Report of the President

Modification of the Agenda order in honour to the efforts and success of Aurelio & Others in the process of

FORMALIN BAN in EU HEALTH SYSTEM

Formalin Ban (Ariza)

Dear Mr Crozier,
thank you for your draft joint letter to support the COM proposal on Formaldehyde in CMD batch 3 and apologies for the delay in our response.
Esther Lynch (ETUC Confederal secretary) is ready to co-sign the letter provided that some small modifications are taken into account (see track changes in the attached document).
She indeed prefers to use the wording "binding minimum requirement" instead of "harmonized regulation".
This is also the wording that we used in our first joint letter in July 2006 to make clear that some Member States have the right to implement stricter national OEL for formaldehyde compared to the OEL adopted in the CMD (this is currently the situation in The NL and IE for example).

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Members EMPL (Committee on Employment and Social Affairs)

http://www.europarl.europa.eu/committees/en/empl/members.html

Laura Agea
Commission Speaker and Draft Reporter

Amendment

(17a) As formalin (37% formaldehyde aqueous solution) is the agent universally used for the preservation of human tissue, a process which plays a role in the diagnosis of disease, it is important that the Commission puts in place safeguards for the continued use of formalin in order to secure Europe's public health.

Amendment

(17) Formaldehyde meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is a local acting genotoxic carcinogen. On the basis of the available information, including scientific and technical data, ***the concentrations of formaldehyde used in healthcare are minimal in comparison with those used in industry, and it is possible*** to set a long and short term limit value for that carcinogen. Formaldehyde is also a contact allergen to the skin (skin sensitiser). It is therefore appropriate to establish a limit value for formaldehyde and to assign a notation for skin sensitisation. In addition, upon request of the Commission, ECHA is also gathering existing information to assess the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses[48].

Amendment

(17a) Formaldehyde is routinely used in European healthcare centres for the standardised fixation of tissue samples; a pathologist's diagnosis of a variety of diseases, including cancer, is based on the recognition of microscopic traces in tissue fixed in formaldehyde.

Amendment

(17c) Healthcare centres in the EU should take all appropriate measures to keep formaldehyde exposure among their staff within safe limits.

Amendment

(17b) Until such time as other fixatives are available in the EU that are able to perform the crucial role that formaldehyde plays in patient care, the healthcare sector should be exempt from any restrictions on formaldehyde use that could give rise to multiple errors in diagnosis, putting countless European patients at risk.

Amendment

(23) In implementing this Directive, Member States should avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings ***and***

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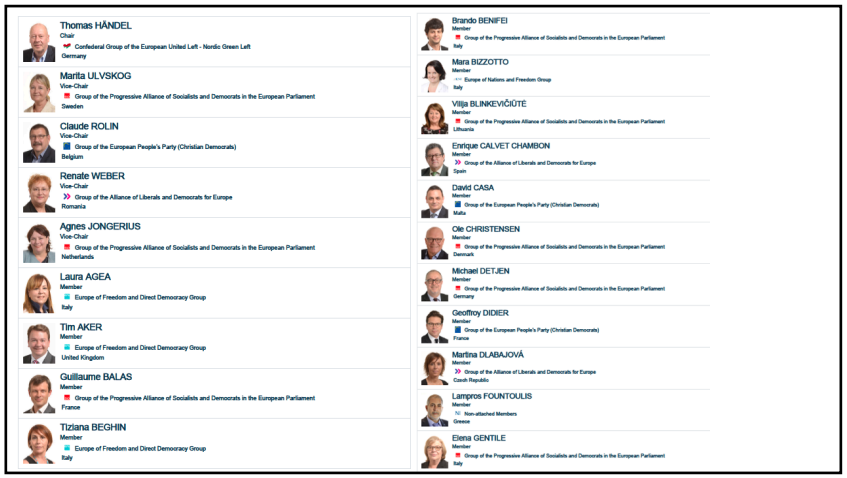
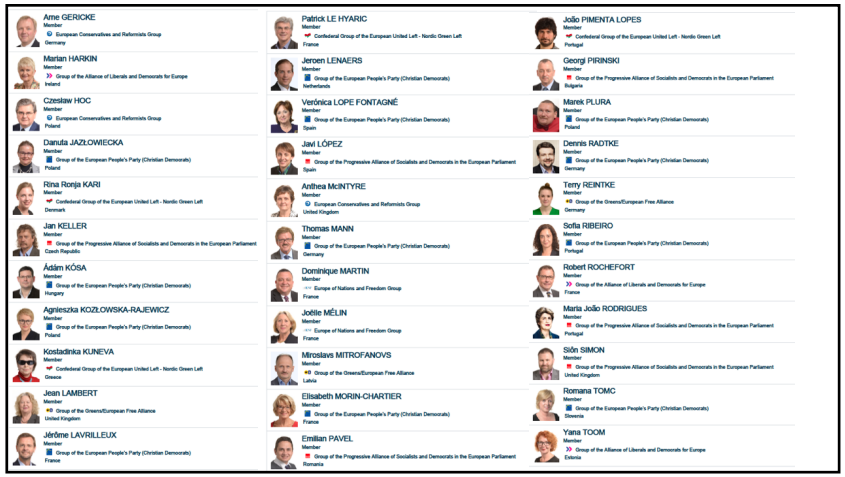
healthcare facilities. Member States are therefore invited to assess the impact of their transposition act on SMEs in order to make sure that SMEs are not disproportionately affected, with specific attention for micro-enterprises and for administrative burden, and to publish the results of such assessments.





Autumn Meeting of the
UEMS Section of Pathology
Padua, 1 December 2018

Update on the formalin situation

Aurelio Ariza & Bernard Maillet

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 health care facilities

↓

So, where is the much talked-about formalin ban coming from?

Formaldehyde classification changes in Resolution (EU) No. 605/2014

↓

Trade unions and labour safety departments promote a formalin ban with workers' protection in mind

↓

Their power to implement a formalin ban in the health care environment ranges from nil to overwhelming according to country

↓

Different perceptions of the problem among pathologists from the various countries (north-south divide?), but with great unity of action!

European Parliament
Committee on Employment and Social Affairs (EMPL Commission)

↓

Report voted at the EMPL Committee On 20 November 2018

↑

Rapporteur: Laura Agea (Italy, Five Stars)

[It had to be previously discussed at ENVI Committee Rapporteur: Joëlle Mélin (France, National Front)]

European Parliament
2014-2019

Committee on Employment and Social Affairs

2018/0081(COD)

19.11.2018

COMPROMISE AMENDMENTS
1 - 14

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
(COM(2018)0171 – C8-0130/2018 – 2018/0081(COD))

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

COMPROMISE AMENDMENT 9

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.

COMPROMISE AMENDMENT 9 (Cont'd)

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.

Amendment 9
Laura Agea
Compromise amendment replacing Amendments 69, 70, 71, 72

Proposal for a directive
Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(17a) Formaldehyde fixatives are routinely used in European healthcare centres for the standardised fixation of tissue sample given their convenience in handling, high degree of accuracy and extreme adaptability, which have not been reached by any other group of fixative 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.***

Amendment 8
Laura Agea
Compromise amendment replacing Amendments 14, 68

Proposal for a directive
Recital 17

Text proposed by the Commission	*Amendment*
(17) Formaldehyde meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is a local acting genotoxic carcinogen. ***It is possible,*** on the basis of the available information, including scientific and technical data, to set a long and short term limit value for that carcinogen. Formaldehyde is also a contact allergen to the skin (skin sensitiser). It is therefore appropriate to establish a limit value for formaldehyde and to assign a notation for skin sensitisation. In addition, upon request of the Commission, ECHA is also gathering existing information to assess the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses[45].	(17) Formaldehyde meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is a local acting genotoxic carcinogen. ***There is sufficient evidence in humans for the carcinogenicity of formaldehyde. Formaldehyde causes cancer of the nasopharynx and leukaemia.*** On the basis of the available information, including scientific and technical data, ***it is possible*** to set a long and short term limit value for that carcinogen. Formaldehyde is also a contact allergen to the skin (skin sensitiser). It is therefore appropriate to establish a limit value for formaldehyde and to assign a notation for skin sensitisation. In addition, upon request of the Commission, ECHA is also gathering existing information to assess the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses[45]. --- [1] 1, https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100F-29.pdf

Amendment 10
Laura Agea
Compromise amendment replacing Amendments 16, 36, 37, 38, 76, 77

Proposal for a directive
Recital 23

Text proposed by the Commission	*Amendment*
(23) In implementing this Directive Member States should ***avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development*** of small and medium-sized undertakings. Member States are therefore invited to assess the impact of their transposition act on SMEs in order to make sure that SMEs are not disproportionately affected, with specific attention for micro-enterprises and for administrative burden, and to publish the results of such assessments.	(23) In implementing this Directive Member States should take into account that ***SMEs, and microenterprises, which represent a large majority of enterprises in the Union, have limited financial, technical and human resources.*** Member States are therefore invited to assess the impact of their transposition act on SMEs in order to make sure that SMEs are not disproportionately affected, with specific attention for micro-enterprises and for administrative burden, and to publish the results of such assessments, ***while maintaining equal protection levels for all the workers, compliance for SMEs and microenterprises should facilitated; against this background, specific measures such as incentives and digital tools could help them to better comply with the obligations laid down in the Directive 2004/37/EC and move towards the elimination of carcinogenic or mutagenic risks; in this regard, social partners should exchange best practices.***

EMPL Committee
↓
European Parliament plenary session
(Strasbourg, December or January)
↓
EU Council
↓
European Parliament
↓
European Commission

European Society of Pathology

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:

European Society of Pathology

Formalin is an indispensable component of what in pathology is called 'pre-analytical' sample treatment.

In spite of intensive research, a suitable alternative for formalin has not been identified.

In view of the reclassification of formalin, the pathology research community will continue its search for alternatives for formalin.

Banning formalin is a simplistic approach. Working conditions in which the measured formalin levels are below those regarded as hazardous.

European Society of Pathology

At present there are no alternative fixatives validated to serve as formalin replacement

Formalin is used in hospital pathology labs with specific precautions that can be further improved

Formalin is a cheap procedure of fixation, any other solution will increase the costs

Formalin and the risk of cancer: highly controversial

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.**
- **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.**

Joint Statement EMOs – Use of Formaldehyde

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 formalin.

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