



Council of the
European Union

Brussels, 27 April 2017
(OR. hr)

8600/17

Interinstitutional Files:
2016/0130 (COD)
2017/0004 (COD)

SOC 289
EMPL 215
SAN 164
IA 67
CODEC 668
INST 178
PARLNAT 125

COVER NOTE

From: The Croatian Parliament
date of receipt: 18 April 2017
To: President of the Council of the European Union

Subject: Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
[doc. 8962/16 SOC 255 EMPL 158 SAN 187 IA 23 CODEC 666 - COM(2016) 248 final]
Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.
[doc. 6004/17 SOC EMPL SAN IA CODEC 142 - COM(2017) 11 final]
- *Opinion on the application of the Principles of Subsidiarity and Proportionality*

Delegations will find attached the above mentioned opinion.



HRVATSKI SABOR
Odbor za zdravstvo i socijalnu politiku

Klasa: 022-03/17-03/39
Urbroj:6521-10-17-03

Zagreb, 7. travnja 2017.

EUROPSKA KOMISIJA

Mišljenje Odbora za zdravstvo i socijalnu politiku

o

Prijedlogu direktive Europskog parlamenta i Vijeća o izmjeni Direktive 2004/37/EZ Europskog parlamenta i Vijeća o zaštiti radnika od rizika zbog izloženosti karcinogenim ili mutagenim tvarima na radu COM (2016) 248

i

Prijedlogu direktive Europskog parlamenta i Vijeća o izmjeni Direktive 2004/37/EZ Europskog parlamenta i Vijeća o zaštiti radnika od rizika zbog izloženosti karcinogenim ili mutagenim tvarima na radu COM (2017) 11

Odbor za zdravstvo i socijalnu politiku Hrvatskoga sabora je sukladno Poslovniku Hrvatskoga sabora na 14. sjednici održanoj 6. travnja 2017. raspravljao o Stajalištu Republike Hrvatske o predmetnim prijedlozima direktiva.

U raspravi je istaknuto da formalin predstavlja jedini univerzalni fiksativ koji se u cijelom svijetu koristi u histopatološkim laboratorijima već više od jednog stoljeća. Na njegovoj uporabi bazirana je ogromna većina analiza koje služe u dijagnosticiranju i liječenju milijuna bolesnika, a među njima u cijeloj Europskoj uniji oko 50 milijuna oboljelih od različitih tumora. I najnoviji revolucionarni pomaci u terapiji – uvođenje tzv. „pametne terapije“ u ogromnoj mjeri bazirano je upravo na uzorcima koji su fiksirani u formalinu. U ovom trenutku ne postoji odgovarajuće zamjensko sredstvo, a čak i kada bi se pojavilo, standardizacija i sistematizacija dijagnostičkih te na njima baziranih terapijskih postupaka dugotrajan je, složen i skup proces s neizvjesnim ishodom, tako da se mora računati na najmanje deset godina prijelaznog perioda. Eventualno trenutno uklanjanje formalina iz patohistoloških laboratorija diljem Europske unije dovelo bi do potpunog sloma patohistološke dijagnostike i nesagledivo unazadilo zbrinjavanje najtežih bolesnika.

Slijedom provedene rasprave Odbor za zdravstvo i socijalnu politiku je radi upućivanja mišljenja Europskoj komisiji u okviru političkog dijaloga nacionalnih parlamenata s institucijama Europske unije donio sljedeće

ZAKLJUČKE

1. Pozdravljaju se prijedlozi Europske komisije radi poboljšanja zdravstvene zaštite radnika smanjenjem izloženosti radnika kancerogenim kemijskim tvarima te provođenje daljnjih procjena učinaka u cilju predlaganja graničnih vrijednosti za dodatne kancerogene tvari.
2. Poziva se Europska komisija na potrebu razmatranja iznimne dopuštenosti upotrebe formalina u europskim zdravstvenim sustavima pritom zahtijevajući pritom istovremenu zaštitu zdravlja, pri transportu ili odlaganju formalina sve dok se ne pronađe zamjensko odgovarajuće sredstvo.

PREDSJEDNICA ODBORA
ZA ZDRAVSTVO I SOCIJALNU POLITIKU

dr. sc. Ines Strenja-Linić, dr. med



CROATIAN PARLIAMENT
Health and Social Policy Committee

Zagreb, 7th April 2017

EUROPEAN COMMISSION

Opinion of the Health and Social Policy Committee

on

Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens or mutagens at work COM (2016) 248

and

Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens or mutagens at work COM (2017) 11

Health and Social Policy Committee, pursuant to the powers conferred by the Standing Orders of the Croatian Parliament, on 6th April 2017 held 14th session to discuss the Position of the Republic of Croatia on the concerned Proposals for a Directive.

The discussion emphasized that formalin represents the only universal fixative that has been used in Pathology and Histology Laboratories all over the world more than a century. Huge majority of analysis have been based on the use of formalin in order to diagnose the disease and treat more than 50 million cancer patients. Even the latest revolutionary steps in therapy – introducing the so called “smart therapy” have been enormously based on samples fixed in formalin. At present there are no alternative fixatives validated to serve as formalin replacement, and even if it were, the standardization and systematization of diagnostic and therapy based procedures may require many years of complex and expensive processes with uncertain outcome, taking into account at least ten years of transitional period. Possible immediate removal of formalin from Pathology and Histology Laboratories throughout

Europe can lead to a complete collapse of patho-histological diagnostics and may cause an unforeseeable downgrade in therapy of most difficult patients.

In line with the discussion held, the Health and Social Policy Committee by sending an opinion to the European Commission within the framework of political dialogue of national parliaments with the institutions of the European Union, has reached the following

CONCLUSIONS

1. We welcome the proposals of the European Commission on the protection of workers from the risk related to exposure to carcinogenic chemical substances and further impact assessment in order to propose safe borders in terms of carcinogenicity.
2. We call on the European Commission to consider the admissibility of the exceptional use of formalin in the European health care system demanding at the same time that health control authorities check transport, personnel exposure and discharge of formalin until a replacement agent is discovered.


**CHAIRPERSON OF THE
HEALTH AND SOCIAL POLICY COMMITTEE**

Ines Strenja-Linić, M.D., Ph.D.