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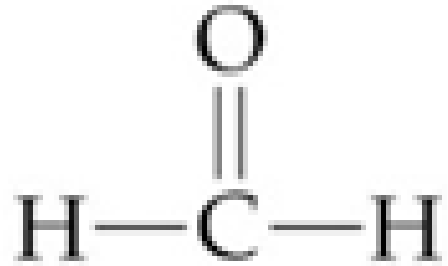
Formaldehyde as Occupational Carcinogen in Healthcare Workers in Spain

Prof Dr Begoña Martínez-Jarreta

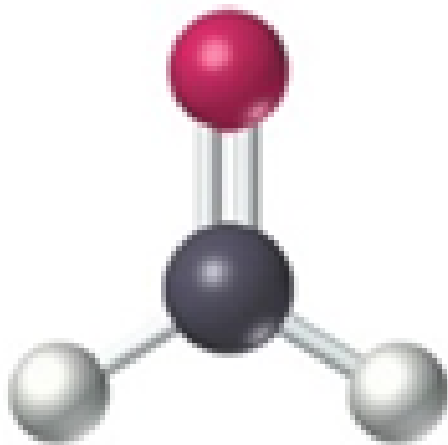
University of Zaragoza & Health Scientific Research Institute
of Aragón (IIS-Aragón), Zaragoza (Spain)



Formaldehyde (FA)



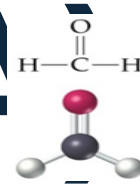
A volatile, colorless, flammable, acrid smelling and highly reactive **aldehyde**



The term “formaldehyde” describes various mixtures of formaldehyde, water, and alcohol

EC / List no.: 200-001-8
CAS no.: 50-00-0,
Mol. formula: CH₂O

Formaldehyde (FA)

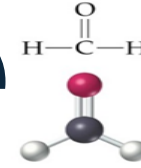


Formalin

- ❖ A saturated solution of formaldehyde dissolved in water, typically with another agent, most commonly methanol, added to stabilize the solution
- ❖ This is typically 37% formaldehyde by weight (40% by volume) and 6-13% methanol by volume in water
- ❖ The formaldehyde component provides the disinfectant effects of formalin

Formaldehyde

Ubiquitous



INDOOR SOURCES

BUILDING MATERIALS such as furniture, particle board, certain insulation materials, paints, varnishes and textiles

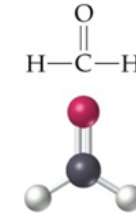
HOUSEHOLD PRODUCTS such as glues, paints, caulks, pesticides, cosmetics, and detergents

Emitted naturally during combustion phenomena (fires, cigarette smoking) and anthropogenic activities (cooking food, using a



Formaldehyde

Ubiquitous



As a natural product
in most living systems and in the
environment

It occurs naturally in fruits and some
foods, and it is formed endogenously in
mammals, including humans, as a
consequence of oxidative metabolism

A NATURALLY OCCURRING SUBSTANCE

Formaldehyde occurs
throughout nature. In fact,
all natural items contain
formaldehyde.



Humans
produce about
24 g per day^[1]



Apples
6 mg/kg^[2]



Coffee
3.95 mg/kg^[2]



Maple Tree
2.39 - 8.92/kg^[3]

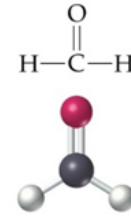


Fish
11 mg/kg^[2]

<https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono100F-29.pdf>
IARC, Working Group on the Evaluation of Carcinogenic Risks to Humans
Chemical Agents and Related Occupations. Formaldehyde, 2-butoxyethanol and
1-tertbutoxypropan-2-ol. *IARC Monogr. Eval. Carcinog. Risks Hum.* **2006**, 88, 1-
478.

<https://www.formacare.eu/about-formaldehyde/factsheets/>

Formaldehyde



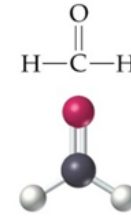
Ubiquitous

OUTDOOR SOURCES

Direct emissions from combustion processes occurring in motor vehicles, power plants, incinerators, refineries



Formaldehyde



Industries and

Workplaces

More than 1 million European
Workers Exposed

One of the most important basic organic compounds in the chemical industry and its annual world production is approximately 21 million tonnes



Textil
Industry

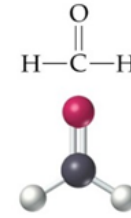


Wood
Industry



Paper Industry

Formaldehyde



Hospital Settings & Other related

EMBALMERS,
MORTUARY WORKERS



**HEALTH
WORKERS**

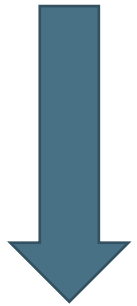
MEDICAL STUDENTS IN TRAINING



Commonly used as a **FIXATIVE** and **PRESERVATIVE** of anatomical specimens, used in medical laboratories and mortuaries, also as **DISINFECTANT**

Carcinogen Risks

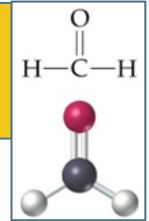
**HUMAN CARCINOGEN(1)
MUTAGEN (2)**



**Nasopharyngeal
cancers**

- Leukemia
- Positive association with sino-nasal cancer
- Other cancers

Formaldehyde

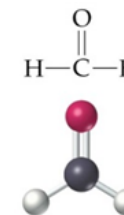


In June 2004, the International Agency for Research on Cancer (IARC) **changed the classification** of formaldehyde from the category of substances that are “probably carcinogenic to humans” (Group 2A) to “carcinogenic to humans” (Group 1) for nasopharyngeal cancers by inhalation, on the basis of epidemiological studies in the workplace

Following an ECHA opinion in November 2012 and ANSES's 2011 proposal to revise its classification, **formaldehyde was classified as a Category 1B carcinogen and Category 2 mutagen** at European level by Commission Regulation (EU) No 605/2014 of 5 June 2014

<https://www.anses.fr/en/content/assessment-health-risks-associated-presence-formaldehyde>

CMR Formaldehyde



(CAS No 50-00-0)



Acute Tox. 3. H301: Toxic if swallowed

Acute Tox. 3. H311: Toxic in contact with skin

Skin Corr. 1B. H314: Causes severe skin burns and eye damage

Skin Sens. 1. H317: May cause allergic skin reaction

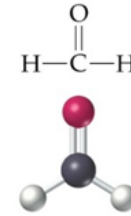
Acute Tox. 3. H331: Toxic if inhaled

Muta. 2. H341: Suspected of causing genetic defects

Carc. 1B. H350: It may cause cancer

EU: In 2015
~~BANNED~~
No SUBSTITUTION

Formaldehyde



Hospital Settings: Where

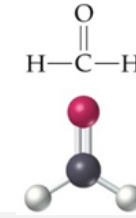
PATHOLOGY LABORATORIES

Formaldehyde exposure IS NOT ONLY in Pathology Labs

FA is present at all points where biological samples are obtained: CONSULTATIONS, SURGICAL AREAS, DELIVERY ROOMS, ENDOSCOPIES, etc., given the need to begin tissue fixation as soon as possible, since from an organisational point of view it is often complicated to send fresh samples immediately to the Pathology Department

Formaldehyde

Hospital Settings:



RADIO ZARAGOZA

CORONAVIRUS COVID-19

Invisibles y esenciales: las limpiadoras de hospital

390 trabajadores, casi todos mujeres, limpian y desinfectan el hospital de referencia en Aragón, el Miguel Servet de Zaragoza. Hemos acudido a su primer turno de la mañana. Nos cuentan cómo se limpia una UCI a tope y cómo, a pesar de las batas y equipos de protección, los pacientes adivinan cuándo les sonríen



CLEANING TASKS

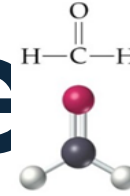
Cleaning Workers

UN-NOTICED ?

FA: broad spectrum disinfectant and active against bacteria, fungi, many viruses and spores



Formaldehyde



-ABSORPTION: At room temperature is **gaseous** and, consequently, mostly absorbed by **inhalation** and deposited in the upper respiratory tract

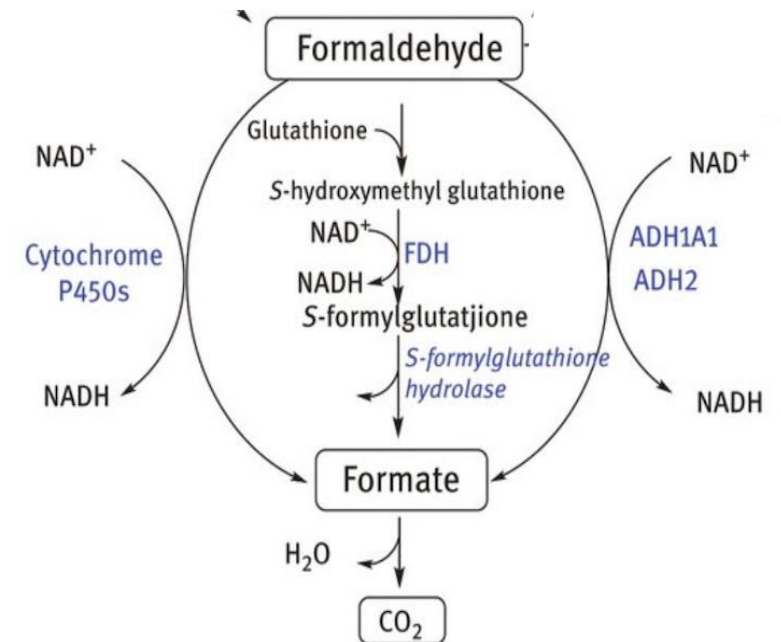
In addition, as an **aqueous solution** of formalin, **skin exposure** is also possible.

By digestive via has been considered ...

-DISTRIBUTION: almost to all tissues of the organism

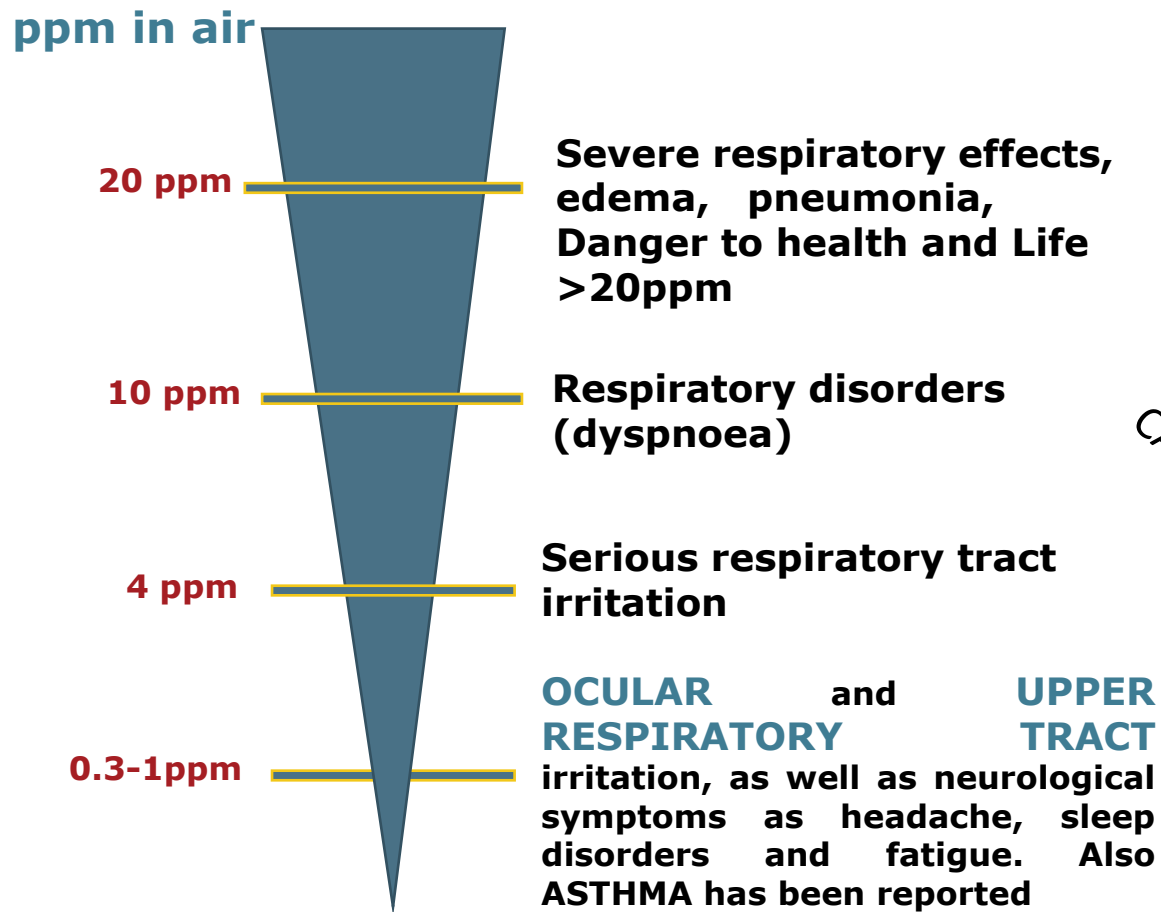
-METABOLISM: by oxidation to **formate** (water soluble) or to **carbon dioxide** (CO₂)

-ELIMINATION: formate eliminated via **urine**, carbon dioxide eliminated via **exhaled air**

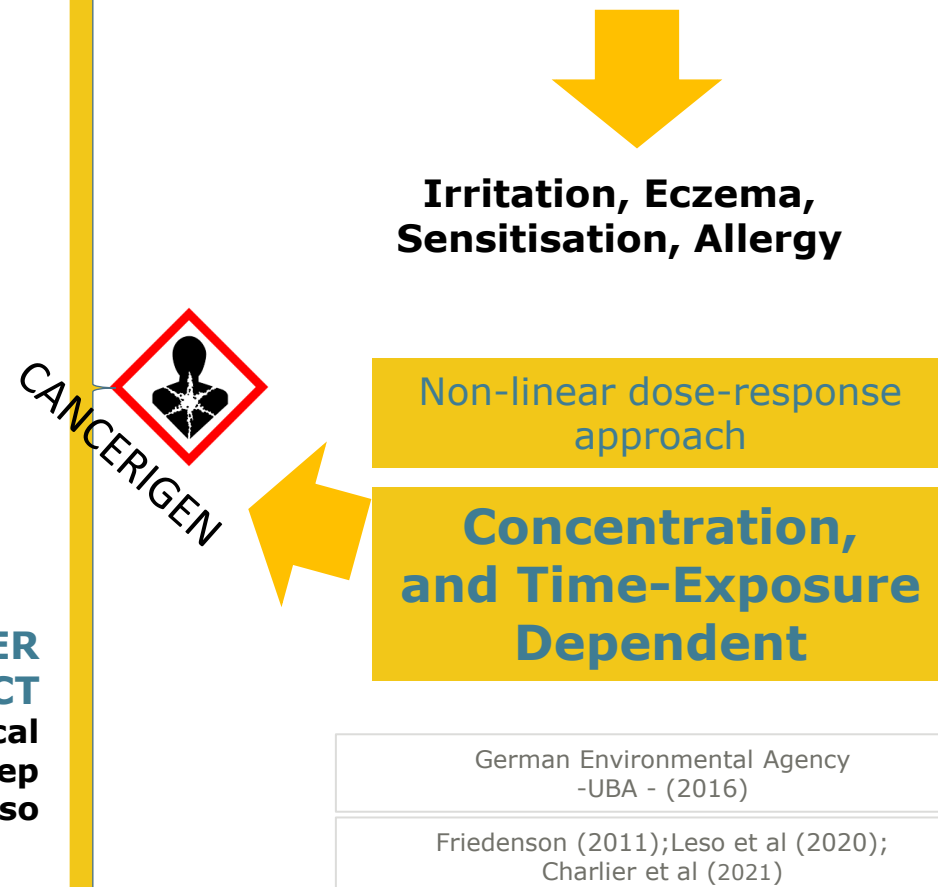


Occupational Exposure to Formaldehyde

Inhalation Effects in Humans



Skin Exposure Effects (dermal contact to FA liquid form)



Occupational Exposure to Chemical Agents

The combination of environmental and biological monitoring becomes an invaluable tool to preserve worker's safety and effectively assess chemical risk in hospital settings

Motta et al (2021)

Occupational Exposure to Formaldehyde

By combined approach involving both

ENVIRONMENTAL MONITORING (EM)

The Commission adopted a Binding Occupational Exposure Limit (**OEL**) for **Formaldehyde (inhalation)** of 0.3ppm (as 8hrs TWA) and 0.6ppm as Short Term Exposure Limit (STEL) (15 min)

and

BIOLOGICAL MONITORING (BM)

- **Biological exposure indicators (BEIs)**
- **Biological response (or effect) indicators (BRIs)**
- **Biological susceptibility indicators (BSIs)**

Several BIs have been investigated for the BM of healthcare workers exposed to FA: Complete blood counts, evaluation of sister chromatid exchange, comet-assay on blood and buccal swab. While the possibility that inhaled FA may be present in biological fluids in significant concentrations needs to be further investigated, quantification of urinary FA at the end of the work shift is so far the most used test

**Substitution
0 Exposure**



Council Directive 89/391 EEC

LEGAL FRAME



Formaldehyde

(CAS No 50-00-0)





(90/394/EEC) (97/42/EC) (1999/38/EC) (2004/37/EC) (2014/27/EU)

COUNCIL DIRECTIVE of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Art 16 (1) of Directive 89/391/EEC) (scope of application: C1 and C2)
-Annex I: List substances, preparation and processes
-Annex II: Health monitoring of workers

COUNCIL DIRECTIVE of 27 June 1997 **amending** for the first time Directive 90/394/EEC
-carcinogen definition
-Annex III: Bencene

COUNCIL DIRECTIVE of 29 April 1999 **amending** for the second time Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work and **extending it to mutagens (scope extensión to M1 and M2)**
-Annex I: Includes work involving exposure to hardwood dust-Annex II: Including threshold limit value for hardwood dust and vinyl chloride monomer

COUNCIL DIRECTIVE 2004/37/EC of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)

Carcinogens and Mutagens Directive

COUNCIL DIRECTIVE of 26 February 2014 **amending** Council Directives 92/58/EEC, 92/85/EEC, 94/33/EC, 98/24/EC and **Directive 2004/37/EC** of the European Parliament and of the Council, in order to align them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
(REACH and CLP)

Transposition

Royal Decree
665/1997

Royal Decree
1124/2000

Royal Decree
394/2003

Royal Decree
665/1997

Royal Decree
598/2015





(2017/2398/EU)

COUNCIL DIRECTIVE of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

13 AGENTS

(2019/130/CE)

COUNCIL DIRECTIVE of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

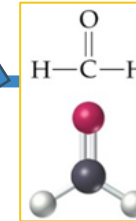
7 AGENTS

(2019/983/EU)

COUNCIL DIRECTIVE of 5 June 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

4 AGENTS

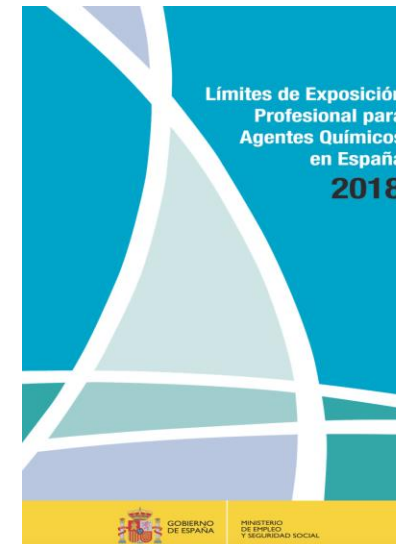


Formaldehyde

Transposition

Royal Decree 1154/2020,

Royal Decree 427/2021



<https://www.insst.es>



ANNEX

In point A of Annex III to Directive 2004/37/EC, the following rows are added:

Name of agent	EC No ⁽¹⁾	CAS No ⁽²⁾	Limit values						Notation	Transitional measures
			8 hours ⁽³⁾			Short-term ⁽⁴⁾				
			mg/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	f/ml ⁽⁷⁾	mg/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	f/ml ⁽⁷⁾		
'Cadmium and its inorganic compounds	—	—	0,001 ⁽¹¹⁾	—	—	—	—	—		Limit value 0,004 mg/m ³ ⁽¹²⁾ until 11 July 2027
Beryllium and inorganic beryllium compounds	—	—	0,0002 ⁽¹¹⁾	—	—	—	—	—	dermal and respiratory sensitisation ⁽¹³⁾	Limit value 0,0006 mg/m ³ until 11 July 2026
Arsenic acid and its salts, as well as inorganic arsenic compounds	—	—	0,01 ⁽¹¹⁾	—	—	—	—	—	—	For the copper smelting sector, the limit value shall apply from 11 July 2023
Formaldehyde	200-001-8	50-00-0	0,37	0,3	—	0,74	0,6	—	dermal sensitisation ⁽¹⁴⁾	Limit value of 0,62 mg/m ³ or 0,5 ppm ⁽³⁾ for the health care, funeral and embalming sectors until 11 July 2024
4,4'-Methylene-bis (2-chloroaniline)	202-918-9	101-14-4	0,01	—	—	—	—	—	skin ⁽¹⁰⁾	

⁽¹¹⁾ Inhalable fraction.
⁽¹²⁾ Inhalable fraction. Respirable fraction in those Member States that implement, on the date of the entry into force of this Directive, a biomonitoring system with a biological limit value not exceeding 0,002 mg Cd/g creatinine in urine.
⁽¹³⁾ The substance can cause sensitisation of the skin and of the respiratory tract.
⁽¹⁴⁾ The substance can cause sensitisation of the skin'.

20.6.2019

EN

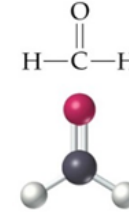
Official Journal of the European Union

L 164/29





Formaldehyde



LIMIT VALUES FOR OCCUPATIONAL EXPOSURE TO CHEMICAL AGENTS

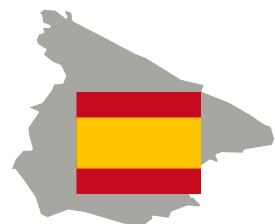
N° CE	N° CAS	AGENTE QUÍMICO (año de incorporación o de actualización)	VALORES LÍMITE				NOTAS	INDICACIONES DE PELIGRO (H)
			VLA-ED® ppm mg/m³		VLA-EC® ppm mg/m³			
200-001-8	50-00-0	Formaldehído (2018)	0,3	0,37	0,6	0,74	C1B, Sen, s	350-341-301-311-331-314-317



<https://www.insst.es>

[https://www.insst.es/resultados-busqueda-textual?
q=Formaldehido#gsc.tab=0&gsc.q=limites%20de%
20exposicion%20ocupacional%20agentes%20quimicos%20202](https://www.insst.es/resultados-busqueda-textual?q=Formaldehido#gsc.tab=0&gsc.q=limites%20de%20exposicion%20ocupacional%20agentes%20quimicos%20202)

LIMIT VALUES FOR OCCUPATIONAL EXPOSURE TO CHEMICAL AGENTS



Reviewed and published Every year from 1999-2021

Actualization of data, definitions and recommendations are included, technical notes and guidance

<https://www.insst.es>



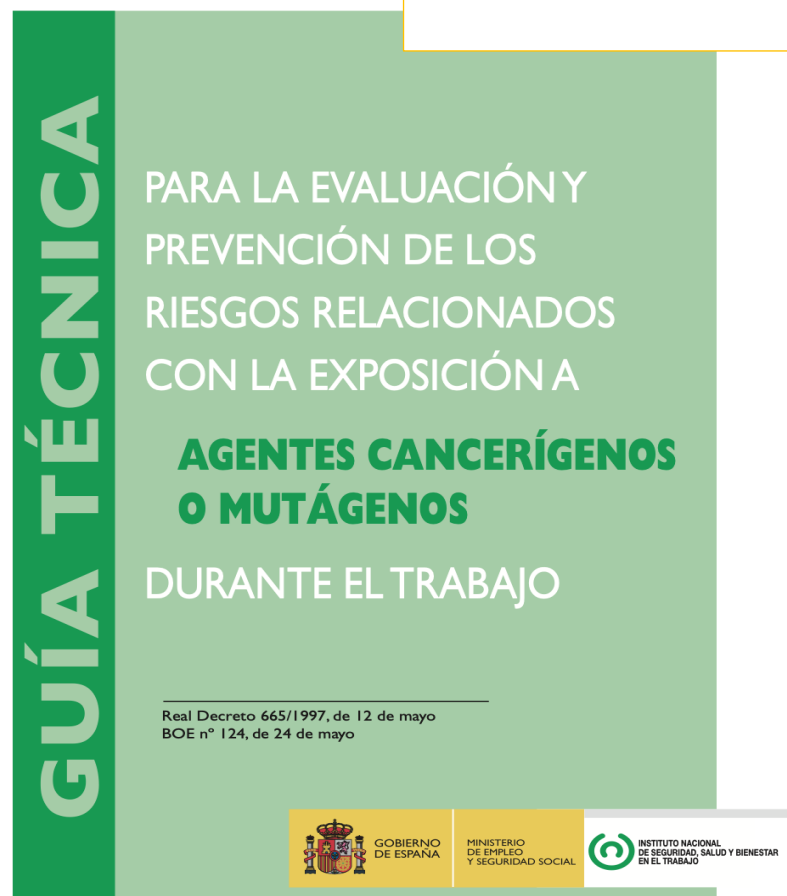


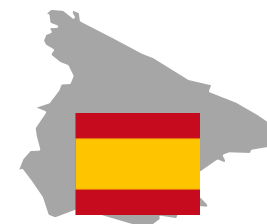
GOOD PRACTICES

NATIONAL INSTITUTE OF SECURITY AND HEALTH AT WORK (INNST)

Collaboration with Universities, Scientific Centres and Scientific Societies (Oncology and Occupational Health). Guidelines, Documentation, Technical Notes, etc.

<https://www.insst.es>





Acceder



INICIO

LA SEAP ▼

CONGRESOS Y REUNIONES ▼

FORMACIÓN ▼

CALIDAD ▼

PUBLICACIONES ▼

PACIENTES ▼

BECAS Y EMPLEO ▼

Publicaciones / Libros Blancos de la SEAP /

**Spanish
National
Society of
Pathology**

Libro Blanco
de la
Anatomía Patológica en España

From 2011 and 2015

**Guidance
Recommendations
Protocols**

Analysis of
Potential FA substitutive
compounds

<https://www.seap.es/libros-blancos>

0 Formaldehyde Approach



GOOD PRACTICES

Local Approaches at Hospitals in Spain

(i.e.: Salamanca, Vigo,
Zaragoza)

<https://www.insst.es>

Multidisciplinary and Integrative
involving:

- General Management
- Medical management
- Nursing management
- Supplies and Supervision of Material Purchasing
- OHS delegates
- Operating theatres
- Pathological Department
- Occupational health and safety Service
- +Waste management

0 Formaldehyde Approach



GOOD PRACTICES

Local Approaches at Hospitals in Spain

(i.e.: Salamanca, Vigo,
Zaragoza)

<https://www.insst.es>

Focused on the Handling of Pathology Samples

- Provide adequate technical means to the different units and workers involved in processes that can imply possible handling or exposure to FA
- Ventilation, sealing of containers, personal protective equipment, and substitution of other substances for formaldehyde where appropriate
- Delimit risk areas and restriction the access to them
- Ensure that all containers, packaging and installations containing carcinogens or mutagens are clearly and legibly labelled.
- Install warning devices
- Have means for the safe storage, handling and transport of carcinogens or mutagens, as well as for the collection, storage and disposal of waste



Formaldehyde Challenge

-It should **not focus exclusively on handling pathology specimens** and should be extended to all workers potentially exposed to FA (e.g. cleaning workers)

-**Awareness & Understanding**
(hospital management staff-society-politicians)

-**Training and awareness:** to all types of workers involved: medical staff, nurses, technicians, cleaning staff (including management staff)

Specialists and doctors are not fully aware and not adequately trained on the occupational risks related to cancer

INTEGRATIVE APPROACHES

+Financial support
0 inequalities

- 
- Undergraduated
 - Post-graduated
 - Specialist Training
 - CME

Gehanno et al, 2014
Abecia et al, 2019

Formaldehyde Challenge



LATVIJAS ARODSLIMĪBU
ĀRSTU BIEDRĪBA
Association of Latvian
Occupational Physicians



Department of Occupational
and Environmental Medicine
RĪGA STRADIŅŠ UNIVERSITY



TEACHING OCCUPATIONAL CANCERS: EXPOSURE PREVENTION AND RETURN TO WORK

Programme of the XIX EASOM Summer School

29-31 August 2019, Riga (Latvia)

Venue

Riga Stradins University, Senate hall, block K, 2 floor

Address: Dzirciema street 16, Riga, Latvia, LV-1007, phone of organizers

- Undergraduated
- Post-graduated
- Specialist Training
- CME

<https://www.easom.eu>

Improving Education and Training to Reduce the Burden of Occupational Cancer.
Int. J. Environ. Res. Public Health 2020, 17(7), 2279; <https://doi.org/10.3390/ijerph17072279>

Occupational Risks in Hospitals

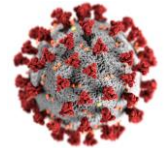
A Great Concern



HEALTH WORKERS



Biological



Psychological



Ergonomic



Chemical

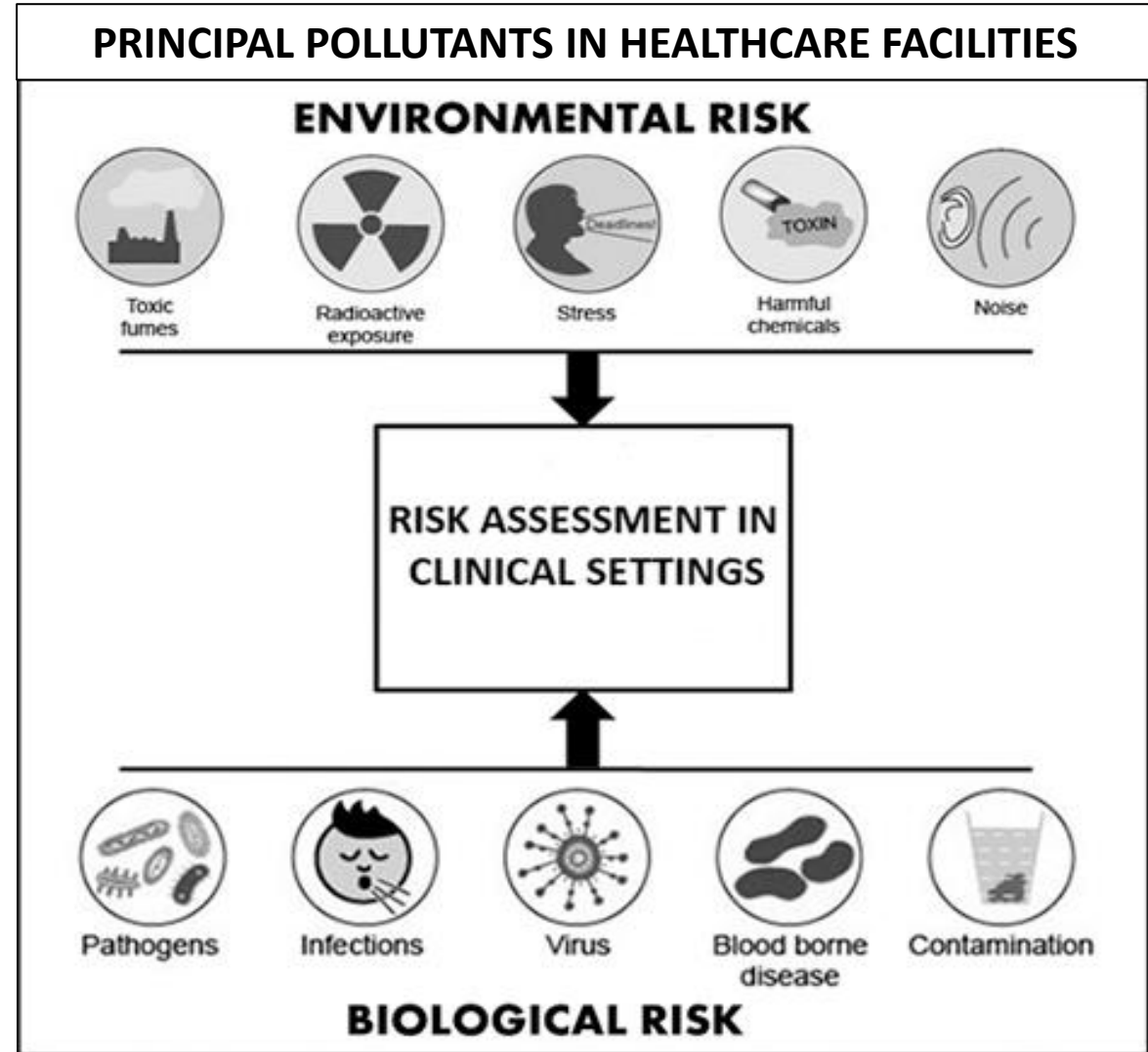
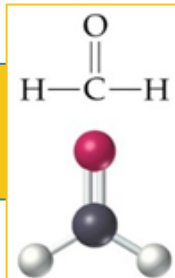
Chemical Risks

"In hospitals and other healthcare facilities, the attention is usually focused on preventing the biological risk to avoid nosocomial diseases and accidental infections

However, healthcare workers are frequently exposed to several types of harmful compounds and, among them, **chemical risk is often underestimated**"

(Charlier et al, 2021)

Formaldehyde





FUTURE



A PRIORITY



**CARE to those
who cares us**

**First Things
First**



HVALA
THANK YOU

