



The ban on formaldehyde in Europe!

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The problem



- New exposure limit values for 5 chemicals in the Carcinogens and Mutagens Directive
 - Cadmium and its inorganic compounds
 - Beryllium and its inorganic compounds
 - Arsenic acid and its salts, as well as inorganic inorganic compounds
 - **Formaldehyde**
 - 4,4'-Methylene-bis(2-chloroaniline) (MOCA)



The problem



- Formaldehyde 40% in water is called 100% formalin
- Present in forest fires, automobile exhaust and tobacco smoke, becomes part of 'smog'
- Ubiquitous in living organisms, present at 0.1 millimolar of humans and primates
- Does not accumulate in the environment, broken down by sunlight or bacteria or metabolised in the body to formic acid



The problem



- Used in
 - Industry: textile, carpeting, manufacturing of automobiles (transmission, brakes, door panels, engine block etc.), insulation, paints, explosives
 - Poultry feed! Desinfectant and biocide
 - **Tissue fixative** and embalming agent
 - Excessive sweating treatment
 - Drug testing and photography



The problem



- Safety: not acutely toxic but chronic exposure by inhalation is! (common indoor air pollutant)
- > 0.1ppm irritating for eyes and mucous membranes, induces burning throat and can trigger asthma
- Probable human carcinogen (1995)
- IARC (2006): known human carcinogen associated with nasal sinus cancer and NPC
- Positive correlation with acute myeloid leukaemia



Formalin banning



- 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:



Formalin banning



- Formalin is an indispensable component of what in pathology is called 'pre-analytical' sample treatment. Any cell or tissue specimen taken out of a patient needs to be preserved in order to allow further processing. Tissue preservation is universally attained by infiltration of the specimen with formalin, which is one of the great examples of standardization in pathology



Formalin banning



- In spite of intensive research, a suitable alternative for formalin has not been identified. Without formalin fixation pathologists will no longer be able to diagnose disease. In the EU this would imply that each year for more than 50 million patients, half of which cancer patients for whom therapy choice depends on the diagnosis of the pathologist, diagnoses will no longer be made. Against this background the ESP and the UEMS Section of Pathology cannot accept the ban on the use of formalin.



Formalin banning



- In view of the reclassification of formalin, the pathology research community will continue its search for alternatives for formalin, with characteristics in the process of fixation equal to or even better without the health hazards ascribed to formalin



Formalin banning



- Banning formalin is a simplistic approach, given what has been outlined in points 1 and 2. It is not only the categorization of formalin that needs to be taken into consideration but, more importantly, the level of exposure at the working place. The workers should and are willing to accept the risk for the benefit of their patients, but at the same time have a legitimate request to healthcare administrators to provide the most safe conditions possible, including necessary investments. In pathology departments those workers regularly exposed to samples fixed in formalin will be offered working conditions in which the measured formalin levels are below those regarded as hazardous



The ban?



- REACH (Registration, Evaluation, Authorization, and restriction of Chemical substances) legislation claims a ban of formaldehyde in Europe
- This is 'fake' news! Formaldehyde is not listed in the Annex I of Regulation (EC) No 689/2008 (export and import of dangerous chemicals regulation), nor on a priority list for risk assessment



The ban?

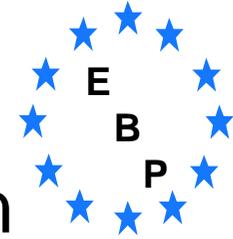


- Formaldehyde is banned from use in certain applications (preservatives for liquid-cooling and processing systems, slimicides, metalworking-fluid preservatives, and antifouling products) under the Biocidal Products Directive
- In poultry feed



European Commission,

Employment, Social Affairs & Inclusion



- Proposes to limit workers' exposure to five cancer causing chemicals
- Marianne Thyssen: this proposal would improve working conditions for $>1.10^6$ EU workers and prevent 22.000 cases of work-related illness



The Parliament Magazine

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The Commission recently answered two questions about use of formaldehyde in pathology. In both cases it said the Commission has no intention to ban it. The second question concludes that “In fact, the adoption of exposure limit values should be seen as providing a practical tool to assist employers to demonstrate that they comply with the general requirements of the directive which already apply in full to this carcinogenic substance.”



Conclusions



- No European ban of formaldehyde at present but need for directors of pathology labs to take necessary precautions to protect the technicians and people working in the labs
- Respect the 0,3ppm European guideline