

Considerations on Directive 98/8 of the European Commission – the biocide directive

Rafał Patryn¹, Mirosław J. Jarosz^{2,3}, Anna Włoszczak-Szubzda^{2,3}, Jarosław Sak¹, Jakub Pawlikowski¹

¹ Department of Ethics and Human Philosophy, Medical University of Lublin, Lublin, Poland

² Nursing Department, University of Economics and Innovation, Lublin, Poland

³ Department of Informatics and Health Statistics, Institute of Rural Health, Lublin, Poland

Abstract

Nowadays, versatile human activity requires the development of technologies in the chemical and biological industries that ultimately enable an increase in human activity, and help create the living conditions in the domain of human civilization. Increasing this activity very frequently requires the implementation of new technologies concerning the active elimination of numerous threats and obstacles which are found in the human and natural environment. The concept of so-called biocidal products has been introduced into the European legislation as long as ten years ago, defining them as various types of 'chemical substances or microorganisms which can deter, render harmless, or exert a controlling effect on any harmful organism, by chemical or biological means'. They can be added to other materials (typically liquids) to protect them against biological infestation and growth. Biocidal products - due to their specificity, toxicity and composition - create a serious risk for human and animal life and health, as well as for the natural environment, it is therefore fully justified to have legal regulations concerning such biocides. Because biocidal products are intended to kill living organisms, and as such, many biocidal products pose a significant risk to human health and welfare, and have significant adverse effects on the natural environment. Great care is required when handling biocides and appropriate protective clothing and equipment should be used. Currently, Directive 98/8/EC is a comprehensive set of legal regulations concerning biocidal products, their specificity, principles relating to their placing on the market, and guidelines for their control. It is worth emphasizing that Directive 98/8/EC implements the clampdown on poisoning cases with biocides, the duty of which was passed to the so-called Centres of Consultation and Toxicological Information. These centres provide round-the-clock (24-hour) medical consultation and assistance in cases of poisonings with these products. The presented study constitutes an in-depth presentation and analysis of the European law concerning biocides and the current regulations applying to them.

Key words

biocides, law, European Union

INTRODUCTION AND OBJECTIVES

Biocides are products which contain dangerous components that exhibit toxic or harmful properties to humans, animals, and the natural environment, which therefore should be subject to special control policy. The genesis of Directive 98/8/EU of the European Commission of 16 February 1998 concerning the principles for placing a biocide on the market is a result of the constant and fast growth of civilisation in contemporary Europe. This concerns all human activity concentrated on the development of technology of the chemical and biological industries which ultimately enable and assist man to develop contemporary civilization. Increasing, this activity requires the implementation of new technologies concerning the active influence or elimination of numerous threats and obstacles which may be potentially found in the human habitat. It is obvious that this development, along with all essential aspects of the dynamic process, gives rise to new challenges and needs which of necessity must be addressed. This study presents and analyzes the European law concerning biocides and the current regulations applying to them.

THE CURRENT STATE OF KNOWLEDGE

Biocides, regarding their specificity, toxicity and composition, pose a real danger for the existence and health of humans and animals, as well as for the natural environment. Therefore, the so-called 'biocides' notion was introduced into the European legislation, defining these substances as various chemicals necessary for combating harmful organisms which destroy natural or manufactured products, while protecting the health of humans and animals. Until the establishment of Directive 98/8/EC of the European Commission of 16 February 1998, concerning principles of launching a biocide, the so-called '8th Amendment' to Council Directive No. 76/769/EU of 27 July 1976 was in force, specifying regulations and provisions of the Member States concerned with restricting the commercial allowance and use of some hazardous substances and chemical preparations (at that time, only Directive 91/414/EEC on commercial allowance of phytopharmaceutical products was in effect)¹. A lack of determined and standardized common regulations concerning biocides, known previously as 'pesticides not intended for use in agriculture', was evident.

Address for correspondence: Rafał Patryn Department of Ethics and Human Philosophy, Medical University, Lublin, Szkolna 18, 20-124 Lublin, Poland.
E-mail: rpatryn@wp.pl

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1. Law Journal of the European Union, No. L 230 of 19.08.1991, page 1. Directive with the latest changes introduced by Directive 96/68/EU (JL EU No. L 277 of 30.10.1996, page 25. JL EU No. C 398 of 30.12.1989, page 19).

The European Commission stated that the provisions of Member States in this matter differed substantially, and that these differences could obstruct the trade of biocides and trade in products subjected to their action. Therefore, the drawing up general regulations concerning the placing of biocides on the market was proposed. It was an essential condition that the regulations should be compulsory and of the utmost importance for the safety of humans, animals, and the natural environment.

The next reason behind the legal regulation of the principles pertaining to biocides was the resolution of the European Community of 1 February 1993 on designing the policy and implementation of due action in the domain of environment protection and its sustainable development². The resolution pertained to the general attitude and strategy of conduct in the situation of risk posed by the pesticides used in agriculture.

The next reason behind the legal regulation pertaining to biocides was the Resolution of the European Community of 1 February 1993, a Community programme of policy and action in relation to the environment and sustainable development (Decision No. 2179/98/EC: 'Towards Sustainability').

Furthermore, it was determined that consistent regulations should specify the release of biocides only for their destined use, and in accordance with procedures determined in the planned directive – that the forthcoming directive constituted the source of law concerning biocides, procedures for their placing on the market, allowance and registration. This means, firstly, that biocides, with proper use for the right objectives, should to a sufficient degree be effective and not trigger any possible unacceptable action, such as undesirable resistance and/or tolerance and, in the case of vertebrates, unnecessary suffering. Secondly, if - in the light of the current state of science and technology - they do not influence in an unacceptable way on the environment, in particular on the health of humans or animals.

One of demands of the Directive is the assumption that one should not create for Member States any obstacles in establishing additional requirements referring to the use of biocides (e.g. peculiar to the markets of individual States), provided the requirements are in agreement with the Community Law. Environmental protection is supposed to be an essential idea of these regulations, as well as such primary objectives as the health of humans and animals, and using these measures to combat epidemics, protect food and animal fodder. The Directive also defines the so-called community list of active ingredients which can be included in biocides, and determines the information that relevant parties must provide in order for the product to enter an active ingredient list.

The directive in question constitutes a unification of the acts, regulations and administrative provisions of Member States concerning the classification, packaging and labelling of dangerous substances³. Next, a system of mutual exchange and transmission of information among Member States,

for which a Committee has been established, as well as a system of specific information and scientific documentation, indispensable for the consent to use biocides⁴. For the purpose of obeying the law, at the moment of releasing biocides onto the market, adequate means of control and inspections are applicable on the part of the Member States. The duty of control of cases of poisoning by biocides is a requirement of the European law which states that a report on cases of poisoning has to be provided to the European Commission once every three years by every Member State of the European Union.

Detailed analysis of Directive 98/8 of the European Commission of 16 February 1998 concerning the placing of biocides on the market allows one to state that it is a comprehensive and complete set of regulations concerning all principles referring to these products. The directive consists of 36 Articles and their 6 Annexes. Every State admitted to the Community must, on the principle of succession, adapt entitlements of their legislation to this Directive.

Directive of 98/8, in the first Article, determines the domain of so-called biocides, the principles of their launching onto the market, as well as the required seals of approval. This article rules out from the list of so-called biocides those pharmaceuticals which have their separate legal authorisation: homeopathic and veterinary products as remedies.

Article 1 of Directive 98/8 concerns the authorisation and placing of biocidal products on the market for use within the Member States and mutual recognition of the authorisation within the Community, together with the establishment at Community level of a positive list of active substances which may be used in biocidal products, but excludes products defined within the scope of specified products, and lays down the conditions governing the preparation, placing on the market and use of a variety of products.

Article 2 defines biocides as products and preparations containing one or more active substance introduced in the form in which they are delivered to the user, which must serve the intended purpose of use, such as: destruction, scaring-off or rendering harmful organisms harmless to prevent their action, or to combat them through chemical or biological action. A list of these products is contained in the Annex to the Directive⁵. Further, the article categorises the biocide posing a slight threat, such as: a base substance, active substance, substance potentially dangerous, and a so-called harmful substrate, the presence of which is undesirable because of detrimental action to humans or animals. This Article also contains the principles for the introduction, registration, and release of the biocide onto the market of a given State.

Article 2 defines the meaning of 'biocidal products' as active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent

2. Ibidem, No. C 138 of 17.05.1993, page 1. Resolution of the European Community of 01.02.1993 on the common community policy and action for environmental protection and its sustainable growth.

3. Ibidem, No. L 154 of 05.06.1992, page 1. Commission Directive No. 92 / 69 / EWG of 31.07.1992, adapting for the seventeenth time Directive 67/548/EU for technical progress, regarding statutory, executive and administrative implementation of dangerous substances regulations referring to classification and labeling.

4. Ibidem, No. L 262 of 06.10.2009. Directive of the European Parliament and Council No. 2009/107/ EC of 16.09.2009, amending Directive 98/8/EC concerning launching biocides onto the market, with reference to extending some dates.

5. Directive 98/8/EC of the European Parliament and Council of 16.02.1998 concerning launching biocides onto the market. (Law Journal of the European Union, No. L 123 of 24.04.1998, page 1, with later Amendment. (Ibidem, special Polish edition, vol. 23, chapter 3, page 3, later known as 'Directive 98/8/EC').

the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. 'Active substance' is defined as a substance or micro-organism, including a virus or a fungus, having general or specific action on or against harmful organisms, in turn defined as any organism which has an unwanted presence or a detrimental effect for humans, their activities, or the products they produce, or for animals or for the environment. Low-risk biocidal products contain as active substances only one or more of those listed (Annex 1A), and which does not contain any substance(s) of concern. Under the conditions of use, the biocidal product can pose only a low-risk to humans, animals and the environment.

Article 3 concerns the principles of issuing a permit for launching a biocide, as well as the principles for using the product in the proper manner⁶. What is worth emphasizing is comprehension of the notion of 'proper manner', which recommends the rational application of joint physical, chemical, and other means, including allowing limitation of use of the product for the minimum of biocide action. If biocides are being used on-the-job, the application must meet the requirements determined in the Directives concerning the protection of employees by both safety rules and workplace hygiene.

Article 3, authorisation for placing on the market of biocidal products, basically stipulates that Member States must prescribe that a biocidal product will not be placed on the market and used in this territory unless it has been authorised in accordance with this Directive. Subject to registration, Member States can permit the placing on the market and use of low-risk biocidal products, providing that its details have been submitted and verified by the competent authorities. All biocidal products must be classified, packaged and labelled in accordance with the provisions of this Directive. All Member States must prescribe that biocidal products are properly used, i.e. include compliance with conditions established (Article 5) and specified under the labelling provisions of this Directive, the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary. Where biocidal products are used at work, use must also be in accordance with the requirements of Directives for the protection of workers.

The following, **fourth Article** concerns mutual seals of approval for the release of a biocide onto individual markets of the Member States⁷. Seals of approval are aimed at respecting legally agreeable conditions of distribution and use of biocides, as well as respecting the principles of health care of persons dealing with the distribution and the users⁸. If the Member State consider that the specific biocide passed by the other Member State does not fulfil specific conditions, it can refuse to issue an allowing certificate, or limit allowance under

certain conditions. However, in this case, the Committee is swiftly notified, as are the other Member States; the petitioner hands over an explanatory document containing the name of the product and its characteristics, and which states the reasons for which the State concerned will refuse or limit public access to the biocide⁹.

Article 4 sets out the requirements for the mutual recognition of an authorisation or registration of a biocidal product already authorised or registered in another Member State. On application being received by the other Member State, and provided the product conforms to all Commission requirements relating to the conditions for distribution and use of biocidal products intended to protect the health of the distributors, users and workers concerned, the authorisation or registration should be issued by the Commission within 120 days or 60 days, respectively

Article 5 contains the principles of the market launch of the biocide, along with the general principle of effectiveness and description of the undesirable impact on target organisms, i.e. the products cannot trigger an undesirable or increased resistance, or unnecessary suffering and pain in vertebrates. Next, if the biocide is classified as toxic, highly toxic, or carcinogenic, it is not certified for universal sale or application.

Article 5 lists the conditions for the issue of an authorisation of a biocidal product. It also lists the factors which make such an authorisation unacceptable, e.g. unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates, or the biocide itself or as a result of its residues, has unacceptable effects on human or animal health, directly, either or indirectly (e.g. through drinking water, food or feed, indoor air or consequences in the place of work, or on surface water and groundwater, and has an impact on non-target organisms.

Also not to be considered for authorisation are biocidal products classified as toxic, very toxic, or as Category 1 or 2 carcinogen, Category 1 or 2 mutagen, or classified as toxic for reproduction human or animal reproduction.

The consecutive **Articles, 6 and 7**, determine special (peculiar) and general (formal) principles for the change or annulment of an authorisation.

Consecutive **Articles 6 and 7**, concern reviews of authorisations previously granted, their cancellation or modification. Authorisation cannot be granted to a biocidal product classified as toxic, very toxic, or as Category 1 or 2 carcinogen, or as Category 1 or 2 mutagen, or classified as toxic for reproduction Category 1 or 2.

Article 8 concerns the application for authorisation by or on behalf of the person who will be responsible for the first placing on the market of a biocidal product in a particular Member State, and shall be the competent authority of that Member State. Every applicant shall be required to have a permanent office within the Community. The requirements for the authorization on biocidal products, include the submission of an application to the competent authority, a dossier on the biocidal product which, in the light of current scientific and technical knowledge satisfy, the requirements laid down by the Commission (Annex II B, and relevant parts of Annex III B). The submitted dossier must include a full and detailed account of all studies and tests conducted on the biocidal product.

6. Directive 98/8/EC of the European Parliament and Council of 16.02.1998 concerning launching biocides onto the market. (Law Journal of the European Union, No. L 123 of 24.04.1998, page 1, with later Amendment. Ibidem, special Polish edition, vol. 23, chapter 3, page. 3, later known as 'Directive 98/8/EC').

7. Directive 98/8/EC of the European Parliament and Council of 16.02.1998 concerning launching biocides onto the market. (Law Journal of the European Union, No. L 123 of 24.04.1998, page 1, with later Amendment. Ibidem, special Polish edition, vol. 23, chapter 3, page. 3, later known as 'Directive 98/8/EC').

8. Ibidem.

9. Ibidem.

Article 9 determines the formal requirements for the seal of approval (forwarding a motion to issue a certificate, identity of the biocide, predicted application, information about efficiency of action, etc.), principles and mode of administration, as well as principles for introducing onto the market substances active in the biocides.

Article 9 details the requirements for placing active substances on the market, in particular its classification, packaging and labelling in accordance with Commission provisions (Directive 67/548/EEC).

The current state of scientific and technical knowledge is discussed in **Articles 10 and 11**, determining the specificity of the active ingredients of biocides, and listing them in Attachments to the Directive.

In **Articles 10 and 11**, details are given for the inclusion and procedure for the inclusion of an active substance which, in the light of current scientific and technical knowledge, can be included for an initial period not exceeding 10 years if the active substances conform with the conditions of the Commission. They will be excluded if classified under Directive 67/548/EEC as carcinogenic, mutagenic, toxic for reproduction, sensitising or bio-accumulative and do not readily degrade. According to Article 11, the competent authority receiving the application for inclusion of an active substance must evaluate the application within 12 months; a copy of the evaluation is sent by the competent authority to the Commission, the other Member States, and to the applicant, together with a recommendation for the inclusion, or otherwise, of the active substance.

The consecutive **Articles 12 and 13**, concern the circulation of information about biocides, mutual applicability, and cooperation in using this information by Member States.

Articles 12 and 13 deal with, respectively, the use of data held by competent authorities for other applicants, cooperation in the use of data for second and subsequent applications for authorisation, and the conditions under which second applications may be granted.

Article 14 imposes the obligation of the exchange of new information or any news to Member States concerning the mode of action of biocides on humans or the environment, and also about changes of an official or other character which have taken place, e.g. change in the type of packaging or substance description¹⁰.

Article 14 concerns the obligatory exchange of information, including new knowledge or information on the effects on humans or the environment of a biocidal product or active substance, changes in the source or composition of an active substance, changes in composition of a biocidal product, development of resistance, or changes in packaging. In particular, any information received concerning potentially harmful effects for humans or the environment, or the new composition of a biocidal product, its active substances, impurities, co-formulants or residues.

Articles 15 and 16 determine exceptions to the decisions of Articles 3 and 5, where a Member State can temporarily be permitted, for a period not exceeding 25 days, to launch a biocide not complying with the requirements of the present Directive, for the purpose of a limited and controlled application, if applying this type of measure is necessary on

account of the appearance of an unpredictable threat which it is not possible to overcome by other means¹¹.

Articles 15 and 16 concern derogation from the requirements of the Commission and transitional measures. A Member State may derogate from Articles 3 and 5 and be temporarily authorised for a period not exceeding 120 days, the placing on the market of biocidal products not complying with the provisions of this Directive for a limited and controlled use if such a measure appears necessary because of an unforeseen danger which cannot be contained by other means. Additionally, provisional authorisation may be granted for a period not exceeding 3 years, the placing on the market of a biocidal product containing an active substance not listed in the relevant Annexes, and not yet available on the market, and intended for purposes other than those specified in Article 2. The transitional measures (Article 16) include ways of derogating certain Articles in which a Member State may, for a period of 10 years after compliance with this Directive and not later than 24 months after its entry into force, may continue to apply its current system or practice of placing biocidal products on the market. In particular, according to its national rules, it may authorise the placing on the market in its territory of a biocidal product containing active substances not listed in the Annexes for that type of product.

Article 17 determines special principles involving examination of the launch of a not-certified biocide or an active ingredient used exclusively in the biocide.

Article 17 covers research and development and specifies the requirements to be met in the case of scientific research and development, including the drawing-up and maintenance of written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied, and details of those receiving the biocidal product or active substance, compilation of a dossier containing all available data on possible effects on human or animal health, or impact on the environment.

Article 18 concerns the order for informing the Commission of all biocides registered in the specific area, or to which allowing the seal of approval was not granted or registration refused, changed, prolonged or annulled.

Article 18 requires the exchange of information in which each Member State, within a period of one month from the end of each quarter, shall inform the Commission and each other of any biocidal products authorised or registered within their territory, or for which an authorisation or registration has been refused, modified, renewed or cancelled. Additionally, each Member State has to draw up an annual list of the biocidal products and communicate that list to the Commission and the other Member States.

The next Article, **Article 19**, concerns the problem of confidentiality for the petitioner, where the petitioner applying for the seal of approval can give only such information regarded as important for the good of the commercial account¹².

10. Directive 98/8/EC of the European Parliament and Council of 16.02.1998 concerning launching biocides onto the market. (Law Journal of the European Union, No. L 123 of 24.04.1998, page 1, with later Amendment. Ibidem, special Polish edition, vol. 23, chapter 3, page. 3, later known as 'Directive 98/8/EC').

11. Directive 98/8/EC of the European Parliament and Council of 16.02.1998 concerning launching biocides onto the market. (Law Journal of the European Union, No. L 123 of 24.04.1998, page 1, with later Amendment. Ibidem, special Polish edition, vol. 23, chapter 3, page. 3, later known as 'Directive 98/8/EC').

12. Directive 98/8/EC of the European Parliament and Council of 16.02.1998 concerning launching biocides onto the market. (Law Journal of the European Union, No. L 123 of 24.04.1998, page 1, with later Amendment. Ibidem, special Polish edition, vol. 23, chapter 3, page. 3, later known as 'Directive 98/8/EC').

Article 19 deals with confidentiality as specified in the Council Directive (90/313/EEC of 07.06.1990) on the freedom of access to information on the environment, whereby an applicant may indicate to the competent authority the information the applicant to be commercially, and the disclosure of which might harm the applicant industrially or commercially, and which of necessity wishes to be kept confidential from all persons other than the Commission and the competent authorities. Full justification is required in each case. Information accepted by the competent authority as being competent is treated as being confidential by the other competent authorities, Commission and Member States.

Articles 20 and 21 contain a set of detailed principles referring to the classification, packaging and labelling of biocides¹³. The importance of recommendations of this type is obvious, as some biocides, through carelessness, can be mistaken for foodstuffs, drinks, or fodder for animals. They should therefore be packaged in such a way that limits the risk of this kind of mistake. This is why specialist cards are enforced with information concerning the safety:

– for biocides classified as dangerous, according to Art. 10 of Directive 88/379/EU – for active ingredients used exclusively in biocides; in compliance with the requirements of Art. 27 of Directive 67/548/EU¹⁴.

Articles 20 and 21 itemise regulations for the classification, packaging and labelling of biocidal products, and the provision of safety data-sheets, in accordance with the relevant Directives 88/379/EEC and Article 6 of the same Directive. As some biocidal products may be mistaken for food, drink, or feeding stuff, it has to be packaged to minimize the likelihood of such a mistake being made; therefore, such products available to the general public must contain components to discourage their consumption. Misleading labels must not mention such indications as 'low-risk biocidal product', 'non-toxic', 'harmless', or similar indications. There follows an itemized list of information that must be included on labels. Changes in packaging and labelling of biocidal products are permitted by Member States if required as a consequence of relevant provisions in so far as they do not conflict with the conditions of the authorisation issued under this Directive. Member States can place biocidal products on the market in their territories only if they are labelled in their national language or languages. Safety data-sheets are dealt with under Article 10 of Directive 67/548/EU specifying biocidal products classified as dangerous. Active substances used exclusively in biocidal products come under the requirements of Article 27 of Directive 67/548/EEC. Article 21 in general requires all Member States to ensure that a system of specific information is established to enable professional, industrial and other users of biocidal products to take the necessary measures to protect the environment, and health and safety at the workplace.

Article 22 determines the principles for advertising biocides, with a general directive suggesting that every

product includes the advertising expression 'Biocides - should be used while taking precautions. Before every use - read the leaflet and information concerning the product'.

Article 22 covers the advertising of biocidal products and is accompanied by the sentences 'Use biocides safely. Always read the label and product information before use', which are clearly distinguishable in relation to the whole advertisement.

Articles 23 and 24, consecutively concern security problems and situations in which poisoning with biocides occurs. Therefore, Member States should appoint one or more individuals to gather information about products released onto the biocide market, together with information concerning their chemical composition. These individuals have the task of providing information to others in the case of poisoning with biocides. A duty also imposed on Member States is reporting every third year on possible poisonings caused by biocide action¹⁵. Within one year of receiving this information, the Committee will prepare and publish a comprehensive report describing analysis of the use and action (also poisoning) with biocides. It is worth emphasizing that Art. 23 of Directive 98/8/EU implements the duty of monitoring poisonings with biocides. Accordingly, Member States appoint one or more individuals who are supposed to gather information about products released, and information concerning their chemical composition. In the case of poisoning (even potential poisoning) with biocides, these institutions will provide information about the characteristic of these products (such as: scale of toxicity, influence, effects of the influence, methods of acting in the case of poisoning, etc.). It is possible to use this information only in response to a request about the medical aspect in order to take both precautionary and healing measures, in particular in the case of emergency poisoning¹⁶.

Articles 23 and 24 concern poison control and compliance with requirements. Member States have to appoint bodies responsible for receiving information on biocidal products which have been placed on the market, including information on the chemical composition of such products, and for making such information available in cases where suspected poisoning arises from biocidal products. The information can only be used to meet any medical demand by formulating preventive and curative measures, in particular in emergencies. It has to be ensured that this information is not used for any other purpose and the Member States must guarantee the confidentiality of the information received. The monitoring of biocidal products placed on the market must be undertaken by the Member States to establish whether they comply with the requirements of this Directive. On 30 November every third year the Member States have to submit a report on their actions in these matters, together with information on any poisonings involving biocidal products. Within a year of the receipt of this information, the Commission prepares and publishes a composite report.

13. On the basis of the regulation of the National Ministry of Defence of 09.11.2010 on the production, manufacture, processing, use, purchase, accumulation, storage, retail, delivery, and use of toxic substances and their precursors (Law Journal 2010, No. 217, position 1432).

14. Directive 98/8/EC of the European Parliament and Council of 16.02.1998 concerning launching biocides onto the market (Law Journal of the European Union, No. L 123 of 24.04.1998, page 1, with later Amendment. Ibidem, special Polish edition, vol. 23, chapter 3, page 3), later known as 'Directive 98/8/EC'.

15. Directive 98/8/EC of the European Parliament and Council of 16.02.1998 concerning launching biocides onto the market (Law Journal of the European Union, No. L 123 of 24.04.1998, page 1, with later Amendment. Ibidem, special Polish edition, vol. 23, chapter 3, page 3), later known as 'Directive 98/8/EC'.

16. Directive 98/8/EC of the European Parliament and Council of 16.02.1998 concerning launching biocides onto the market (Law Journal of the European Union, No. L 123 of 24.04.1998, page 1, with later Amendment. Ibidem, special Polish edition, vol. 23, chapter 3, page 3), later known as 'Directive 98/8/EC'.

Article 25 concerns the charges payable by those seeking to place biocidal products and active substances on the market. As far as possible, the costs should correspond to the carrying out of all the different procedures arising from compliance with the provisions of this Directive. **Article 26** simply states that a competent authority or authorities must be designated by all Member States to be responsible or fulfilling the duties imposed on the Member States pursuant to this Directive, while **Article 27** itemises Commission procedures to be followed concerning evaluations, recommendations and proposals for the refusal to issue an authorisation or registration for an active substance, and issue a draft for a decision.

Article 28 refers to committees and procedures whereby the Commission is assisted by a Standing Committee on Biocidal Products (Standing Committee). This Committee is composed of the Member States and chaired by a representative of the Commission. The Standing Committee adopts its own rules of procedure.

Article 29 – Adaptation to technical progress: concerns Amendments necessary for adapting relevant Annexes to keep pace with technical progress and for satisfying data requirements for each product type. Article 30 deals with the same subject in the form of modification or adaptation of relevant Annexes.

Article 31 raises the issue of civil and criminal liability and the Commission grants the authorisation and all other measures in conformity with this Directive, without prejudice to general civil and criminal liability in the Member States, of the manufacturer and where applicable, of the person responsible for placing the biocidal product on the market or using it.

Article 32 is a safeguard clause where if a Member State has valid reason(s) to consider that an authorised or registered biocidal product, or one that is bound to be authorised, constitutes an unacceptable risk to human or animal health, or the environment, it can provisionally restrict or prohibit the use or sale of the product on its territory. Such action has to be communicated to the Commission and other Member States and give reasons for the decision. The Commission must come to a decision within 90 days.

The final Articles, 33-36, cover technical notes for guidance to facilitate the day-to-day implementation of this Directive (published in the 'C' series of the *Official Journal of the European Commission*), implementation of the Directive by the Member States no later than 24 months after its entry into force and provide the Commission with the texts of the provisions of national law which they adopt in the field covered by this Directive. The Directive came into force on 16 February 1998.

Annexes I-IV to this Directive concern specialist issues for biocidal products regarding the kinds and description of such biocides, lists of active and basic substances, with requirements applied for biocidal products, sets of shared data and required documentation, principles of toxic screens, means needed for the safeguarding of humans, animals, and the natural environment, chemical, physical and technical specificity of biocidal products, as well as concerns for the harmful effects of biocides. Biocidal products are therefore divided in 4 categories and groups.

Category I covers disinfecting products and biocides for general application. Cleansing products are excluded from this category, including washing liquids and powders, and

similar products the action of which is not biocidal. Category II products used for preservation purposes, applied for the maintenance of coatings, wood, fibres, leather, rubber and polymerised materials, building structures, radiator liquids, and applied in various technological processes. It also includes products for preventing the infestation and growth of mucus and fungi, and products for the maintenance of liquids in the processing of metals. Category III covers biocides for pest control, combating rodents, birds, molluscs, fish, insects, saprophytes, and other arthropods. Products for scaring off (repellents) and for decoying (attractants) – applied in combating harmful organisms (invertebrates, e.g. fleas; vertebrates e.g. birds), acting as a deterrent or as a decoy, including products used in a direct or indirect way to maintain human and animal hygiene. Category IV – other biocides, such as products for the preservation of food and animal foodstuffs, products for the protection of objects and devices against undesirable organisms in the aquatic environment, products applied for the inhibition of the growth and sedimentation of organisms (micro-organisms of both higher forms of plants and animals) on vessels, equipment applied for hydroponic cultivations, and on other devices used in the aquatic environment, liquids for embalming and preparing the bodies of humans or animals, or their parts.

It is worth emphasizing again that of Directive 98/8 of the European Commission (Article 23) implements the duty to monitor poisonings with biocidal products. To conform with the Directive, Member States must appoint at least one individual to gather information about biocidal products placed on the market and the chemical composition of such products. In the case of poisoning with a biocidal product (or even potential poisoning), the appointed authority will provide information on the scale of toxicity, way of having an influence, effects of such an influence, and method of acting in the case of poisoning. This information can only be used in response to a medical request for the sole purpose of taking precautionary and healing measures, especially in the case of emergency poisoning.

CONCLUSIONS

Analysis of the current law of the European countries concerning biocidal products allows the drawing of the following conclusions:

1. The tremendous progress of civilization in the modern world is indisputable; however, often attained at the cost of the destruction of other forms of life categorised as parasitic and harmful. Therefore, it seemed to be of the utmost importance to provide a formalised legal framework for combating these undesirable life forms while bearing in mind that the least damage as possible should be caused. This mainly concerns the specification of these products which should minimise the suffering of life forms against which they are directed.
2. A valuable merit of the Directive is the outlining of specific regulations on the production, application and scope of action of biocidal products which, due to their toxicity, pose a great threat to human life and activities, and also to animals and the natural environment. However, the application these products is necessary and justified, and application can be undertaken according to certain

rules and principles which are described in the analysed directive.

3. The cohesive and overall character of the Directive which constitutes the source of law in this particular and important issue must be emphasized. The Directive includes detailed information concerning the definition and principles of defining criteria for the production, application, placing on the market, and dealing with biocidal products.
4. The legal authorisation, essential in the Directive, regarding the safety rules and action in the case of poisoning of humans or the environment with biocidal products must be stressed. The objective is the obligation of Member States to monitor, announce, and if necessary, render effective assistance and action in cases of poisoning with biocidal products.

To sum up, at the present stage of development of European civilization, Directive 98/8 of the European Commission constitutes the best possible comprehensive legal solution concerning the production, issue and application of biocidal products.

REFERENCES

1. Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocides on the market (L 123 of 24.4.1998)
 2. Directive 2009/107/EC of the European Parliament and Council of 16 September 2009, amending Directive 98/8/EC concerning the placing of biocides on the market, as regards the extension of certain time periods.
 3. Resolution of the Council and the Representatives of the Governments of the Member States, meeting within the Council on 1 February 1993 on a Community programme of policy and action in relation to the environment and sustainable development - A European Community programme of policy and action in relation to the environment and sustainable development (OJ C 138, 17.5.1993).
 4. Commission Directive 92/69/EEC of 31 July 1992 for technical progress, adapting for the seventeenth time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.
- LITERATURE**
- Ayliffe GAJ, Brightwell KM, Collins BJ, Lowbury EJ. Varieties of aseptic practice in hospital wards. *Lancet* 1969; 2(7630):1117-20.
- Badach H, Nazimek T, Kamiński R, Turski WA. Organochlorine pesticides concentration in the drinking water from regions of extensive agriculture in Poland. *Ann Agric Environ Med* 2000; 7: 25-28.
- Baker S: Biocides Directive 98/8/EC. Complementary Therapies in Nursing & Midwifery 2000; 6(1): 48-49.
- Baumann W, Hesse K, Pollkläsner D, Kummerer K, Kumpel T. Gathering and Review of Environmental Emission Scenarios for Biocides. European Chemical Bureau. Institute for Environmental Research. Bruselas 2000; p.236.
- Bloomfield, Sally F. Significance of biocide usage and antimicrobial resistance in domiciliary environments. *J Appl Microbiol* 2002; (Suppl):144-57.
- Borkow G, Gabbay J. Putting copper into action: copper-impregnated products with potent biocidal activities. *The FASEB Journal* 2004; 18(14):1728-1730.
- Daschner F, Schuster A. Disinfection and the prevention of infectious disease: no adverse effects? *Am J Infect Control* 2004; 32: 224-5.
- De luca G, Sacchetti R, Zanetti F, Leoni E. Comparative study on the efficiency of peracetic acid and chlorine dioxide at low doses in the disinfection of urban wastewaters. *Ann Agric Environ Med* 2008; 15: 217-224.
- Fraise AP. Decontamination of the environment and medical equipment in hospitals. In: Fraise AP, Lambert PA, Maillard JY (Eds.). Principles and practice of disinfection, preservation and sterilization. 4. Oxford: Blackwell Sci 2004; pp. 563-85.
- Kähkönen E, Nordström K. Toward a nontoxic poison: current trends in (European Union) biocides regulation. *Integr Environ Assess Manag* 2008; 4(4): 471-477.
- Levy SB. Antibiotic and antiseptic resistance: impact on public health. *Pediatr Infect Dis J* 2000; 19(10): 120-2.
- Levy SB. Antibacterial household products: cause for concern. *Emerg Infect Dis*. 2001; 7 (3 Suppl): 512-515.
- Maillard JY. Antimicrobial biocides in the healthcare environment: efficacy, usage, policies, and perceived problems. *Ther Clin Risk Manag* 2005; 1(4): 307-320.
- Moreno-Mari J, Meli LA, Oltra-Moscardó MT, Jiménez-Peydro R. Situación actual en España de los aerosoles insecticidas registrados en sanidad ambiental para uso doméstico. *Rev Esp Salud Pública* 2003; 77(3): 383-91.
- Nelson DB. Infection control during gastrointestinal endoscopy. *J Lab Clin Med* 2003; 141(3): 159-67.
- Rasmussen K, Chemin P, Haastrup P. Regulatory requirements for biocides on the market in the European Union according to Directive 98/8/EC. *J Hazard Mater* 1999; 67(3): 237-51.
- Röhm-Rodowald E, Jakimiak B, Podgórska M. The principle of registration, evaluation and testing of disinfecting preparations [in Polish: Zasady rejestracji, oceny i badania preparatów dezynfekcyjnych] *Przegl Epidemiol* 2008; 62(3): 661-8.
- Russell AD. Antibiotic and biocide resistance in bacteria: comments and conclusion. *J Appl Microbiol* 2002; 92(Suppl): 171-3.
- Russell AD, Suller M.T, Maillard JY. Do antiseptics and disinfectants select for antibiotic resistance? *J Med Microbiol* 1999; 48(7): 613-5.
- Rutala WA, Weber DJ. Surface disinfection: should we do it? *J Hosp Infect* 2001; 48 (Suppl A): 64-8.
- Rutala WA. APIC guideline for selection and use of disinfectants. *Am J Infect Control* 1990; 18(2): 99-117.
- Rutala WA, Weber DJ. The benefits of surface disinfection. *Am J Infect Control* 2004; 32 (4): 226-31.
- Schultz TP, Nicholas DD, Preston AF. A brief review of the past, present and future of wood preservation. *Pest Manag Sci* 2007; 63(8): 784-8.
- Schweizer HP. Triclosan: a widely used biocide and its link to antibiotics. *FEMS Microbiol Lett* 2001; 202(1): 1-7.
- Thomas L, Russell AD, Maillard JY. Antimicrobial activity of chlorhexidine diacetate and benzalkonium chloride against *Pseudomonas aeruginosa* and its response to biocide residues. *J Appl Microbiol* 2005; 98(3): 533-43.
- Van Hemmen JJ. Biocides Steering Group on human exposure assessment: a preliminary report. *Toxicol Lett* 1999; 107(1-3): 95-102.