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## **LEGAL REGULATION OF WORKERS' HEALTH AND SAFETY WORKING WITH BIOLOGICAL AGENTS IN THE EUROPEAN UNION**

This article is dedicated to legal regulation of workers' health and safety from influence of the biological agents. The EU directive on this area either provides a protection of workers' health and safety or clearly regulates employer's duties about workers' protection. The Directive 2000/54/EC determines four groups of biological agents according to the level of their infectious risk and makes the employer to avoid using of unhealthy biological agent if the production permits replacing it by another biological agent which is not dangerous or less dangerous for workers' health in these terms of use according to the modern awareness. According to the national laws and practice the Member States are obligated to conclude agreements about organization of appropriate medical examination for workers that need it according to the evaluation results.

**Key words:** biological agent, micro-organism, cell culture, groups of biological agents, health surveillance, information and consultation.

Today the European Union is one of the largest dynamic social phenomenon of modern world. In terms of market economy and Ukraine's desire to become full member of EU is spending radical reform of national labor legislation. Successful spending of reform is not possible without consideration of positive experience of regulation of labor relations on EU legislation.

For national legal practice especially important is researching those areas of legal regulation of labor relations that are better developed on EU and will be used either for mutual cooperation or for developing and perfection national labor legislation in accordance with requirements of EU. This is in particular legal regulation of workers' health and safety from exposure of biological agents.

The question of workers' health and safety on EU is explored on their scientific works such domestic scientists as U.V. Baranyk, S.V. Drigchana, L.P. Garaschenko, N.M. Khytoryan and also such foreign scientists as B. Bercasson, I. Boruta, P.A. Kalinichenko, S.U. Kashkin, F. Sutcliffe, S. Sciarra.

In the same time the question of workers' health and safety from biological agents on EU was the subject of special comprehensive study about domestic science of labor law.

The aim of this study is to identify key principles of legal regulation workers' health and safety from exposure of biological agents and making reasonable offers for improvement national labor legislation in the context Ukrainian European integration aspirations.

The need to improve working conditions is the collective concern, prompted by both humane and economic considerations. To create employment of better quality is one of the main objectives of the EU social policy. The safe and healthy working environment is the essential element of the quality of work.

The EU action in health and safety at work has its legal basis in Article 153 of the EU Treaty. The community action is not limited by legislation. The Commission has widened the scope of its activities, in favor of information, guidance and promotion of the healthy working environment by paying particular attention to small and medium-size enterprises.

The European Union has embarked with the series of Directives in the field of health and safety, all of which when agreed by the Council of Ministers and the Commission become binding in all member countries. They have proceeded on the basis of individual hazards, setting standards which are enforced by the appropriate national agencies. Recently they include Directives about the noise, visual display units, manual handling of loads, carcinogens and biological agents. The European Directives are accepted by consensus between representatives of the national governments and their experts and, once promulgated, give a time limit within which member nations must comply<sup>1</sup>.

<sup>1</sup> *Health and safety at work legislation.* <<http://www.agius.com/hew/resource/hswlaw.htm>>.

The main characteristic of the EU strategy about the safety and health at work is the directive framework and according it, the directives in the field covered by this Directive should be adopted.

Such framework directive is the Council Directive of 12 June 1989 about the introduction of measures to encourage the improvements in the workers' safety and health at work (89/391/EEC)<sup>1</sup>.

The object of this Directive is to introduce measures to encourage improvements in the workers' safety and health at work.

The Annex of the Directive lists some of the areas where individual directives were adopted.

One of such directives is the Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>2</sup>.

This Directive has as its aim the workers' protection against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to biological agents at work.

It lays down particular minimum provisions in this area.

For the purpose of this Directive:

– «biological agents» shall mean micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity;

– «micro-organism» shall mean a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material;

– «cell culture» shall mean the in-vitro growth of cells derived from multicellular organisms.

«Biological agents» shall be classified into four risk groups, according to their level of risk of infection:

– group 1 biological agent means one that is unlikely to cause human disease;

– group 2 biological agent means one that can cause human disease and might be a hazard for workers; it is unlikely to spread to the community; there is usually effective prophylaxis or treatment available;

– group 3 biological agent means one that can cause severe human disease and present the serious hazard for workers; it may present risk of spreading to the community, but there is usually effective prophylaxis or treatment available;

– group 4 biological agent means one that causes severe human disease and is the serious hazard for workers; it may present the high risk of spreading to the community; there is usually no effective prophylaxis or treatment available.

This Directive shall apply to activities in which workers are potentially exposed to biological agents as a result of their work.

In the case of any activity that involves the risk of exposure to biological agents, the nature, degree and duration of workers' exposure must be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken.

In the case of activities involving exposure to several groups of biological agents, the risk shall be assessed on the basis of the danger presented by all hazardous biological agents.

The assessment must be renewed regularly when any change occurs in the conditions which may affect workers' exposure to biological agents.

The employer must supply the competent authorities, at their request, with the information used for making the assessment.

This assessment shall be conducted on the basis of all available information including:

– classification of biological agents which are or may be a hazard to human health, as referred to in Article 18;

– recommendations from the competent authority which indicate that the biological agent should be controlled in order to protect workers' health when workers are exposed or may be exposed to such a biological agent as a result of their work;

– information on diseases which may be contracted as a result of the work of the workers;

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<sup>1</sup> Directive 89/391/EEC of 12 June 1989 about the introduction of measures to encourage the improvements in the workers' safety and health at work. <<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML>>.

<sup>2</sup> Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC). *Official Journal L* 262, 17/10/2000, P. 0021-0045.

- potential allergenic or toxigenic effects as a result of the work of the workers;
- knowledge about the disease from which a worker is suffering and which has direct connection with his work.

Directive 2000/54/EC charges some duties on the employer in the field of safety and health at work.

The employer shall avoid the use of the harmful biological agent if the nature of the activity so permits, by replacing it with the biological agent which, under its conditions of use, is not dangerous or is less dangerous for workers' health.

Directive 2000/54/EC provides some measures that are directed to reduction of risks.

Where the results of the assessment reveal the risk to workers' health or safety, workers' exposure must be prevented.

Where this is no technically practice of having regard to the activity and the risk assessment, the risk of exposure must be reduced to as low level as necessary in order to protect the workers' health and safety concerned, in particular by the following measures which are to be applied in the light of the results of the assessment:

- keeping as low as possible the number of workers exposed or likely to be exposed;
- design of work processes and engineering control measures so as to avoid or minimise the release of biological agents into the place of work;
- collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;
- hygiene measures compatible with the aim of the prevention or reduction of the accidental transfer or release of a biological agent from the workplace;
- use of the biohazard sign depicted in Annex II and other relevant warning signs;
- drawing up plans to deal with accidents involving biological agents;
- testing, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of biological agents used at work;
- means for safe collection, storage and disposal of waste by workers including the use of secure and identifiable containers, after suitable treatment where appropriate;
- arrangements for the safe handling and transport of biological agents within the workplace.

Employers shall inform forthwith the competent authority of any accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection and/or illness.

Directive 2000/54/EC provides some measures that are directed on hygiene and individual protection.

Employers shall be obliged, in the case of all activities that contain the risk to the workers' health or safety because of working with biological agents, to take appropriate measures to ensure that:

- workers do not eat or drink in working areas where there is the risk of contamination by biological agents;
- workers are provided with appropriate protective clothing or other appropriate special clothing;
- workers are provided with appropriate and adequate washing and toilet facilities, which may include eye washes and/or skin antiseptics;
- any necessary protective equipment is:
  - 1) properly stored in well-defined place,
  - 2) checked and cleaned if possible before, and in any case, after use,
  - 3) repaired, where defective or is replaced before further use;
- procedures are specified for taking, handling and processing samples of human or animal origin.

Working clothes and protective equipment, including protective clothing, which may be contaminated by biological agents, must be removed on leaving the working area and, before taking the measures referred to in the second subparagraph, kept separately from other clothing.

The employer must ensure that such clothing and protective equipment is decontaminated and cleaned or, if necessary, destroyed.

Workers may not be charged for the cost of the measures referred to in paragraphs 1 and 2 of Article 8.

Appropriate measures shall be taken by the employer to ensure that workers and/or any workers' representatives in the undertaking or establishment receive sufficient and appropriate training, on the basis of all available information, in particular in the form of information and instructions, concerning:

- potential risks to health;

- precautions to be taken to prevent exposure;
- hygiene requirements;
- wearing and use of protective equipment and clothing;
- steps to be taken by workers in the case of incidents and to prevent incidents.

The training shall be:

- given at the beginning of work involving contact with biological agents,
- adapted to take account of new or changed risks, and
- repeated periodically if necessary.

Directive provides that employers shall provide written instructions at the workplace and, if appropriate, display notices which shall, as a minimum, include the procedure to be followed in the case of:

- a serious accident or incident involving the handling of a biological agent;
- handling a group 4 biological agent.

Workers shall immediately report any accident or incident involving the handling of a biological agent to the person in charge, or to the person responsible for safety and health at work.

Employers shall inform forthwith the workers and/or any workers' representatives of any accident or incident which may have resulted in the release of the biological agent and which could cause severe human infection and/or illness.

In addition, employers shall inform the workers and/or any workers' representatives in the undertaking or establishment as quickly as possible when serious accident or incident occurs, of the causes thereof and of the measures taken or to be taken to rectify the situation.

Workers and/or any workers' representatives in the undertaking or establishment shall have access to anonymous collective information.

Article 11 of Directive obliges the employers shall keep a list of workers exposed to group 3 and/or group 4 biological agents, indicating the type of work done and, whenever possible, the biological agent to which they have been exposed, as well as records of exposures, accidents and incidents, as appropriate.

The list shall be kept for at least 10 years following the end of exposure, in accordance with national laws and/or practice.

In the case of those exposures which may result in infections:

- with biological agents known to be capable to establish persistent or latent infections;
- that, in the light of present knowledge, are undiagnosable until illness develops many years later;
- that have particularly long incubation periods before illness develops;
- that result in illnesses which recrudescence at times over a long period despite treatment, or
- that may have serious long-term sequelae,

The list shall be kept for an appropriately longer time up to 40 years following the last known exposure.

Article 13 of Directive obliges employers will notify to the competent authority.

Prior notification shall be made to the competent authority of the use for the first time of:

- group 2 biological agents;
- group 3 biological agents;
- group 4 biological agents.

The notification shall be made at least 30 days before the commencement of the work.

In accordance with Directive 2000/54/EC the Member States shall establish, in accordance with national laws and practice, arrangements for carrying out relevant workers' health surveillance with the purpose of the assessment referred in Article 3, reveal the risk to health or safety.

Those arrangements shall be such to make possible of implement individual and occupational hygiene measures.

When necessary, effective vaccines should be made available for those workers who are not already immune to the biological agent to which they are exposed or are likely to be exposed.

When employers make vaccines available, they should take account of the recommended code of practice set out in Annex VII to Directive.

If a worker is found to be suffering from an infection and/or illness which is suspected to be the result of exposure, the doctor or authority responsible for workers' health surveillance shall offer such surveillance to other workers who have been similarly exposed.

In that event, the reassessment of the risk of exposure shall be carried out in accordance with Article 3.

In cases where health surveillance is carried out, an individual medical record shall be kept for at least 10 years following the end of exposure, in accordance with national laws and practice.

In the special cases referred to in Article 11(2) second subparagraph, an individual medical record shall be kept for an appropriately longer time up to 40 years following the last known exposure.

The doctor or authority responsible for health surveillance shall propose any protective or preventive measures to be taken in respect of any individual worker.

Information and advice must be given to workers regarding any health surveillance which they may undergo following the end of exposure.

In accordance with national laws and/or practice:

- workers shall have access to the results of the health surveillance which concern them, and
- the workers concerned or the employer may request a review of the results of the health surveillance.

All cases of diseases or death identified in accordance with national laws and/or practice as resulting from occupational exposure to biological agents shall be notified to the competent authority.

In the summary we should say that the Directive 2000/54/EEC consolidates the main principles of prevention exposure of dangerous biological agents, adapting the work to the individual person, adapting to technical progress replacing the dangerous biological agents by the non- or the less dangerous, developing a coherent overall prevention policy, prioritizing collective protective measures (over individual protective measures), giving appropriate instructions to the workers. These principles are the basis for the EU legislation of health and safety at work with biological agents.

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### References:

1. *Health and safety at work legislation*. <<http://www.agius.com/hew/resource/hswlaw.htm>> [in English].
2. *Directive 89/391/EEC* of 12 June 1989 about the introduction of measures to encourage the improvements in the workers' safety and health at work. <<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML>> [in English].
3. *Directive 2000/54/EC* of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC). *Official Journal L* 262, 17/10/2000, P. 0021-0045. [in English].