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Use of antibiotics in organic livestock farming: Some aspects of legal regulation

Tamara Novak*

PhD in Law, Associate Professor
National University of Life and Environmental Sciences of Ukraine
03041, 15 Heroiv Oborony Str., Kyiv, Ukraine

Article's History: Abstract

Received: 13.04.21 Revised: 25.05.21 Accepted: 15.06.21	The article analyses the national and international legal framework for the use of antibiotics in organic livestock farming and formulates conclusions and proposals aimed at improving the current agricultural legislation in this area. It is determined that the reform of Ukrainian legislation on veterinary medicine and feed takes into account the main international requirements for regulating the use of antibiotics in animal husbandry, in particular Regulation (EU) 2019/6 of the European Parliament and of the Council of 11.12.2018 on veterinary medicinal products and repealing Directive 2001/82/EC. For the effective implementation of legislative requirements in practice, the author substantiates the need to continue work in the following areas: development of bylaws in the field of antimicrobial use in animal husbandry; collection, accumulation and analysis of information on the volume and types of antibiotics used by agricultural producers; development of improved animal husbandry technologies without the use of antimicrobial agents, taking into account the positive experience of other countries; dissemination of knowledge about such
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*Corresponding author

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technologies among the subjects of animal husbandry. As a result of the study of the current legislation in the field of organic agricultural production, it was concluded that the legal regulation of the use of antibiotics in organic livestock farming generally meets international requirements, namely such basic documents as Commission Regulation (EC) No. 889/2008 of 5.09.2008 "Detailed rules on organic production, labelling and control to implement Council Regulation (EC) No. 834/2007 on organic production and labelling of organic products" and Council Regulation (EC) No. 834/2007 on organic. To improve the mechanism of control and traceability of the use of antibiotics in the treatment of farm animals in organic livestock, it is proposed to: accelerate the work on the adoption of the Procedure for the Use of Antimicrobial Products in Veterinary Medicine; supplement the Procedure (detailed rules) for organic production and circulation of organic products with provisions on the requirements for documentary evidence of the use of antimicrobial products by operators, and the storage periods for relevant documents

Keywords: antibiotics, antibiotic resistance, safety of organic products, organic livestock products, organic agricultural production, organic livestock production, legal regulation, quality of organic products

Introduction

In the current realities of agricultural production, the problem of antibiotic use in livestock production is becoming increasingly acute. The practice of their active use for prophylactic purposes (to prevent the spread of diseases of farm animals, especially pigs and poultry), to stimulate the growth of productive animals, etc., which has become widespread in recent decades, has led to the emergence of antibiotic resistance, i.e., the resistance of bacteria to one or more antibiotics. As a result, an increasing number of antimicrobial drugs are becoming ineffective in treating animal diseases, and the presence of such antibiotic-resistant bacteria in meat and other animal products is already a threat to human health.

Instead, organic farming and its sub-sector, organic livestock, are gaining popularity.

The number of consumers willing to buy more expensive organic meat, milk and other organic products is growing, provided that they are of higher quality and safer than their "non-organic" counterparts. In turn, one of the basic conditions for the production of organic products, including livestock, is the establishment of clear legal requirements for the relevant activities, which has been repeatedly emphasized by scientists [1]. This makes it important to study the state of legal regulation of organic agricultural production, in particular, such an aspect as the regulation of the use of antibiotics in organic livestock.

Despite the importance of this issue, there are currently no works in the modern legal doctrine that deal specifically with the legal aspects of the use of antibiotics in

organic agricultural production. Most of the existing scientific works on the subject are the works of specialists in the field of veterinary medicine, economics, and other sciences, for example, V. Danchuk & V. Ushkalov [2], M. Kucheruk and others. The works of such legal scholars as S.I. Bugera, O.V. Gafurova [1], V.M. Yermolenko, T.V. Kurman [3], V.O. Melnyk, D.S. Piddubna, A.M. Stativka, V.Y. Urkevych and others cover the legal regulation of organic production in general or touch upon this area in a fragmentary manner.

The purpose of the article is to analyse the domestic and international legal framework for the use of antibiotics in organic livestock farming, as well as to formulate conclusions and proposals aimed at improving the current agricultural legislation in this area.

Results and Discussion

Recognizing the threat to humans if the pace of antibiotic resistance accelerates, European countries are already actively working to reduce the use of antibiotics in agriculture. For example, since 2012, the UK has reduced the use of antibiotics in poultry farming by about 70% through the use of alternative medicines, changes in the housing system to improve animal health, and the use of less intensive livestock systems [4]. In Sweden, livestock farming without the use of feed antibiotics has been introduced since 1985, and the experience of this country has proven the possibility of successful livestock farming without the use of growth promoter antibiotics [5].

The EU will introduce a ban on the use of antibiotics in livestock for prophylactic purposes starting in 2022. Accordingly, the legal

framework is also being updated: in 2018, Regulation (EU) 2019/6 of the European Parliament and of the Council of 11.12. 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, which stipulates that: antibiotics should be used only in exceptional cases for administration to individual animals, but not for prophylactic purposes; antimicrobials should not be used regularly or used to compensate for poor sanitary conditions, insufficient agro-zoo-technology or lack of care, or poor farm management (Article 107 of the Regulation).

In fact, experts say, there are two main ways to control the problem of antibiotic resistance of pathogenic microorganisms at the global level:

- legislative restrictions on the circulation and use of antibiotics;
- collection of information on the use of antimicrobial agents in various spheres of human activity.

In addition, monitoring of the presence and migration of antibiotic-resistant strains of microorganisms is beginning to be used in developed countries [2].

As for Ukraine, the situation with the use of antibiotics in livestock is disappointing: they are actively used for prevention, treatment, and growth promotion. For example, in 2019, Vinnytsia Poultry Farm alone purchased 85 tons of salinomycin, an antimicrobial drug for the prevention of intestinal infections [6]. Moreover, due to the lack of funding for the State Service of Ukraine on Food Safety and Consumer Protection, the system for determining residual amounts of antibiotics in livestock products does not work properly in our country, and there are

no statistics on the volume of use of these substances on farms.

Within the framework of international cooperation, only a few steps are being taken to improve the system of control over the use of antimicrobial drugs in livestock. For example, the cooperation of the Food and Agriculture Organization of the United Nations (FAO) and the Pig Breeders of Ukraine Association on the project “Strengthening National Capacity to Address the Risks of Antimicrobial Resistance (AMR)” [7].

However, the international obligations of our country, the risk of losing foreign markets for livestock products, and the awareness of the consequences of antibiotic resistance for human health and life are prompting the reform of domestic legislation in the field of veterinary medicine and livestock production.

To improve the situation, the Cabinet of Ministers of Ukraine approved the National Action Plan to Combat Antimicrobial Resistance by its Resolution No. 116-r dated March 6, 2019. It provides for the development and adoption of regulations on limiting the use of antimicrobials as growth stimulants in livestock, poultry, and crop production by the fourth quarter of 2020. Despite the established deadlines, as of the beginning of 2021, only the Draft Procedure for the use of antimicrobial drugs in veterinary medicine [8] has been developed, which defines the rules for the use of antimicrobial drugs, the responsibilities of persons using them, measures aimed at reducing the use of antimicrobial drugs, and measures to control the use of antimicrobial drugs in veterinary medicine.

Significant changes in the issue under consideration should occur after the entry into force in 2023 of the new Law of Ukraine “On Veterinary Medicine” of 04.02.2021 No. 1206-IX, which defines the implementation of measures to prevent antibiotic resistance as one of the directions of state policy in the field of veterinary medicine (Art. 4), and the excess of the risk to human health in the event of the development of antibiotic resistance over the benefits of a veterinary medicinal product for animal health is recognized as a ground for refusal of state registration of a veterinary medicinal product (part 21 of article 55). Another act of agrarian legislation, the Law of Ukraine “On Feed Safety and Hygiene” dated 21.12.2017 No. 2264-VIII, introduces a direct ban on the use of antibiotics, except for coccidiostats and histomonostats, as feed additives or their components from 21.03.2023 (part 6 of Article 17).

As for the legal regulation of the use of antibiotics in the field of organic livestock, domestic legislation is more progressive.

First of all, it should be noted that currently the Law of Ukraine “On Basic Principles and Requirements for Organic Production, Circulation and Labelling of Organic Products” of 10.07.2018 No. 2496-VIII establishes a mandatory general condition for organic production – the prohibition of the use of antibiotics for preventive purposes (part 2 of Article 14). In addition, part 1 of Article 19 of the same regulatory act contains an additional instruction prohibiting the use of antibiotics for disease prevention and veterinary treatment in organic livestock. Exceptions are cases established by this Law, including

to prevent animal suffering. Among the additional requirements for organic aquaculture, Art. 22 of the Law of Ukraine "On Basic Principles and Requirements for Organic Production, Circulation and Labelling of Organic Products" also prohibits the use of antibiotics for disease prevention and veterinary treatment. The same legal provision also states that "inappropriate use of phytotherapeutic, homeopathic or other products" is an exception to this rule.

According to T. Kurman [3], the grounds and conditions for organic agricultural production in the field of animal husbandry are determined by legislation of two levels. The first level includes general regulations that define the grounds and conditions for organic agricultural production in general. This is the aforementioned Law of Ukraine "On Basic Principles and Requirements for Organic Production, Circulation and Labelling of Organic Products". The second level is represented by regulations that define the grounds and conditions for organic agricultural production in certain livestock sectors (dairy and beef cattle breeding, aquaculture, beekeeping, etc.) [3].

These include, first of all, the Procedure (detailed rules) for organic production and circulation of organic products, approved by the Resolution of the Cabinet of Ministers of Ukraine No. 970 dated 23.10.2019 (hereinafter – the Procedure).

The first thing we would like to point out is that the said Procedure, in paragraph 19, in addition to the requirements of the Law of Ukraine "On Basic Principles and Requirements for Organic Production, Circulation and Labelling of Organic Products",

establishes an unconditional ban on the use of antibiotics to stimulate animal growth or productivity. As for treatment, clause 25 of the Procedure allows for the possibility of antibiotic therapy in organic livestock farming only if the use of phytotherapeutic, homeopathic and other products is ineffective. This thesis is further elaborated in clause 63 of the Procedure.

Very important from the point of view of the professional use of antibiotics in organic livestock is the establishment in clause 64 of the Procedure of a mandatory condition for the use of such drugs – the use of antibiotics is possible only under the supervision and responsibility of a licensed veterinarian.

We would also like to emphasize that clause 66 of the Procedure establishes the rule that "if an animal or a group of animals receives more than three courses of treatment with veterinary drugs, including antibiotics, within 12 months or more than one course of treatment if the productive life cycle of animals is less than one year, except for the application of mandatory measures for the prevention and control of animal pathogens, including vaccinations, preventive treatments against parasites, the relevant animals or products obtained from them are not considered organic". Such animals must undergo a transition period in accordance with the legislation on organic production, circulation, and labelling of organic products. The requirements for such a transition period are set out in Article 25 of the Law of Ukraine "On Basic Principles and Requirements for Organic Production, Circulation and Labelling of Organic Products".

At the international level, the prohibition to sell as organic animals or products derived from them if such animals have received more than three courses of antibiotic treatment within 12 months, or more than one course of treatment if the productive life cycle of these animals is less than one year, is established by the basic act for organic agricultural production – Commission Regulation (EC) No. 889/2008 of 5.09.2008 “Detailed rules on organic production, labelling and control to implement Council Regulation (EC) No. 834/2007 on organic production”. In other words, in this part, the national legislation fully complies with international standards.

The following requirements of national and international legislation are extremely important for the practical implementation of the above-mentioned requirements and for monitoring compliance with them by organic livestock producers. In accordance with paragraph 4 of Article 24 of Commission Regulation (EC) No. 889/2008 of 5.09.2008 and para. 67 of the Procedure (detailed rules) for organic production and circulation of organic products, the operator (legal entity or individual entrepreneur engaged in the production and/or circulation of products in accordance with the requirements of the legislation in the field of organic production, circulation and labelling of organic products) must keep records and store documentary evidence of the use of antibiotics to provide them at the request of the certification body and/or the State Service of Ukraine on Food Safety and Consumer Protection. However, the requirements for the form of such records and the duration of their storage by

the operator are not currently defined at the legislative level, which in practice may lead to disagreements between the parties during inspections.

We have already mentioned above the Draft Procedure for the use of antimicrobial drugs in veterinary medicine developed by the Ministry of Economy [8]. It is this document that, in paragraphs 24-29, sets out the requirements for documentary evidence of the use of antibiotics in veterinary medicine.

In particular, it requires legal entities – operators of facilities that own (keep) animals – to draw up an act on the use of antimicrobial drugs. For individuals, it is mandatory to keep records on the use of antimicrobials.

Clause 25 and Clause 28 of the Procedure for the Use of Antimicrobial Agents in Veterinary Medicine [8] clearly regulate the scope of information to be specified in the act and records, respectively, ranging from information about the operator of the facilities to the results of animal treatment.

In our opinion, it is correct to establish in clauses 26 and 27 of the Procedure [8] the obligation to draw up an act in two copies (for the veterinary specialist who uses the antibiotic and for the owner (keeper) of the animals) and register it in the logs of the operator of the facilities that own (keep) the animals and the veterinary specialist who uses the antibiotic.

If the Procedure for the Use of Antimicrobials in Veterinary Medicine is adopted [8], compliance with its requirements will simplify control over the use of antibiotics in livestock, including organic livestock, and will help establish a process for traceability of the use of such drugs.

In our opinion, it is advisable to supplement clause 67 of the Procedure [8] (detailed rules) for organic production and circulation of organic products with an indication of the Procedure for the use of antimicrobial agents in veterinary medicine (if adopted). We also consider it mandatory to supplement clause 67 of the Procedure [8] (detailed rules) for organic production and circulation of organic products with information on the storage period of acts on the use of antimicrobial agents and records on the use of antimicrobial agents.

Conclusions

Thus, the reform of Ukrainian legislation on veterinary medicine and feed takes into account the main international requirements for regulating the use of antibiotics in livestock. For the effective implementation of legislative requirements in practice, it is necessary to continue work on: developing bylaws in the field of antimicrobial use in

livestock; collecting, accumulating and analysing information on the amount and types of antibiotics used by agricultural producers; developing improved livestock technologies without the use of antimicrobials, taking into account the positive experience of other countries; disseminating knowledge about such technologies among agricultural entities.

The legal regulation of antibiotic use in organic livestock farming generally meets international requirements. In order to improve the mechanism of control and traceability of antibiotics use in the treatment of farm animals in organic livestock, we propose to accelerate the work on the adoption of the Procedure for the Use of Antimicrobials in Veterinary Medicine; to supplement the Procedure (detailed rules) for organic production and circulation of organic products with provisions on the requirements for documentary evidence of the use of antimicrobials by operators, and the storage periods for relevant documents.

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Використання антибіотиків в органічному тваринництві: окремі аспекти правового регулювання

Тамара Сергіївна Новак

Кандидат юридичних наук, доцент
Національний університет біоресурсів і природокористування України,
03041, вул. Героїв Оборони, 15, м. Київ, Україна

Анотація

Стаття присвячена аналізу вітчизняних та міжнародних правових засад використання антибіотиків у органічному тваринництві, а також формулювання на його основі висновків та пропозицій, спрямованих на удосконалення чинного аграрного законодавства у зазначеній сфері. Визначено, що реформування українського законодавства про ветеринарну медицину та про корми враховує основні міжнародні вимоги щодо регулювання застосування антибіотиків у тваринництві, зокрема Регламенту (ЄС) 2019/6 Європейського Парламенту та Ради від 11.12.2018 р. «Про ветеринарні лікарські засоби та скасування Директиви 2001/82/ЄС». Для ефективного впровадження законодавчих приписів у практичну площину обґрунтовано необхідність продовження роботи за такими напрямками: розробка підзаконних актів у сфері застосування протимікробних препаратів у тваринництві; збір, накопичення та аналіз інформації про обсяги та види антибіотиків, які використовують виробники сільськогосподарської продукції; розробка удосконалених технологій тваринництва без використання протимікробних препаратів, враховуючи позитивний досвід інших країн; поширення знань про такі технології серед суб'єктів аграрного господарювання. У підсумку дослідження чинного законодавства у сфері органічного сільськогосподарського виробництва зроблено висновок, що правове регулювання застосування антибіотиків у органічному тваринництві відповідає в цілому міжнародним вимогам, а саме таким базовим документам, як Постанова Комісії (ЄС)

від 5.09.2008 р. № 889/2008 «Детальні правила щодо органічного виробництва, маркування і контролю для впровадження Постанови Ради (ЄС) № 834/2007 стосовно органічного виробництва і маркування органічних продуктів» та Постанови Ради (ЄС) № 834/2007 стосовно органічного виробництва і маркування органічних продуктів, та скасування Постанови (ЄЕС) № 2092/91». Для удосконалення механізму контролю та відстежуваності застосування антибіотиків при лікуванні сільськогосподарських тварин у органічному тваринництві запропоновано: прискорити роботу щодо прийняття Порядку використання протимікробних препаратів у ветеринарній медицині; доповнити Порядок (детальні правила) органічного виробництва та обігу органічної продукції положеннями про вимоги до документального підтвердження використання протимікробних препаратів операторами, строки зберігання відповідних документів

Ключові слова: антибіотики, антибіотикорезистентність, безпечність органічної продукції, органічна продукція тваринництва, органічне сільськогосподарське виробництво, органічне тваринництво, правове регулювання, якість органічної продукції
