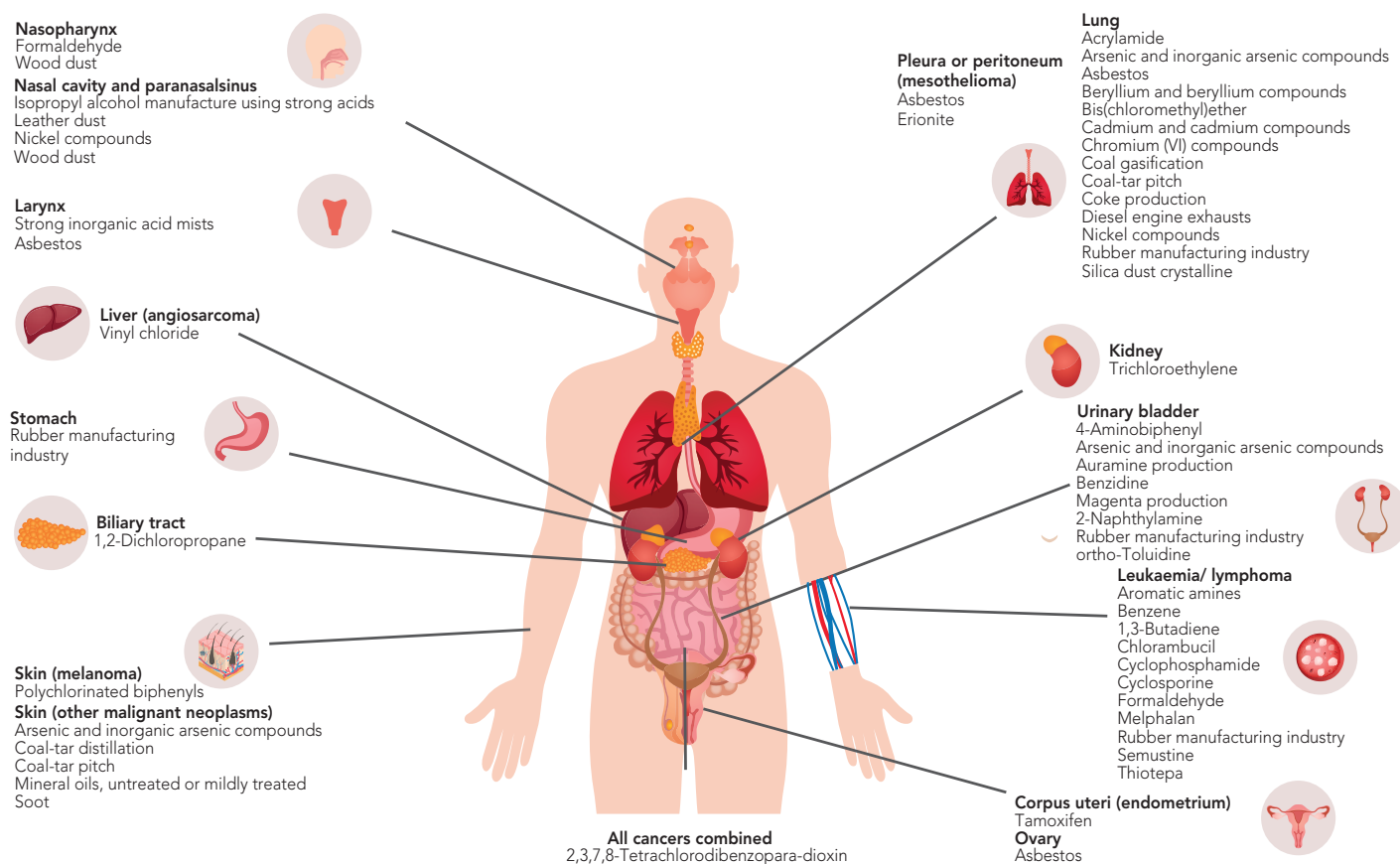


Figure 2. Association between chemical carcinogens or mutagens and tumour location

4. Exposure assessment

It sets out the most important information to be taken into account by the technical staff of the prevention services when performing the risk assessment for each agent, such as the different methodologies that may be applied, environmental and biological limit values, representativeness of the samples, etc.

5. Controlling exposure

It provides a reminder of the technical and organizational prevention measures to be applied when working with carcinogenic agents with recommendations for their application to the specific agent. It also outlines innovative good practices and provides sources for further information about substitution and other applicable prevention measures.

6. Health surveillance

This section gives some indications on the occupational diseases that are related to the agent, the specific health surveillance protocols that can be applied, if any, and other recommendations on health surveillance.

7. Other preventive measures

Remember the other preventive measures that are mandatory whenever working with carcinogenic agents, referring to the applicable legislation. For some agents, particularly important preventive measures have been highlighted, such as personal hygiene and cleaning in the case of used mineral engine oils, or training in the case of diesel engine exhaust emissions.

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