LEGISLATIVE CONDITIONS FOR TRADE IN BIOLOGICAL MATERIAL OF FARM ANIMALS FROM A HEALTH PERSPECTIVE

LEGISLATÍVNE PODMIENKY OBCHODOVANIA S BIOLOGICKÝM MATERIÁLOM HOSPODÁRSKÝCH ZVIERAT Z POHLADU ZDRAVIA

Izabela LIPIŃSKA*

I. Introduction

The functioning of the European Union is characterized by the free movement of goods, which is one of the fundamental principles under the Treaty (Article 28 TFEU). Biological material, which is very important in animal reproduction, can be a specific object of trade. As defined in Article 3(28) of Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the field of animal health ("Animal Health Law"), biological material should be understood as semen, oocytes and embryos intended for artificial reproduction and hatching eggs⁽¹⁾.

The subject of the article are issues related to livestock biological material trade. It consists of its storage, movement, use and disposal for commercial and non-commercial purposes.

The starting point for this discussion is a statement that due to the subject of trade, special rules apply to it. They result from the fact that biological material constitutes the essence

of genetic resources used in animal breeding as well as in scientific research. At the same time, as Krawczyk and Kurpiński emphasize, effective and appropriate use of animal resources is the best form of their protection⁽²⁾.

This issue is very important especially from the health point of view, both in international and national dimension. Moved biological material may contain pathogens. This is the case with transmissible animal diseases, which can cause enormous damage to animals, their owners and to the economy⁽³⁾. The range of these diseases is very broad and constantly changing. Individual diseases are not only transmitted by direct contact between animals or animals and humans. They are also transmitted by means of vectors. These include oocytes and embryos used for artificial insemination, semen, oocyte donation or embryo transfer⁽⁴⁾. Therefore, the legislator has formulated specific legal standards to limit the transmission of diseases in line with the European Union Animal Health Strat-

⁽¹⁾ Regulation (EU) 2016/429.

⁽²⁾ Krawczyk, Kurpiński (2016).

⁽³⁾ Lipińska (2017).

⁽⁴⁾ Gliński, Kostro, Zoń (2007).

Abstract (EN)

This article addresses issues related to the movement of livestock biological material that is used for reproduction. Its movement may be accompanied by the spread of pathogens. To avoid this, specific instruments have been adopted at EU and national level. The aim of this paper is to evaluate the legal standards adopted in this field, which shape the circulation of biological material in the aspect of livestock health safety. In conclusion, it was stated that the normative solutions established at the EU level lead to the unification and harmonization of conditions concerning trade in biological material of livestock, and thus meet the objectives set out in it. Nevertheless, national regulations should be modified in this respect and supported by executive acts allowing for full implementation of the EU solutions.

Keywords (EN)

biological material, trade, genetic resources

Abstrakt (SK)

Príspevok sa zaoberá otázkami súvisiacimi s pohybom biologického materiálu hospodárskych zvierat, ktorý sa používa na reprodukciu a ktorého pohyb môže byť sprevádzaný šírením patogénov. Ako prevencia tohto šírenia boli na úrovni EÚ a na vnútroštátnej úrovni prijaté osobitné nástroje. Cieľom príspevku je zhodnotiť prijaté právne normy v tejto oblasti, ktoré upravujú obeh biologického materiálu z hľadiska zdravotnej bezpečnosti hospodárskych zvierat. Vo výsledku môžeme konštatovať, že normatívne riešenia stanovené na úrovni EÚ vedú k zjednoteniu a harmonizácii podmienok obchodu s biologickým materiálom hospodárskych zvierat, a tým naplňajú stanovené ciele. Vnútroštátne predpisy by sa však v tomto smere mali upraviť a podporiť vykonávacími aktmi, aby umožnili úplnú implementáciu riešení EÚ.

Kľúčové slová (SK)

biologický materiál, obchod, genetické zdroje

* Poznań University of Life Sciences

egy (2007–2013) adopted in 2008 and its principle of “prevention is better than cure”. The European Union’s Animal Health Strategy (2007–2013) and its “prevention is better than cure” principle⁽⁵⁾.

There are many reasons for choosing this issue. Properly isolated and marketed biological material reduces the occurrence and spread of infectious diseases in animals by eliminating potential infection routes. At the same time, the use of biological material which meets normative requirements has an impact on the environment and on the preservation of biodiversity, limiting its changes in an undesirable natural and economic direction. In turn, the acquisition and marketing of defective biological material may result in deformation of production and its loss, which entails certain economic losses on the part of the producer, and in extreme cases, may adversely affect food safety. Finally, compliance with certain marketing rules aims not only to prevent risks potentially posed to public and animal health, but to minimize them in terms of protecting the safety of the entire complex food and feed chain. This has a direct impact on livestock production planning, but also on the profitability of the entire sector.

The essence of the discussed issue is also shaped by practical considerations. According to the report for 2020 made available by the Veterinary Inspectorate, the total number of supervised entities dealing with biological material in Poland amounted to 3922, out of which 2533 plants were inspected (This data applies only to entities engaged in semen collection, semen storage, embryo collection and semen production). As a result, the Inspectorate found some irregularities in 236 of which 26 were subject to administrative or criminal proceedings⁽⁶⁾.

II. Objects and Methods

The aim of this article is to assess the legal standards adopted at EU and national level which shape the trade in biological materials in terms of livestock health security. Moreover, it aims at answering the question to what extent the legislator has unified the rules of trading in it so that no technical barriers are created between Member States.

The basic method used in the work is a dogmatic analysis of the legal text. It refers to specific conditions occurring in agriculture in which these regulations function. Therefore, selected legal norms were examined *de lege lata*. In the article, because of its nature the descriptive method was also used, as well as foreign and Polish literature on the subject.

III. Biological Material Versus Diseases

Issues related to the circulation of livestock biological material are included in the aforementioned Regulation (EU) 2016/429 of the European Parliament and of the Council, in which the legislator referred, among other things, to measures aimed at the surveillance of its trade. Their background is the prevention, control and eradication of transmissible animal diseases.

⁽⁵⁾ Rezolucja (2008).

⁽⁶⁾ Weterynaryjna (2021).

In the first place, he recognized that effective recognition is one of the basic elements of elimination of disease entities. Therefore, he formulated requirements for biological material of each species of kept animals in terms of their identification and registration. It should be emphasized that the legislator does not limit trade, but defines legal instruments for its proper conduct, taking into account the welfare of humans and animals. Their selection is not accidental, because it refers to the most sensitive area of the supply chain – the initial production. It undoubtedly includes donation and insemination procedures, as well as accompanying activities. He also defined the catalog of farm animals, which includes cattle, sheep, goats, pigs and equines, as well as the specific requirements for the biological material collected.

The legal standards developed are based on the assumption that biological material can present a similar risk of spreading portable animal diseases as the animals themselves. In addition, certain characteristics of its production, linked to high animal health requirements for farm animals, call for more stringent specific conditions for donor animals. Their essential purpose should be to ensure the safe movement of the biological material, to maintain its expected high level of performance and to take into account its specific uses. Consequently, the power to adopt acts in accordance with Article 290 TFEU has been delegated to the Commission in respect of certain requirements for the movement of biological material of particular animal species as well as special requirements applicable also to derogations from the obligations laid down in that legislative act⁽⁷⁾.

The legal solutions adopted in the regulation are shaped by two tracks. Firstly, they refer to entities directly involved in internal trade, i.e. plants and transporters. In their case the legislator has adopted certain requirements for registration and approval. In addition, in order to monitor trade, it has indicated ways to proceed with the movement and traceability of biological material. Secondly, they shape the rules for the introduction into the Union and the export outside the Union to third countries.

IV. Certification and Endorsement

The acquisition, production, processing or storage of biological material may only take place in certified facilities. By establishment is meant any premises, structure (environment or place) in which – temporarily or permanently – this material is kept. However, it does not include farms where animals are kept and animal treatment facilities are excluded (Article 4, point 27 of Reg. 2016/429). An establishment dealing with biological material is thus: a) for semen, the establishment where it is collected, produced, processed and stored; b) for oocytes and embryos, a group of specialists or a structure supervised by a team veterinarian with competence in the collection, production, processing and storage of oocytes and embryos; and c) for hatching eggs, a hatchery.

Prior to the commencement of the aforementioned activities, each of the aforementioned entities is required to undertake

⁽⁷⁾ Wątek (2016).

certain steps for registration. These include, according to Article 84 (1) of Reg. 2016/429, the obligation to notify the competent authority in the Member State where they operate of each of their establishments for which they are responsible. The legislator also requires the provision of information in terms of basic personal data, address, description of the facilities; information on the type and quantity of biological material to be kept in the establishment, together with an indication of its potential and any other matter relevant to the potential risk of spreading diseases. Establishments which are subject to approval under Article 94(1) of Regulation 2016/429 are exempt from this information requirement, such as (a) gatherers of ungulates and poultry; (b) dealers of biological material of bovine, porcine, ovine, caprine and equine species; (c) hatcheries; and (d) poultry establishments from which animals, biological material or poultry other than for slaughter or hatching eggs are moved to another Member State.

This registration is necessary as it allows the competent authority to supervise the sourcing and collection of material which serves to prevent, control and eradicate transmissible animal diseases. At the same time, in order to avoid unjustified administrative burdens and costs, Member States have the possibility to exempt certain types of establishments from registration if they pose a low animal health risk. Provisions in this regard shall be established by the Commission under the delegation in Article 86 of Regulation 2016/429.

As part of the information instrument for obtaining an establishment's approval, operators shall provide the competent authority with, inter alia, such data in addition to the address as: a) the location of the establishment and the characteristics of its facilities; b) the categories, species and number of terrestrial animals kept or the categories, species and quantity of biological material collected in the establishment; c) the type of establishment; and d) other matters concerning the establishment related to its specificity which are relevant for determining the risk posed by the establishment, if any (Article 96(1) of Reg. 2016/429).

Approval of an entity occurs when it meets several conditions together. In the first instance, these relate to the fulfilment of the requirements for bio-assurance measures. Their primary purpose is to minimize the risk of the introduction and spread of pathogenic agents in its area. Measures appropriate to the animal species prevent the occurrence of diseases by eliminating or reducing as much as possible potential sources of disease⁽⁸⁾. In addition, the establishment should meet surveillance requirements appropriate to its type and the associated risks to detect the presence of potential diseases in the biological material. At the same time, the establishment must demonstrate that it has adequate facilities and equipment, appropriate to its potential in relation to the quantity of biological material involved, and properly trained personnel to conduct its activities.

Establishments, in addition to the required registration, must comply with related record keeping obligations (Article 103 of Reg. 2016/429). Their scope concerns (a) the breed, age, identification data and health status of the donor animals used to produce the biological material; (b) the time and place of capture, processing and storage of the biological material

captured, produced or processed; (c) the identification data with details of its destination, if known; (d) the documents required to be attached when the biological material arrives at or leaves the establishment concerned; (e) the results of clinical and laboratory tests, if applicable; and (f) the laboratory techniques used. These records must be kept for a minimum period specified by the competent authority and for no less than three years and may be exempted for establishments posing a low risk of spreading listed or emerging diseases. Exemption may be granted by the Member State.

The question of circulation of biological material is of particular importance in terms of disease control measures to be taken in the case of confirmation of disease in livestock. Accordingly, the legislator requires that, pursuant to Article 65(1) (d) of Regulation 2016/429, the competent authority of the Member State shall ensure that, subject to national provisions on obtaining access to private property, one or more disease control measures are implemented in the restricted area to prevent the further spread of a listed disease referred to in Article 9(1)(d). These include bio-assurance requirements concerning, inter alia, the collection, storage and handling of biological material. Another very important obligation of the establishment is to fulfil the requirements concerning the identification and traceability of the material (Article 9(1) h)⁽⁹⁾.

V. Traceability

As far as the traceability of biological material is concerned, this includes material derived from kept animals of the species indicated above. According to Article 121 of the said Regulation, operators producing, processing or storing biological material shall label it in such a way that the donor animals, the date of acquisition; and the establishments handling the biological material where the material was acquired, produced, processed and stored can be unambiguously identified. Such labelling should be designed to ensure the effective application of disease prevention and control measures as well as the traceability of its movements within and between Member States and of the introduction of the material into the Union. During movement, it is essential in relation to the spread of animal diseases that appropriate precautionary measures are taken to ensure that the biological material does not jeopardise the health status of terrestrial animals kept at the place of destination with regard to both officially listed and emerging diseases.

In order to ensure control and security of internal trade, the legislator requires notification of all movements of livestock biological material to other Member States. This is done by the integrated computerized veterinary system TRACES, the notifier being the competent authority of the Member State of destination.

VI. Movement and Circulation of Biological Material

Biological material may be moved only if it meets certain normative prerequisites. It must come from registered establish-

⁽⁸⁾ Realizacja (2018).

⁽⁹⁾ Obal, Lesiów, Śmiechowska (2017).

ments and meet traceability requirements. On the other hand, operators of establishments at the place of destination who receive biological material from an establishment in another Member State are obliged to verify the labelling and animal health certificates. They shall inform the competent authority of the place of destination of the correctness of the movement. In the event of irregularities, the operator concerned shall isolate the biological material until the competent authority has taken a decision on the matter.

As regards movements of animal genetic material to other Member States, operators must verify that the biological material was obtained, produced, processed and stored in appropriate facilities. In addition, donors must be verified that they meet the necessary animal health requirements and the operators involved in its transport (Article 159 of Regulation 2016/429).

Biological material may be moved provided that it is accompanied by an animal health certificate issued by the competent authority of the Member State of origin (Article 161(1) of Reg. 2016/429). It should contain information about the establishment, the type of material, the species of donor animals kept, its quantity or number and, if required, its labelling. On the other hand, biological material that is subject to restrictions due to a suspected disease and for which specific eradication or emergency measures have been taken shall be excluded from the movement. The restrictions in question do not apply if the material was obtained before the outbreak and was stored separately from other biological material.

The above-mentioned rules on the movement of biological material are intended to avoid the spread of animal diseases. However, their application does not prevent Member States from taking specific measures. If a disease other than a listed disease poses a significant risk to animal health, the Member State concerned may introduce national measures to control the disease in question and may restrict the movement of the biological material. This is allowed as long as these measures do not impede distribution and do not go beyond what is appropriate and necessary to control the disease (Article 171 of Reg. 2016/429).

The legislator also allows the introduction into the Union of biological material from third countries as long as it is not covered by a derogation granted under Article 239(2) of Reg. 2016/429. At the same time, the Commission, by means of implementing acts, may draw up lists of countries from which the introduction into the Union of biological material is permitted. In the case of its introduction, it must be demonstrated that the animal health requirements are as stringent as in this Regulation and in the rules adopted pursuant to it that apply to the movement of biological material within the Union, or offer guarantees equivalent to those indicated in the Regulation (Article 234 of Reg. 2016/429).

The movement of biological material is also subject to internal and external verification under Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls⁽¹⁰⁾. Internal control under Article 20 of Regulation 2017/625 covers every stage of production, processing and distribution. The external one, on the other hand, concerns

material entering the Union. Control is carried out by the competent official authorities at the border inspection post of first arrival in the Union regarding the prevention of risks to public and animal health (Article 47 of Reg. 2017/429). It includes verification of the consignment, documentation, including identification and physical checks. Checks are carried out by the official veterinarian or designated staff.

VII. National Legal Conditions of Trade In Biological Materials of Farm Animals

Issuance of the EU regulation required adjustment of national regulations. Accordingly, the issues related to trade in biological material of farm animals in Poland are regulated by the provisions of the Act of 11 March 2004 on the protection of animal health and combating infectious animal diseases⁽¹¹⁾. The act, in its Article 1(f), contains veterinary requirements for undertaking and carrying out activities in the field of, inter alia, commercial production, acquisition, preservation, treatment, storage, marketing or use of biological material. The legislature independently defines its circulation and trade. By trading it means its import, placing on the market and export to third countries. On the other hand, trade in biological material is free trade between Member States of the European Union within the meaning of Article 28(2) of the Treaty on the Functioning of the European Union (Article 2(12)). At the same time, it makes its admissibility conditional on holding a certificate confirming the origin of the material, in accordance with applicable EU regulations.

The legislator treats the concept of biological material in a broader manner, including semen, ova, embryos and tissues used in their production, originating from animals, intended for use in reproduction, with the exception of hatching eggs from poultry and aquaculture animals (Article 2(10) of the Act).

Considering biological material as the essential core of reproduction, it is necessary to refer to its zootechnical conditions, which must be met. They have been defined in the Regulation of the Minister of Agriculture and Rural Development of 26 November 2009 on the biological material used in reproduction of farm animals⁽¹²⁾ under the disposition contained in Article 39 of the Act. In principle, semen used in artificial insemination, as well as ova or spores, should come from animals registered in herd books or registers. Their material must meet the veterinary requirements set out in these regulations on the protection of animal health and the control of infectious animal diseases. This also applies to stored material. In addition, veterinary requirements for carrying out activities related to the production, collection, preservation, treatment, storage, marketing or use of semen, as well as its import and trade, have been formulated for individual livestock species by regulation⁽¹³⁾.

Turning to the analysis of the solutions concerning the trade

⁽¹¹⁾ Act (2020).

⁽¹²⁾ Regulation (2009).

⁽¹³⁾ Regulation (2009), Regulation (2011), Regulation (2013).

⁽¹⁰⁾ Regulation EU 2017/625.

itself, which are contained in the Act, it should be noted that certain principles for the “safe” movement of material have been defined. During the movement and transport of biological material, as noted when discussing the EU regulation, appropriate certificates are required. These are issued by breeders’ associations or entities maintaining herd books or registers. In addition to those mentioned, other entities may also have the right to grant them if: 1) have been authorised to engage in the business of collecting, packaging, storing and supplying or storing and supplying semen, or 2) are engaged in the business of collecting, preserving, storing and supplying or storing and supplying ova or embryos, in accordance with the provisions on the protection of animal health and the control of infectious animal diseases. The holder of the certificate is obliged to keep it for at least 12 months from the date of its issuance, which is potentially to facilitate possible tracing of the material being moved. It is worth mentioning that the supervision over the health quality of biological material and poultry hatching eggs is carried out by the Veterinary Inspection⁽¹⁴⁾.

In addition to the certificate, each batch of biological material marketed on the national territory is provided with a commercial document containing, inter alia, data allowing the identification of the donor or donors⁽¹⁵⁾. In addition, it specifies the date of collection or production of the material and information about its producer and recipient. In the case of bovine embryos and semen, that document shall also include (a) the results of an assessment of breeding value carried out on the national territory, if such an assessment has been carried out, (b) the results of an international assessment of breeding value, if any, carried out by a reference body, (c) in the case of bulls of the Holstein-Friesian breed, the results of an international assessment of breeding value made available on the website of a breeders’ association or other body which has been authorised by the minister responsible for agriculture to carry out such an assessment of cattle of that breed, and (d) the results of a test for the carrier of genetic defects in the bull, if such a test has been carried out.

With regard to the health of the animals and the biological material collected from them, the legislator, in accordance with Article 16 of the Act, allows their movement from Poland to another Member State. However, it is subject to compliance with the veterinary requirements for trade in it. In particular, each consignment should be accompanied by the original health certificate issued by an official veterinarian of the country from which the material was imported, or a certified copy of this certificate. Movement also implies the holding of a veterinary border crossing certificate issued by the border veterinarian. In duly justified cases the movement of material may be prohibited. This occurs when there is a fear of the occurrence or appearance of an infectious disease on the territory of a third country from which the material is imported. The minister responsible for agriculture in each Member State is competent in this respect. He shall impose a ban on movement with a view to protecting public health and safeguarding animal health, acting on the basis of the aforementioned EU provisions (Article 17 of the Act). The introduction of a trade restriction must

be justified and the other Member States and the European Commission must be informed immediately. The ban remains in force until the Commission issues a decision on the import ban of the biological material.

Based on the disposition contained in Article 268 of Reg. 2016/429, the national legislator has established provisions on sanctions applicable in case of violation of the established rules for the circulation and trade of biological material. It is worth mentioning that underlying their formulation was the assumption that sanctions must be effective, proportionate and dissuasive.

As a result, failure to meet the discussed requirements for the marketing of biological material entails criminal or administrative penalties. Well, in accordance with Art. 77 of the Act, whoever, among others 1) while conducting supervised activity, fails to meet the veterinary requirements provided for it, thus causing an epizootic or epidemic threat or an inappropriate health quality of the products, or conducts such activity without confirming that the veterinary requirements have been met; 3) trades,..., without complying or in breach of the veterinary requirements applicable in this scope, 7) carries out research and other activities with genetic material, for research, diagnostic or production purposes without approval – shall be subject to a fine, penalty of restriction of liberty or imprisonment of up to one year. In turn, in accordance with Art. 85a of the Act section 1 who: 1) conducts supervised activities without registration or obtaining approval or conditional approval, 2) does not possess commercial documents or health certificates that meet certain requirements, imports animal by-products or derived products that do not meet the requirements – shall be subject to a fine.

VIII. Conclusions

The analysis conducted allows to conclude that the normative solutions established at the EU level lead to the unification and harmonization of conditions concerning trade in biological material of farm animals. This is a result of, among other things, the need to meet accepted international standards in this area, as well as to ensure the health security of humans and livestock. Due to the risk posed by transmissible infectious diseases, there is a concern that the emergence of an epidemiological threat would affect several Member States simultaneously and could even spread across borders with significant economic and social impact. The introduction of identical rules and procedures in all Member States with a preventive character will undoubtedly limit the risks associated with it.

It should be underlined that the approach of the legislator allows for safe biological material to be obtained as a result of the controls on its circulation. Member States participate in internal trade but also have the possibility to trade with third countries. This exchange is not free as it implies certain requirements such as registration and approval of establishments involved in the trade, professional qualifications for certain highly specialised establishments or activities (e.g. embryo collection teams), the necessary documentation and specific supervision by the competent authority. Nevertheless, it does not lead to technical barriers to trade in biological material used for reproduction.

⁽¹⁴⁾ Act (2004).

⁽¹⁵⁾ Act (2020).

References

1. REGULATION (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'), OJ L 84, 31.3.2016, pp. 1–208.
2. KRAWCZYK, J. – KRUPIŃSKI J. 2016. Perspektywy ochrony bioróżnorodności zwierząt gospodarskich w warunkach biogospodarki. In Roczniki Naukowe SERIA vol. XVIII, no. 1, 145, DOI: 10.22004/ag.econ.257364.
3. LIPIŃSKA I. 2017. Zwalczenie chorób zakaźnych zwierząt gospodarskich – wybrane aspekty prawne. In Studia Iuridica Agraria vol. XV, ISSN 1642-0438, pp. 157–172.
4. GLIŃSKI Z. – KOSTRO K. – ZOŃ M. T. 2007. Choroba niebieskiego języka. In Życie Weterynaryjne, no. 5, pp. 380–383.
5. Animal health strategy 2007–2013 European Parliament resolution of 22 May 2008 on a new animal health strategy for the European Union 2007–2013 (2007/2260(INI)). OJ C 279E, 19.11.2009, pp. 89–98.
6. Weterynaryjna sprawozdawczość statystyczna (RRW). 2020, <https://www.wetgiw.gov.pl/publikacje/rrw-sprawozdawczosc-statystyczna> 2021.12.12.
7. PLOT NO. 133 REGULATION (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'), OJ L 84, 31.3.2016, pp. 1–208.
8. Realizacja programu bioasekuracji jako element zwalczania afrykańskiego pomoru świń, 2018, NIK, KRR 430.006. Warszawa, p. 4.
9. Obal M. – Lesiów T. – Śmiechowska M. 2017. Identyfikowalność surowca mięsnego w wybranej firmie handlowej. In Nauki Inżynierskie i Technologie, no. 3, e-ISSN: 2449-9773, pp. 28–59.
10. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) Text with EEA relevance. OJ L 95, 7.4.2017, pp. 1–142.
11. Act of 11 March 2004 on the protection of animal health and combating infectious animal diseases. Journal of Laws of 2020, item 1421.
12. Regulation of the Minister of Agriculture and Rural Development of 26 November 2009 on the biological material used in reproduction of farm animals. Journal of Laws no. 209, item 1610.
13. Regulation of the Minister of Agriculture and Rural Development of 20 May 2009 on specific veterinary requirements applicable to bovine semen (Journal of Laws 2014, item 69), Regulation of the Minister of Agriculture and Rural Development of 10 March 2011. on detailed veterinary requirements applicable to semen of ovine, caprine and equine animals and ova and embryos of ovine, caprine, equine and porcine animals requirements for the porcine semen collection center (Journal of Laws of 2011, No. 63, item 330), Regulation of the Minister of Agriculture and Rural Development of 5 August 2013 on detailed veterinary requirements applicable to porcine semen (Journal of Laws of 2013, item 1016).
14. Act of 29 January 2004 on Veterinary Inspection, Journal of Laws of 2018, item 1557.
15. Act of 10 December 2020 on the organization of breeding and reproduction of farm animals, Journal of Laws of 2021, item 36.

Contact address/ Kontaktná adresa

Izabela Lipińska, associated professor

Poznań University of Life Sciences,

Faculty of Economics,

Department of Law and Organization of Agribusiness Enterprises,

Wojska Polskiego 28, 60–637 Poznań, Poland,

e-mail: izabela.lipinska@up.poznan.pl