Pathology & EU Affairs:
The Formalin Ban Case

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Formaldehyde & Furniture
Commission Resolution (EU) No. 605/2014 of 5 June 2014 changes formaldehyde classification as both carcinogen and mutagen.

Formaldehyde is now considered:
  • **category 1B carcinogen**
    (it may cause cancer),
  instead of its previous category 2
  (suspected of causing cancer)
  • **category 2 mutagen**
    (suspected of causing genetic defects)
The resolution makes no allusion to the use (and much less the prohibition) of formaldehyde in the healthcare sector.

So, where is the much talked-about formalin ban coming from?
Formaldehyde classification changes
in Resolution (EU) No. 605/2014

Trade unions and occupational safety departments
promote a formalin ban
with workers’ protection in mind

Their potential to implement an across-the-board
formalin ban in the healthcare sector
ranges from nil to overwhelming according to country
(banning law enacted in France!)

Different perceptions of the problem
among pathologists from the various countries
(north-south divide?), but with great unity of action
Reactions of the pathology community?
Joint Statement of the

European Society of Pathology & UEMS Section of Pathology

FORMALIN BANNING IN EUROPE IN 2016

ESP Molecular Pathology Pre-analytical Tissue Condition WG* and
UEMS Section of Pathology

Executive summary

With the reclassification of formalin in terms of carcinogenicity from category 2/3 to category 1B/2 the EU intends to ban the use of formalin in 2016. In the considerations leading to these decisions and in the underpinning data the medical use of formalin is almost completely ignored.

In close interaction with the National Societies of Pathology of the European countries, the European Society of Pathology (ESP) and the UEMS Section of Pathology have deemed it necessary to take position in this issue which can be summarized as follows:
Conclusions:

• The use of formalin and its banning cannot be considered in the European health system without generating major harm to the quality of diagnosis for patients. This will especially compromise the new type of molecular diagnosis that is mostly based on IHC and is strictly related to the new biological type of therapies.

• Discussion on this problem is extremely urgent because of the short time before specific rules are applied in Europe, which brings about different approaches in the different European countries, generating confusion in the health institutions.
Conclusions:

• At the same time the risk of exposure under current working conditions should be carefully taken into consideration: any technical improvement to reduce it to safe borders should be adopted.

• It is necessary to consider special exemptions for formalin use in the European health systems, demanding at the same time that health control authorities check transport, personnel exposure and discharge.
The European Medical Organisations representing the Medical Profession at EU level welcome the European Commission efforts to improve and strengthen high standards of worker protection against the risk to health and safety at work.

We understand that the European Commission will present in early 2018 a third amendment of the Carcinogens and Mutagens Directive (2004/37/EC) which may comprise a modification of the classification of formaldehyde.
Following the Joint Statement of the European Society of Pathology and UEMS Section of Pathology dated November 2016 (see annex 1), the European Medical Organisations would like to strongly request that the European Commission refrain from any classification of formalin that could restrict its use in Pathology Services and threaten the future health of EU patients.

We would like to kindly recall that currently, formalin is the only agent available for the preservation of human tissues for the diagnosis of disease and its ban would threaten the delivery of proper healthcare to all patients.

We would be very happy to set a date to meet with you in order to further explain our position, at your best convenience.

Sincerely Yours,

Joao de Deus - President of Association of European Hospital Physicians- AEMH
Jose Santos- President of European Council of Medical Orders - CEOM
Jacques de Haller - President of Standing Committee of European Doctors - CPME
Sascha Reiff - President of European Junior Doctors - EJD
Stefan Ulrich Hardt - President of European Medical Students Association - EMSA
Enrico Reginato - President of European Federation of Salaried Doctors - FEMS
Aldo Lupo - President of European Union of General Practitioners - UEMO
Romuald Krajewski - UEMS President of European Union of Medical Specialists - UEMS
European Parliament
What can we do?

Jaime Medrano
International Department
Organisation of Medical Colleges (OMC)
Madrid, Spain
European Parliament

Employment and Social Affairs
(EMPL) Committee
One of the many draft amendments proposed
Formalin is routinely used in healthcare facilities for standardized fixation of patients’ tissue samples such as biopsies. The pathologist’s diagnosis of a variety of diseases, including cancer, is based on the recognition of characteristic microscopic findings in formalin-fixed tissue. Moreover, criteria for the evaluation of diagnostic, prognostic and predictive biomarkers have been progressively developed along many years also in reference to formalin-fixed tissue.
Validation of other fixatives putatively able to replace the crucial role of formalin in patients’ care will require a number of years. Consequently, the healthcare sector must be explicitly exempt from a formalin ban that would result in multiple diagnostic errors and serious harm to countless European patients. Healthcare facilities must implement appropriate measures for keeping formalin exposure of their personnel within safe limits.
Rapporteur: Laura Agea, Italy

Draft report
Laura Agea
(PE623.825v02-00)

Protection of workers from the risks related to exposure to carcinogens or mutagens at work

Proposal for a directive
The final result of the vote on Laura Agea Report was:

43 IN FAVOUR
0 AGAINST
2 ABSTENTIONS

Vote on formaldehyde compromise amendments:

Compromise amendment 8, APROVED
Compromise amendment 9, APROVED
Compromise amendment 10, APROVED
Formaldehyde fixatives are routinely used in European healthcare centres for the standardised fixation of tissue samples given their convenience in handling, high degree of accuracy and extreme adaptability, which have not been reached by any other group of fixatives so far. As a result, a pathologist’s diagnosis of a variety of diseases, including cancer, is based on the recognition of microscopic traces in tissue fixed in a formaldehyde fixative.
The concentrations of formaldehyde used in healthcare are minimal in comparison with those used in industry and, while healthcare centres in the Union should take all appropriate measures to keep formaldehyde exposure among their staff within safe limits, the healthcare sector should have no difficulty to respect the limit value set in the present Directive.
EMPL Committee

European Parliament Plenary Session (Strasbourg)

EU Council

European Parliament

European Commission
TEXTS ADOPTED
Provisional edition

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Protection of workers from the risks related to exposure to carcinogens or mutagens at work *** I

Formaldehyde fixatives are routinely used in the healthcare sector across the Union because of their convenience of handling, high degree of accuracy and extreme adaptability.
In some Member States, it is foreseeable that the healthcare sector will have difficulties in complying, in the short term, with a limit value of 0.37 mg/m$^3$ or 3.3 ppm. It is therefore appropriate to introduce for that sector a transitional period of five years, during which the limit value of 0.62 mg/m$^3$ or 0.5 ppm should apply.
EU

- **No** to the formalin **ban**
- **Yes** to formalin **safe limits**
10% NEUTRAL BUFFERED FORMALIN
General fixative, formaldehyde (4%)

FORMALINA 10% NEUTRA TAMPONATA
Fissattivo generale, formaldeide (4%)

FORMALINE NEUTRE TAMPONNÉE 10%
Fixateur universel, formaldéhyde (4%)

20000 ML    CAS: NA

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Danger

Pericolo

H302: May cause an allergic skin reaction. H341: Suspected of causing genetic defects: refer to labeling for more information. If you are pregnant or breastfeeding, consult a healthcare professional. P264: Wash thoroughly with soap and water. P301+330+331: IF SWALLOWED: Call a POISON CENTER or get medical advice/attention.

NO GHS SYMBOL

CE IVD
Pathologists are the doctors who diagnose cancer... and many other diseases
European pathologists

ESP

UEMS