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Legal Obstacles in the Eradication of Bovine Tuberculosis in European bison (*Bison bonasus*)—A Threat to an Effective Reintroduction Strategy

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Abstract: In Poland, bovine tuberculosis (BTB) is most often detected in cattle, although some cases have also been reported in pigs and in other non-domestic species. BTB is believed to be mainly present in the Bieszczady region, in the south-eastern part of the country. The present study analyses the practical applications of the law regarding the eradication of tuberculosis among European bison in Poland, as well as the influence of legal rules in species conservation effects. Its aim is to present and evaluate the effectiveness of legal provisions in selected cases of BTB detected in European bison. The analysis highlights key "critical points" in the management of cases of BTB in European bison, which resulted from the problematic interpretation and application of the existing legal provisions. Findings indicate that before the Animal Health Law, the eradication of BTB in European bison in Poland was not regulated clearly enough by the applicable laws in force prior to 2021. This posed a threat to an effective reintroduction strategy for bison based on creating larger metapopulations and maintaining small, isolated reservoir herds (breading centers) for fallback in the case of infectious disease. It should be emphasized that in the current legal system, there is no doubt that a District Veterinary Officer has the competence to prevent and control tuberculosis in European bison.

Keywords: European bison; animal health law (AHL); bovine tuberculosis; EU law; veterinary administration

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1. Introduction

In Poland, bovine tuberculosis (BTB) is most often detected in cattle [1], although some cases have also been reported in pigs [2] and in other non-domestic species. BTB is believed to be mainly present in the Bieszczady region, in the south-eastern part of the country, where it has been confirmed microbiologically in wild boars (*Sus scrofa*), European bison (*Bison bonasus*) and gray wolves (*Canis lupus*) [3–5].

Until recently, only bovine (*Mycobacterium bovis*) and human (*M. tuberculosis*) Mycobacteria were legally considered etiological factors of BTB in Poland before 21 April 2021. In addition, in 2009, *M. caprae* was added to the list of etiological factors in some European Union member states [6]. According to EU Regulation 2021/620 [7], the territory of Poland is officially recognized as being free from infection with Mycobacterium tuberculosis complex (MTBC), that is, according to the current law, Mycobacteria of the genera *M. bovis*, *M.*

caprae and *M. tuberculosis* [7–11]. Free status applies only to livestock: the occurrence of tuberculosis in wild animals does not affect this status.

Tuberculosis is a very serious disease for wild species, livestock and pets. It is also a matter of concern for public health (zoonosis) and an important feature for species conservation efforts, such as those concerning the European bison in Poland.

In Poland, the legal framework regarding free-living animals is complex: many of the relationships between its regulations and legal provisions tend to be obscure or incomplete. The legal system has an abundance of laws and legal provisions, bound by complex and sometimes contradictory relationships between them. In the face of such potential legal ambiguity, it can be very hard to establish clear procedures that can be followed by authorities, resulting in transfers of responsibility or failures to act appropriately in response to specific crisis situations, particularly when it is possible for one law to have different interpretations. This posed a threat to an effective reintroduction strategy based on creating larger metapopulations and maintaining small, isolated reservoir herds (breading centers) for fallback in the case of infectious disease.

As bison demonstrate weak resistance to infection, a particular threat is posed by disease outbreaks. For instance, the whole bison herd from Pszczyna (Poland) died out due to the foot and mouth disease outbreak in 1953/1954, about one third of bison from the German breeding center Hardehausen were lost due to blue-tongue disease in 2007 and a bovine tuberculosis outbreak in the Bieszczady Mountains in 2012/2013 resulted in the elimination of the entire herd. Many free-living herds today occur at high densities with winter feeding; as such they are at high risk of epidemics if herds are connected into larger metapopulations. It is therefore important to establish reservoir herds free of any infections (i.e., bovine tuberculosis) that can serve to restock larger herds in such cases; such efforts should proceed in parallel with those intended to link and expand extant herds [12]. However, these activities can be disrupted by legal obstacles.

The present study analyses the practical applications of the law regarding the eradication of tuberculosis among European bison in Poland, as well as the influence of legislation on species conservation. Its aim is to present and evaluate the effectiveness of legal provisions in selected cases of BTB detected in European bison.

2. Materials and Methods

Intervention studies involving animals or humans, and other studies that require ethical approval, must list the authority that provided approval and the corresponding ethical approval code. The presented paper examines statutes from both Polish [13–20] and European legislation [7–11,21–23]. The legal texts themselves were subjected to linguistic, systemic, teleological, functional and pro-European legal interpretation and analysis.

The study also examines selected factual and legal cases performed to reconstruct and evaluate the actions taken to eradicate BTB in European bison in Poland [24–42]. The case studies were performed of actual state with the aim of exemplifying certain legal and epizootic aspects of BTB monitoring and control.

The study adopts the legal status as appropriate for the reported cases. The case studies were compared with the current (since 21 April 2021) legal state, with the aim of exemplifying certain relations between legal and epizootic aspects of BTB monitoring and control, together with the consequences of decisions made to ensure *B. bonasus* species conservation.

3. Results

3.1. The Historical Background and Geographical Distribution of BTB in European bison in Poland

The highest frequencies of BTB cases among non-domesticated animals in Poland were detected in the European bison population in the Bieszczady region. A total of 45 confirmed cases of BTB were noted in the Bieszczady region in the years 1996–2013 [3]. Two such cases were detected in 1997 [4], and in the period 1997–2001, 13 of the 18 bison eliminated in the Brzegi Dolne herd were posthumously found to be infected with BTB. In 2009, after

detecting BTB in a single animal in the Górny San herd in the same region, the whole herd of 24 animals was eliminated. *M. bovis* infection was posthumously detected in 23 of them [14]. BTB was later detected in other species of free-living animals in the region, including wild boar [2]. Molecular analysis found the *M. caprae* strains isolated from the local population of wild boar to be identical to those from the European bison of the Górny San herd [4].

In 2016, *M. bovis* infection was microbiologically confirmed in two free-living European bison in Borecka Forest, Giżycko district, north-eastern Poland [43]. Continued monitoring showed no more new cases in that region [44].

BTB has also been reported among European bison kept in captive breeding centers and in zoological gardens. In the years 2009–2010, BTB was reported in animals kept in the Silesian Zoological Garden in Chorzów [45,46], and the highest infection rates have been confirmed in the European Bison Breeding Center in Smardzewice (Figure 1) [3,47].

Figure 1. The location of bison herds.

3.2. Eradication of Bovine Tuberculosis in European bison—Description of Cases Regarding the Legal Act on Infectious Diseases in Animals

The study presents three selected cases of BTB infection, recorded in European bison before 21 April 2021 [11]. These cases highlight the juridical and practical problems associated with the eradication of BTB in protected species.

3.2.1. A Case of BTB Infection in the European bison Breeding Center, Smardzewice (Kampinoski National Park)

The first reported fatal case of BTB in the reservoir herd in Smardzewice was observed in 2013 [47], in a six-year-old bull born in the Smardzewice breeding center. The most probable source of infection was the mother: she had been brought to the Silesian Zoological Garden in Chorzów in 1998 [45,46], and then moved to Smardzewice in 2005, where she calved two years later. The cow was not tested for any infectious diseases when she was transferred from the zoo to the breeding center.

Following the death of the bull in Smardzewice, other animals were tested. Any BTB-positive European bison were isolated from the herd, and permission was obtained from the Minister of the Environment to eliminate six animals [27]. Among these six, three animals demonstrated BTB-typical anatomical and pathological post-mortem lesions, and the presence of *M. caprae* was confirmed in laboratory testing. The material from the other three animals was free of acid-fast Mycobacteria. In September 2014, during follow-up ante-mortem tuberculosis testing, two individuals were found to be positive to both the

intradermal tuberculin test and gamma interferon test, two to the tuberculin test alone and two to the interferon gamma test alone. The Director of the Kampinoski National Park applied for permission from the Minister of the Environment to shoot all individuals (16 animals) kept in the European Bison Breeding Center in Smardzewice at that time; however, permission was only given to shoot the six which had demonstrated a positive response to the in vivo diagnostic tests. Their elimination took place on 21 January 2015. The rest of the herd was culled in December 2018 [47].

In Poland, if the animals are located in the area of the National Park, permission must be obtained from the Ministry of Environment and, currently, the Ministry of Climate and Environment; however, if they are located in other areas, consent must be granted by the General Director of Environmental Protection

3.2.2. A Case of Tuberculosis Associated with the Transfer of European bison from the Breeding Center in Smardzewice to the Quarantine Enclosure in the Borki Forest District

In 2013, two animals from the European Bison Breeding Center in Smardzewice were transferred to the quarantine enclosure Wolisko in the Borki Forest District (Giżycko district). After 30 days of quarantine, the animals were joined with other four animals in the enclosure in Wolisko (Giżycko district). No disease symptoms were revealed in clinical examination. After gaining information about the occurrence of BTB in the breeding center in Smardzewice, the Chief of Borki Forest District applied to the General Director for Environmental Protection for permission to eliminate the two transferred animals. With the permission of the General Director for Environmental Protection [24], two animals were eliminated. The post-mortem examination performed immediately after the shooting, however, revealed no anatomical or pathological changes that could indicate tuberculosis. Tissue samples were collected and sent to the National Veterinary Research Institute in Puławy. The resulting microbiological analysis found one European bison to be negative but indicated the presence of *M. bovis* in the other. As the latter had been in contact with other animals in enclosure during the last three months, all other animals could also have been infected. Under the circumstances, it was necessary to establish a method to eliminate the risk of the disease spreading outside the enclosure and to protect the free-roaming basic herd. The Regional Director of the State Forest in Białystok appointed a commission to develop a procedure for handling the other animals kept in the Wolisko enclosure.

Considering the substantial risk of infection to the animals in enclosure and free-roaming herds in the Borecka Forest, the decision was made to eradicate the BTB outbreak by eliminating the whole herd kept in the enclosure. The District Veterinary Officer (DVO) in Giżycko issued an opinion sanctioning the elimination of European bison as the only way to eradicate the BTB outbreak. The Chief of Borki Forest District applied to the General Director for Environmental Protection for permission to eliminate the remaining animals in the enclosure because all of them had been in direct contact with the infected animal and could be potentially infected with BTB [47]. After a thorough examination of the subject matter, the General Director for Environmental Protection gave permission to proceed with the aim of protecting the free-roaming European bison. Therefore, a decision was issued permitting four European bison from Wolisko to be shot [25]. A post-mortem examination was performed on all the animals [29]. Tissue samples were collected and were tested for the presence of *M. bovis*, as recommended by the commission; no sign of acid-fast Mycobacteria was found [36]. Based on the recommendations of the commission and of the Giżycko DVO, the facility where the animals had been kept was disinfected [36].

3.2.3. A Case of Tuberculosis in a Herd of Free-Roaming European bison in the Borecka Forest

In 2016, a cyclical review (a periodic herd inspection of the condition of a given population of bison present in a given area performed by a group of specialists) detected the presence of BTB in free-living European bison in the Borecka Forest (Giżycko district). The Regional Director of the State Forest in Białystok appointed a commission to evaluate the regulation of the local European bison population. The commission recommended

the elimination of 12 animals [15,37]. Under the circumstances, the Borki Forest District contacted the General Director for Environmental Protection, requesting administrative permission to shoot 12 animals [42]. Such permission was given in the case of six animals.

The herd of European bison was officially inspected by the commission, to select the animals to be shot [37]. One of the selected animals was an apathetic bull which would arrive last to the feeding spots and on which visible lesions were present in the foreskin region (*Posthitis*) [31,33]. An apathetic cow with noticeable feeding problems and a thin body showing muscle atrophy was also selected [32].

Documentation was prepared for the elimination [31–33] and samples were collected for laboratory BTB testing [38,39]. The presence of *M. bovis* was confirmed microbiologically in tissue material obtained from the dead bull [38]—but not from the cow [39].

The Giżycko DVO subsequently introduced BTB monitoring of the game species living in the Borecka Forest. The procedure included collecting tissue samples from hunted animals and testing them for the presence of *M. bovis*, as well as training hunters in recognizing the symptoms and pathological anatomical lesions, which were potentially indicative of BTB in game species [28].

In addition, in accordance with the issued permission [26], another four animals were shot for diagnostic purposes [30,35]. The collected samples were found to be BTB negative [40].

3.3. Legal Analysis

Before the Animal Health Law (AHL) [11] came into force on 21 April 2021, the existing relevant legislation in Poland comprised the Act on Animal Health Protection and Control of Infectious Diseases in Animals [18], the Regulation concerning the control of bovine tuberculosis [13] and the Nature Protection Act [20]. The norms concerning BTB [13] existed as a more detailed version of the general provisions of the Act on Animal Health Protection and Control of Infectious Diseases in Animals [18].

This legal status was further complicated by the existence of numerous norms in the form of various statutory acts concerning protection of nature and protection of animal species (Nature Protection Act [46] and its executive regulation [37]), protection of animals, responsibilities of veterinary inspection authorities, performance of the veterinary profession, as well as general legal provisions regarding administrative procedures.

Typically, a legal norm can only be reconstructed after the application of a number of provisions originating from a wide range of legal references. In analyzed cases, especially problematic was the application of the current law to the European bison as a protected wild animal species. It should be noted, however, that the protection of nature, including legally protected species, is a separate form of protection to the humanitarian protection of animals and the protection of animal health, including that afforded to officially controlled diseases. Nevertheless, it would not be correct to assume that it must be understood separately; this is especially true in the context of officially controlled diseases. A multifaceted and teleologically-focused manner of approaching the problem was inherent.

The authors realize that this was a very difficult task for every competent authority (e.g., DVO). Moreover, in the absence of a national program adopted by the Chief Veterinary Officer, the competent authorities considering the examined cases adopted the form of interpretation, according to which they were only permitted to control the disease in farm animals, but not in European bison.

The authorities assumed that the conducted case analysis revealed, before April 2021, effective application of legal measures would have been possible only if the Chief Veterinary Officer had established a program for eradicating tuberculosis in European bison, specifying measures that should have been taken to control the disease. This program was needed to compensate for the inability of the DVOs (as the competent authorities for a particular territory, having relevant legal obligations and competences) to apply measures indicated in Article 44 of the Act on Animal Health Protection and Control of Infectious Diseases in Animals. These could not be applied unless they were also specified

in the executive regulation issued under Article 61 Section 1 by the Minister of Agriculture. Although the Minister issued a regulation concerning the control of bovine tuberculosis on 23 November 2004 [13], its content regarding administrative control is inconsistent. Despite the fact that the name of the regulation itself mentions "bovine tuberculosis" and not "tuberculosis in bovine species", the authorities comprehended its content implies as applying to domesticated cattle only. This interpretation, based on simple linguistic understanding, but not taking into account the coherence of the law or teleological values, such as the protection of public health, effected in non-applicated of the legal norms to European bison.

In the authors' opinion, another interpretational path was possible. Assuming that "bovine tuberculosis" is the name of a disease which was (and is) subject to compulsory control, any administrative measures intended to guarantee disease control could have been also applied to European bison.

Provisions of the Act on Animal Health Protection and the Control of Infectious Diseases in Animals, and of the Regulation concerning the methods of eradication of tuberculosis, included information on the competence and powers of the DVO in the discussed scope [36,44]. These rules could have been applied in BTB cases in European bison in an analogous manner as for the tuberculosis of cows, mutatis mutandis, by considering the differences regarding the protection of the European bison.

Since 2021 [11], MTBC infection has been subject to compulsory control in all EU member states, and each state is required to adopt compulsory eradication programs, until it is not recognized as a disease-free zone. Bison spp., including *B. bonasus*, is also listed as being susceptible to mycobacterial tuberculosis infection. If the competent DVO suspects or officially confirms an outbreak of disease, it must use the control measures set out in the AHL appropriate to the affected area [11,21,22].

Hence, the DVO must follow the procedures of EU law in any establishment in which tuberculosis has been found, such as zoos or breeding centers in which European bison are kept under human control, and in wild animals such as free-living European bison (e.g., in the Bieszczady Mountains); indeed, the AHL is part of EU law. The DVO should select appropriate control measures to facilitate the epidemiological investigation, and to perform eradication, prevention, surveillance and disease control in relation to the appropriate population of wild animals or their habitats [11,21,22]. The competent veterinary authority is also required to consider investigating wild animals from additional animal populations believed to share epidemiological links with any (kept and wild) animals, as indicated by epidemiological investigation. The competent authority is required to order proportionate risk mitigation measures to prevent re-infection of the establishment, and these should consider any relevant risk factors revealed by epidemiological investigation. These measures must at least account for the persistence of the MTBC in the environment or in wild animals, and any biosecurity measures that have been adapted to the specificities of the facility.

Pursuant to the AHL, the protection of an animal species such as the European bison implies the introduction of modified measures for the eradication of disease by a competent authority. The necessity to eradicate BTB, and the measures, methods and techniques used for its eradication, must not pose any risk to the European bison population. On the other hand, no adopted modification may obstruct the procedures carried out to eradicate the disease [35].

It should be noted that the existing national law was not derogated, but only supplemented and modified by the EU law.

4. Discussion

It should be noted that the protection of nature, including animal species protection, implemented in creation of laws and application of their provisions, is not separate to the protection of animals or animal health, and should never be perceived as such.

The legal norms in force in Poland before 2021 were ambiguous and their mutual relations were confusing. Interpreting a uniform, coherent and purposefully correct norm from the text of statutory acts was very complicated. Especially problematic was the application of the statutory law to European bison as a protected species of wild animal. This was the very reason for the response to critical situations in all examined cases. When considering legal obstacles to the eradication of bovine tuberculosis in European bison, it needs to be highlighted that the European bison was successfully recovered from only 12 founder animals that had survived in captivity following its extinction in the wild at the beginning of the 20th century. The strong founder effect caused a dramatic loss of a genetic diversity. For instance, an average inbreeding coefficient estimated from pedigree records was 0.50 in Lowland line individuals and about 0.30 in Lowland-Caucasian individuals. At the genome level, individuals belonging to a population that has recently experienced a strong bottleneck have a greater probability of carrying identical-by-descent (IBD) alleles, i.e., those inherited twice from a common ancestor; these can include deleterious variants that may contribute to inbreeding depression and threaten the recovery process due to low anti-infective immunity [48].

The authors found that in all examined cases, the competent authorities adopted a form of legal interpretation, according to which they were only permitted to control the disease in farm animals, but not in European bison. It should be noted that, in the opinion of the authorities that considered the examined cases, the regulations of that time only allowed for the eradication of the disease in farm animals. All the factual and administrative reactions, no matter if they were correct or questionable, were a corollary of this form of interpretation and resulted from the adopted legal optics.

Present analysis indicates that the problem was not related to the construction or use of legal provisions as such, but rather to their misinterpretation or insufficient application. The cases analyzed in this study were characterized by an abundance of legal norms with unclear legal status, making it hard to understand a single legal norm and act in line with it. Furthermore, some provisions seemed to exclude each other, and many of the legal norms could only have been reconstructed using advanced, complex methods of functional and teleological interpretation, requiring specialist legal knowledge. In the cases discussed in the present study, this confusing legal status resulted in the misconstrued legal provisions, and their eventual misapplication. This was compounded by the fact that the authority in question had insufficient forces and measures to react.

As it was revealed above, the ambiguity of legal standards and the adopted interpretation, or their absence, before 2021, left many crucial problems unregulated. Lack of coherent system solutions can be indicated. A dangerous zoonosis was left without proper administrative supervision.

According to the authors, it was (and is) necessary to approach the discussed problem in a multifaceted and functional manner, and to have broad horizons of thought. The alternative interpretational path, as described in the present study, is an example of how to deal with the epidemic outbreak in case of legal incertitude.

The conclusion presented above can be reached through functional and teleological, as well as systemic interpretation, considering the whole legal order. It assumes a holistic view of the problem and is focused on its real, rather than fragmentary, solution. Regulation [36] was applicable to European bison analogously. After all, the European bison has a similar biology to domestic cattle, and both species demonstrate similar BTB development. The authors are aware that adoption of such an interpretation of the regulations by the administration authority required both courage and extensive knowledge. It could also raise justified, yet not unsolvable, concerns about DVO's competence in this area. Still —a pressing need to protect public health, health of different animal species, including those endangered, should be seen as superior values.

The provisions of the AHL have since come into force, and the law concerning the eradication of infectious diseases has changed. The AHL is directly in force and is applied in the legal system of every member state.

It should be noted that Polish law should be interpreted from a pro-European perspective. The AHL was introduced to unify and simplify the application of legal procedures throughout the EU and make it more flexible. Its rules comprise a number of requirements intended to prevent animal diseases which can be transmitted to other animals or humans and allow their eradication. They are based on the principal meta-rule of "one health".

Not only does the AHL constitute a new quality regarding the eradication of tuberculosis, but it also creates new legal responsibilities and reinforces existing ones. Our present findings indicate the responsibilities, and the competence of the national veterinary inspection authorities, currently stemming from the EU law and Polish national law.

Conducted analysis and legal interpretation proves that the DVO was granted by the AHL the unquestionable competence to act in all investigated cases of tuberculosis in European bison and should therefore now act in line with the AHL when combating bovine tuberculosis.

This calls into question whether the aforementioned crisis cases (that took place before 2021, i.e., while earlier provisions were in force) were properly managed. It is unclear whether the measures taken to combat the disease were sufficient, or whether their scope was too narrow.

To determine whether the veterinary authority took adequate, effective and legally correct actions as a state administration body, it is necessary to examine the situation within a broader context. Such analysis also requires the correct interpretation of the legal provisions of the time, which were complicated and confusing, and could have been misconstrued by the competent authorities. Nevertheless, this does not justify the use of epizootically inadequate methods of eradication of BTB in European bison.

Although the European bison is a strictly protected species, the discovery of an epizootic such as BTB requires the whole herd to be eliminated [14,20,23]. In addition to ensuring public health, such measures also serve to protect the species as a whole.

This statement is in line with the circumstances justifying a derogation from the prohibition of killing the European bison, as given in the catalog of Article 56 Section 4 of the Nature Protection Act [20]. Such circumstances include lack of alternative solutions, no risk of harm to the condition of the wild European bison population, agreement with the best interest of such protected species, and accordance with the interest of public health.

The above circumstances were sufficiently considered in the case of BTB which occurred in the Borki Forest District in 2016, resulting in the swift eradication of the disease focus. The decision of the General Director for Environmental Protection issued in the matter was a standard instance of the abovementioned derogation [20]. More specifically, the elimination of the individual referred to in the permission to shoot was not detrimental to preserving the free-roaming population of European bison in an appropriate condition: the elimination of five animals out of a population of 110 European bison living in the Borecka Forest could not bring any major harm to that population.

Allowing the infected animals to stay within the range, instead of shooting them, poses a risk of disease transmission to humans, as well as free-roaming European bison, and other wild or domesticated animals.

The case of BTB detected in the EBBC Smardzewice in 2013 [47] is an example of the incorrect application of legal norms: the decision to control the disease and eliminate the animals in a stepwise fashion, rather than eliminating the whole herd as a single operation, proved to be a failure. It should be emphasized that Regulation 2020/689 [22] clearly indicates that animals with a suspected infection may have to be shot, together with those with proven infection.

In the case referred above, the DVO should have considered a wide array of other available instruments for disease eradication in addition to the radical elimination of the disease focus, i.e., killing all animals representing the susceptible species, to ensure epizootic security [18]. When choosing such instruments, those that best limit or eliminate the risks to public health, and the spread of infection to livestock and other susceptible wild animals, should be prioritized.

The type of measures used for eradication of BTB and their scope are listed rather generally in the EU regulations, and the specific method of their application is subject to the decision of the DVO conducting the procedure [11,18,21,22]. The discussed provisions use some indeterminate expressions, which give the DVO the liberty of using certain measures that are deemed to be proper in each specific case, based on the circumstances. The measures referred to in both the EU and national legislation are currently subject to the proportionality criterion that it must be adequate and proportional to the risk posed by tuberculosis in a given case [35].

A key disadvantage of the solutions adopted in the Smardzewice case was the extended length of time between detecting the infection and taking measures, i.e., delayed action. Currently, to confirm the presence of disease in its earliest stages, the AHL requires any suspect animals to undergo clinical examination and laboratory testing; this forms the basic component of epizootic investigation in the case of BTB in European bison. However, in all the cases examined herein, it became evident that the plan of action was incorrect and BTB infection was confirmed too late.

It should be stressed that there is more to the control of infectious diseases in animals than just the detection and reporting of infections, the prevention and control of their spread, and their eventual eradication; it should also include preventive actions and measures. In the described cases, it is doubtful that this need was satisfied: the Smardzewice herd was joined by one animal from a zoological garden where tuberculosis in animals had been detected previously, and that particular animal was not tested for Mycobacteria. It appears that this cow may have been the source of infection for that herd [47]. It is therefore reasonable to construe that the unsatisfactory state of the legal provisions regarding the transfer of wild animals was a key factor in the spread of BTB. It was changed by breeders themselves who implemented rule as a good practice and all transferred animals within the country are checked. It is hence of great importance to conclude that the new European provisions concern wild animals in terms of epizootic and epidemic safety, supervision and biosecurity [11,22].

The case of the 2016 Borecka Forest outbreak underlines the importance of veterinary supervision and monitoring tuberculosis in non-domesticated animals. This case was detected during the annual evaluation and review of the European bison herd in the Borecka Forest, performed in accordance with the provisions of the "Strategy for the protection of *Bison bonasus* in Poland" [15]. The current study confirms that such monitoring is in line with necessary supervision, as specified by the AHL.

The essential rules for controlling infectious diseases were not, however, properly implemented in the case of the 2013 Smardzewice case. This was due to a number of factors, including the misinterpretation of the relevant legal provisions, which themselves were unclear; in addition, the tools, financial means and coercive measures needed to prevent infection and the spread of disease were not available to the competent authorities or responsible entities.

5. Conclusions

The analysis highlights key "critical points" in the management of cases of BTB in European bison, which resulted from the problematic interpretation and application of the existing legal provisions. Our present findings indicate that before the AHL, the eradication of BTB in European bison in Poland was not regulated clearly enough by the applicable laws in force before the year 2021. It should be emphasized that in the current legal system, there is no doubt that a DVO has the competence to prevent and control tuberculosis in European bison. Thus, the introduction of AHL has helped to clear legal obstacles to the eradication of bovine tuberculosis in European bison. This is extremely important also in the context of threats of other infectious diseases. However, it is important to note that European bison herds remain at high risk of disease, as demonstrated by a number of previous incidents, due to their low genetic diversity, which makes herds vulnerable to pandemics.

On the other hand, the provisions of the new European law are not very clear either. They raise numerous doubts with regard to legal dogmatic, as well as veterinary, epizootiological or administrative issues. Furthermore, the EU law does not diminish nor derogate the provisions of the national law, but rather modifies their application. The reconstruction of a single legal norm requires the use and interpretation of a wider array of provisions, originating in a variety of European and national statutory acts. There is no doubt that this affects the legibility of the norms, and that it complicates their use by veterinary administration authorities. The application of the AHL in the eradication of BTB in the European bison clearly requires further investigation.

Current analysis of the relevant legal provisions and case studies indicates that ignoring scientific data can result in serious errors in the formation and application of legal norms. Only a thorough knowledge of the relevant legal provisions, and their correct and thoughtful interpretation, enables their effective application in controlling the spread of BTB in European bison, and in other species.

The presented cases clearly point out that proper usage of legal rules is a crucial factor in effectiveness of species conservation.

Usefulness of legal provisions as such is dependent on many factors. Proper and in-depth interpretation of statutory acts has been demonstrated as the most important of them, even more important than the wording itself. Legal effectiveness in the discussed BTB cases was low due to many circumstances. Currently, as the law has changed, its effectiveness is postulated to increase.

The present study demonstrates that proper veterinary control is only feasible when simple and effective statutes exist, which can be implemented easily and without delay. It is essential that tuberculosis is monitored effectively and eliminated. The eradication of diseases in wildlife, including BTB in European bison, minimizes the risk of transmission to free-living animals and livestock, as well as to humans.

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References

1. Lipiec, M.; Radulski, Ł.; Szulowski, K. A case of bovine tuberculosis in pigs in Poland-a country free from the disease. *Ann. Agric. Environ. Med.* **2019**, *26*, 29–32. [CrossRef] [PubMed]
2. Krajewska, M.; Lipiec, M.; Zabost, A.; Augustynowicz-Kopeć, E.; Szulowski, K. Bovine tuberculosis in a wild boar (*Sus scrofa*) in Poland. *J. Wildl. Dis.* **2014**, *50*, 1001–1002. [CrossRef] [PubMed]
3. Didkowska, A.; Krajewska-Wędzina, M.; Bielecki, W.; Brzezińska, S.; Augustynowicz-Kopeć, E.; Olech, W.; Anusz, K.; Sridhara, A.A.; Johnathan-Lee, A.; Elahi, R.; et al. Antibody responses in European bison (*Bison bonasus*) naturally infected with Mycobacterium caprae. *Vet. Microbiol.* **2021**, *253*, 108952. [CrossRef] [PubMed]
4. Orłowska, B.; Augustynowicz-Kopeć, E.; Krajewska, M.; Zabost, A.; Welz, M.; Kaczor, S.; Anusz, K. Mycobacterium caprae transmission to free-living grey wolves (*Canis lupus*) in the Bieszczady mountains in southern Poland. *Eur. J. Wildl. Res.* **2017**, *63*, 21. [CrossRef]
5. Radulski, Ł.; Lipiec, M.; Krajewska-Wędzina, M. Bovine tuberculosis in wild and free-living animals-laboratory studies 2008–2018. *Życie Wet.* **2019**, *94*, 51–53.

6. Aranaz, A.; Cousins, D.; Mateos, A.; Domínguez, L. Elevation of Mycobacterium tuberculosis subsp. caprae Aranaz et al. 1999 to species rank as Mycobacterium caprae comb. nov., sp. nov. *Int. J. Syst. Evol. Microbiol.* **2003**, *Pt 6*, 1785–1789. [CrossRef] [PubMed]
7. Directorate-General for Health and Food Safety; European Commission. Commission Implementing Regulation (EU) 2021/620 of 15 April 2021 Laying down Rules for the Application of Regulation (EU) 2016/429 of the European Parliament and of the Council as Regards the Approval of the Disease-Free and Non-Vaccination Status of Certain Member States or Zones or Compartments Thereof as Regards Certain Listed Diseases and the Approval of Eradication Programmes for Those Listed Diseases. EU OJ L 131/78 of 16 April 2021. pp. 78–119. Available online: https://eur-lex.europa.eu/eli/reg_impl/2021/620/oj (accessed on 16 April 2021).
8. Directorate-General for Health and Food Safety; European Commission. Commission Decision 2009/342/EC of 23 April 2009 amending Decision 2003/467/EC as Regards the Declaration that Certain Administrative Regions of Italy are Officially Free of Bovine Tuberculosis, Bovine Brucellosis and Enzootic-Bovine-Leukosis, That Certain Administrative Regions of Poland are Officially Free of Enzootic-Bovine-Leukosis and That Poland and Slovenia are Officially Free of Bovine Tuberculosis. EC OJ L 104/51 of 24 April 2009. pp. 51–56. Available online: http://data.europa.eu/eli/dec/2009/342(1)/oj (accessed on 24 April 2021).
9. European Commission. Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the Application of Certain Disease Prevention and Control Rules to Categories of Listed Diseases and Establishing a List of Species and Groups of Species Posing a Considerable Risk for the Spread of Those Listed Diseases. EU OJ L 308 of 4 December 2018. pp. 21–29. Available online: http://data.europa.eu/eli/reg_impl/2018/1882/oj (accessed on 21 April 2021).
10. The European Parliament and the Council of the European Union. Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the Monitoring of Zoonoses and Zoonotic Agents, Amending Council Decision 90/424/EEC and Repealing Council Directive 92/117/EEC. EC OJ L 325 of 12 December 2003. pp. 31–40. Available online: http://data.europa.eu/eli/dir/2003/99/2013-07-01 (accessed on 21 April 2021).
11. The European Parliament and the Council of the European Union. 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'). EU OJ L 084 of 31 March 2016. p. 1. Available online: http://data.europa.eu/eli/reg/2016/429/oj (accessed on 21 April 2021).
12. Perzanowski, K.; Bleyhl, B.; Olech, W.; Kuemmerle, T. Connectivity or isolation? Identifying reintroduction sites for multiple conservation objectives for wisents in Poland. *Anim. Conserv.* **2019**, *23*, 212–221. [CrossRef]
13. Regulation of the Minister of Agriculture and Rural Development of 23 November 2004 on Combating Cattle Tuberculosis, Journal of Laws 2004 No. of 2004, No. 258, Item 2585. Available online: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20042582585 (accessed on 21 April 2021). (In Polish)
14. Regulation of the Minister of the Environment of 16 December 2016 on the Protection of Animal Species, Journal of Laws of 2016, No. of 2016, Item 2183. Available online: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20160002183 (accessed on 21 April 2021). (In Polish)
15. Strategy for the Protection of the European Bison (*Bison bonasus*) in Poland, 2007.
16. The Act of June 14, 1960 Code of Administrative Procedure, i.e.; Journal of Laws of of 2021, Item 735, 1491, 2052. Available online: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu19600300168 (accessed on 21 April 2021). (In Polish)
17. The Act of December 21, 1990 on the Profession of a Veterinarian and Medical and Veterinary Chambers, i.e.; Journal of Laws of of 2019, Item 1140. Available online: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU19910080027 (accessed on 21 April 2021). (In Polish)
18. The Act of March 11, 2004 on the Protection of Animal Health and Combating Infectious Animal Diseases, i.e.; Journal of Laws of of 2020, Item 1421. Available online: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20200001421 (accessed on 21 April 2021). (In Polish)
19. The Act of January 29, 2004 on the Veterinary Inspection, i.e.; Journal of Laws of of 2021, Item 306. Available online: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210000306 (accessed on 21 April 2021). (In Polish)
20. The Act of April 16, 2004 on Nature Protection, i.e.; Journal of Laws of 2021, Item 1098, 1718, of 2022, Item 84. Available online: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20040920880 (accessed on 21 April 2021). (In Polish)
21. European Union. Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as Regards Rules for the Prevention and Control of Certain Listed Diseases, EU OJ L 174 of 3 June 2020. pp. 64–139. Available online: http://data.europa.eu/eli/reg_del/2020/687/oj (accessed on 21 April 2021).
22. European Union. Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as Regards Rules for Surveillance, Eradication Programmes, and Disease-Free Status for Certain Listed and Emerging Diseases, EU OJ L 174 of 3 June 2020; pp. In *211–340.*. Available online: http://data.europa.eu/eli/reg_del/2020/689/oj (accessed on 21 April 2021).
23. European Union. Council Directive 92/43/EEC of 21 May 1992 on the Conservation of Natural Habitats and of Wild Fauna and Flora, EEC OJ L 206 of 22 July 1992. pp. 7–50. Available online: http://data.europa.eu/eli/dir/1992/43/oj (accessed on 21 April 2021).
24. Decision of the General Director for Environmental Protection no. DOP-OZ.6401.06.8.2013.bp of August 7, 2013.
25. Decision of the General Director for Environmental Protection no. DOP-OZ.6401.06.22.2013.bp of December 12, 2013.

26. Decision of the General Director for Environmental Protection no. DZP-WG.6401.06.8.2016.JRO of February 29, 2016.
27. Decision of the Minister of the Environment no. DLP-III-4102-121/111622/14/ZK of March 24, 2014.
28. Letter of the District Veterinarian in Giżycko no. PIWz.510.5.2016 of April 13, 2016 to the Borki Forest Inspectorate.
29. Reports of the post-mortem examinations of European bison, performed on 16–17 January 2013 in Wolisko.
30. Report of the commission for the elimination of bison from free breeding in the Borki Primeval Forest of March 29, 2016.
31. Report No. 8-15/16 from the qualifying round of February 17, 2016.
32. Report No. 10-15/16 from the qualifying round of March 3, 2016.
33. Report on the dissection of the animal No. 8-15/16 performed by a veterinarian on February 17, 2016.
34. Report of the post-mortem examination of an animal, performed by a veterinarian, No. 8-15/16, of 17 February 2016.
35. Report of the post-mortem examination of an animal, performed by a veterinarian, No. 10-15/16, of 3 March 2016.
36. Report of the post-mortem examination of free-living European bison in the Borecka Forest, of 29 March 2016.
37. Commission report of the evaluation and review of the European bison herd in the Borecka Forest on 24–25 October 2013.
38. Research report of PIW-PIB in Puławy No. P/16/06394 of April 6, 2016.
39. Research report of PIW-PIB in Puławy No. P/16/08326 of April 28, 2016.
40. Research report of PIW-PIB in Puławy No. P/16/10783 of May 24, 2016.
41. Request of the Forest Inspectorate of the Borki Forest District No. ZŁ-7554-25/13 of October 28, 2013 to the General Director of Environmental Protection.
42. Request of the Forest Inspectorate of the Borki Forest District No. ZŁ-7211.10.2015 of March 30, 2015 to the General Director of Environmental Protection.
43. Didkowska, A.; Krajewska-Wędzina, M.; Orłowska, B.; Krzysiak, M.; Żygowska, M.; Wiśniewski, J.; Bielecki, W.; Olech, W.; Anusz, K. Further epidemiological investigation of tuberculosis in European bison (*Bison bonasus*). *Eur. Bison Conserv. News* **2018**, *11*, 43–48.
44. Didkowska, A.; Orłowska, B.; Witkowski, L.; Olbrych, K.; Brzezińska, S.; Augustynowicz-Kopeć, E.; Krajewska-Wędzina, K.; Bereznowski, A.; Bielecki, W.; Krzysiak, M.; et al. Biopsy and Tracheobronchial Aspirates as Additional Tools for the Diagnosis of Bovine Tuberculosis in Living European Bison (*Bison bonasus*). *Animals* **2020**, *10*, 2017. [CrossRef] [PubMed]
45. Augustynowicz-Kopeć, E.; Krajewska, M.; Zabost, A.; Napiórkowska, A.; Zwolska, Z. Characterisation of Mycobacterium bovis strains isolated from farm and wild animals from Poland. *Bull. Vet. Inst. Pulawy.* **2011**, *55*, 381–383.
46. Krajewska, M.; Załuski, M.; Zabost, A.; Orłowska, B.; Augustynowicz-Kopeć, E.; Anusz, K.; Lipiec, M.; Weiner, M.; Szulowski, K. Tuberculosis caused by Mycobacterium bovis in antelopes in a zoo in Poland. *Pol. J. Microbiol.* **2015**, *64*, 405–407.
47. Krajewska, M.; Orłowska, B.; Anusz, K.; Welz, M.; Bielecki, W.; Wojciechowska, M.; Lipiec, M.; Szulowski, K. Bovine tuberculosis in the bison breeding in Smardzewice. *Życie Wet.* **2016**, *91*, 50–53.
48. Druet, T.; Oleński, K.; Flori, L.; Bertrand, A.R.; Olech, W.; Tokarska, M.; Kaminski, S.; Gautier, M. Genomic Footprints of Recovery in the European Bison. *J. Hered.* **2020**, *111*, 194–203. [CrossRef] [PubMed]