

## ABOUT THE LEGAL FRAMEWORK FOR *EX-SITU* CONSERVATION OF FARM ANIMAL GENETIC RESOURCES IN ALBANIA

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The Albanian National Action Plan for FANGR considers the *ex-situ* conservation of local/native animal breeds as one of the main priorities. The law “On Livestock Breeding” serves as a legal base to implement actions that are foreseen in the National Action Plan. It provides the implementation and establishment of the genebank for cryoconservation and/or *ex-situ in vivo* conservation of local breeds at risk of extinction. Meanwhile it should be noted that, the Albanian legislation does not cover issues related to property rights and use of the materials that are stored in the Cryobank and *ex-situ in vivo* Genebank. Yet, they are treated and considered as a public asset. The establishment and the administration of the Cryobank and *ex-situ in vivo* Conservation bank, are defined as a public institutions right/duty. The Albanian legislation lacks the necessary legal framework in order to regulate the relations between stakeholders and other actors, also misses the specific legal framework in order to develop the transboundary and/or regional issues regarding the exchange of genetic material. The legal and regulatory framework concerning the entirety of the storage conditions and documentations (storage facilities and rules, data management and documentations, genebank security, special sanitary arrangement and legal issues related to the genetic material and data, ownership and IP, collecting new materials and access to genebank) should be developed. Given the lack of necessary infrastructure and human capacities to enable collection, management and administration of semen, oocytes and embryos, the establishment of the Genetic Bank for somatic cells conservation should be a priority. Drafting of the necessary legal framework for the establishment of somatic cells genebank, its management, ownership rights and veterinary rules that should be implemented during collection, handling and storage of biologic materials, has to be elaborated, as an important part of the legal framework.

**Key words:** animal genetic resources; *ex-situ* conservation; legislation; Albania

### ЗА ПРАВНА РАМКА ЗА *EX-SITU* КОНЗЕРВАЦИЈА НА ГЕНЕТСКИ РЕСУРСИ НА ДОМАШНИТЕ ЖИВОТНИ ВО АЛБАНИЈА

Албанскиот национален акционен план за FANGR ја вклучува *ex-situ* заштитата на локалните/автохтоните животни како еден од главните приоритети. Законот "за сточарство" служи како правна основа за спроведување на активностите кои се предвидени во Националниот акционен план. Се грижи за имплементирање на основањето на ген банка за криоконзервација и/или *ex-situ in vivo* конзервација на локалните раси кои се во ризик од исчезнување. Во меѓувреме треба да се напомене дека албанската легислатива не ги опфаќа прашањата поврзани со правата на сопственост и користење на материјали кои се чуваат во Крио-банка и *ex-situ in vivo* Ген-банка. Сепак, тие се третираат и се сметаат како јавна предност. Воспоставувањето и администрацијата на Cryobank и *ex-situ in vivo* конзервација банка, се дефинираат како јавни установи право/ должност. На албанската легислатива и недостига потребната правна рамка со цел да се регулираат односите меѓу засегнатите страни и други актери, а исто така недостасува и посебна правна рамка со цел да се развие на прекуграничните и/или регионални прашања во врска со размена на генетскиот материјал. Законската и регулативната рамка во врска со целината на условите за складирање и документација (објекти за складирање и правила, управување со податоци и документација, безбедност на ген-банка, специјални санитарни аранжмани и правни прашања поврзани со генетски материјал и податоци, сопственост и IP, собирање на нови материјали и пристап до ген-банката) треба да се развива. Со оглед на недостатокот на потребната инфраструктура и човечки капацитети за да се овозможи собирање, управување и администрација на сперма, ооцити и ембриони, воспоставувањето на ген-банка за соматски клетки, конзервацијата треба да биде приоритет. Изготвување на потребната правна рамка за воспоставување на ген-банка за соматски клетки, нејзиното управување, сопственичките права и ветеринарни правила кои треба да се спроведуваат во текот на собирањето, ракувањето и чувањето на биолошки материјали, мора да биде образложен, како важен дел на правната рамка.

**Клучни зборови:** животински генетски ресурси; *ex-situ* конзервација; законодавство; Албанија

## INTRODUCTION

In order to implement the necessary *ex-situ* conservation methods to preserve the indigenous genetic fund, and in particular local breeds at risk of extinction, among others, the drafting of a fully detailed national legislation is required. Referring to the international legal and regulatory framework, this legislation should develop issues related to establishment, operation and work coordination between different institutions, public and private infrastructures responsible for these methods implementation. The drafting of this legislation is not an easy task (“At the national level, the development of adequate AnGR-legislation is not an easy task, especially for developing countries, in that it should ideally strike a balance between conservation and sustainable use on the one hand, and maximization of the national export potential on the other (FAO, CGRFA, November, 2004, 2005 [8]; FAO [9]).

The Albanian Strategy and National Action Plan for Conservation and Sustainable Management of Farm Animal Genetic Resources, underlines: “Approaching Albanian legislation to the EU one, at all its levels, will create real possibility for the implementation of EU standards for FAnGR conservation and management”. In order to accomplish this task, active participation of all stakeholders is necessary.

The object of this paper is the analysis of the actual Albanian legislation for the implementation of *ex-situ* conservation methods for the local genetic fund at risk of extinction. The comparative analysis with the international law and other countries of the region was used to formulate recommendations in order to improve and supplement the national legislation.

### ALBANIAN NATIONAL LEGAL FRAMEWORK FOR *EX-SITU* CONSERVATION OF FANGR

Law No. 9426 of 28.01.2008 “On Livestock Breeding” governs relations between different public and private institutions and all other stakeholders undertaking activities in the livestock and animal production field. In regard to animal genetic resources, the purposes of this law are sustainable use and protection, improvement and conservation through conservation programs (*in-situ*, *ex-situ in vivo*, *ex-situ cryoconservation*).

Article 58 of the above mentioned law, entitled “Conservation of genetic variability”, states

that the Republic of Albania holds and provides genetic resources, in a minimal number of animals, doses of semen, eggs and embryos, for specific species, breeds and lines of farm animals. For breeds and/or lines conservation purposes and in order to ensure the sufficient animal production, the breeding program provides genetic variability of farm animals. Funds for conservation and maintenance of genetic recourses are provided by the State Budget and/or private donors and the Modalities and procedures of conservation and maintenance of genetic recourses are defined by the Council of Ministers. The funds for this purpose shall come from the state budget.

This provision prepares the necessary terrain for further developments of all issues related to the preservation, management and use of farm animal genetic resources. In particular, it can serve as a legal base for drafting the regulatory framework. This framework should regulate the establishment and operation of different structures, infrastructures and institutions that will implement programs for *ex-situ* conservation of local breeds at risk of extinction.

Article 59 sets out the basic principles for the implementation of programs regarding conservation and sustainable use of biological diversity of farm animals. According to this article, the Genetic Bank is defined as a tool for the protection of the biological diversity. Referring to provision 2(a) art. 59, it can easily be noted, that the “Genetic Bank” concept, is used in the most general terms possible. As such, it is considered as a final product, obtained by a set of actions, provided by the breeding programs. This provision provides the establishment of genetic banks for all species/breeds of indigenous, local and exotic animals, regardless of their situation (being at risk of extinction or not). Such liberal vision derives from the definition that the law has given to the genetic bank concept. In fact, this solution does not create real possibilities for effective developments. The intangibility associated with this concept, as well as the very large areas of application, makes its implementation quite hard.

Moreover, the Genetic Bank, considered as a public service tool for the protection of the biological diversity of farm animals, is required to be established and to operate, according to article 59, in compliance and as an integral part of the breeding program. Meanwhile, referring to articles 26 and 30, the time lasting of a breeding program is limited. Therefore, the provision 59/2dh stipulates, that the time lasting of the biological diversity pro-

gram shall be the same with the one of the breeding program. Consequently, by the end of this time, the law provides the cessation of the Genetic Bank activities. Such consequence, contradicts the role of the “Genetic Bank” institution. In particular, in the case of ex-situ biological diversity conservation programs, this situation produces a non-sense product.

Law No 9426 of January 28<sup>th</sup> 2008 does not contain any specific disposition that provides the ex-situ in vivo or cryo ex-situ conservation for local breeds declared at risk of extinction. This issue is treated only in general terms. It is addressed on the provisions for preservation of the genetic diversity of farm animals, but it states only about the in-situ conservation, stressing that, “Programs for protection of the biological diversity of farm animals includes: a) protection of farm animals breeds bred in the Albanian territory, protecting in particular, indigenous breeds at their native environment” (Law No 9426 of January 28<sup>th</sup> 2008 “On Livestock Breeding”, Article 59/2/a.). Not even in the specific provision for the indigenous breeds, (Article 60: Indigenous farm animal breeds are placed under special State protection and the State promotes and supports their typical livestock products), is possible to find any statement related to the need of ex situ conservation as a complementary action of the in in-situ one.

Article 60/5 establishes the protective measures for the indigenous breeds at extinction or at risk of extinction, are defined by the decisions of the Council of Ministers. This provision can be considered as an opportunity for further developments of the legal framework. In fact, the Council of Ministers acts, guidelines, regulations and orders of the Minister of Agriculture, may serve as the legal source for the establishment and the operation of the necessary structures and infrastructures for the implementation of the ex-situ methods.

The legislation that supports ex-situ conservation of AnGR it is usually named, establishment and management of genebanks or cryo-conserved genetic material. This is due to the fact, that the instrument used by the ex-situ conservation programs is the genetic cryobank. Consequently, in order to draft an adequate legislation, the use of concepts such as, semen, oocytes and embryos, body tissues, blood and/or somatic cells is necessary. Law No 9426 of January 28<sup>th</sup> 2008 “On Livestock Breeding” contains specific provisions that deal with these concepts and other issues related to

them, such as production, collection storage and use (Article 26 “Semen”, Article 40 “Oocytes and embryos”, Article 55 “Collection of embryos”).

The Albanian legislation and/or the regulatory framework does not contain any statement regarding the Ex-situ in vivo conservation as an alternative for the conservation of local animal breeds at risk of extinction.

The lack of human and financial capacities for the implementation of Ex-situ conservation methods, as well as the weak attention of the public authorities in order to develop these capacities, are among the main factors influencing the current situation of the Albanian legislation in this field.

For developing countries, which have limited capacities for the implementation of the ex-situ conservation methods for local animal breeds at risk of extinction, as an emergency solution, the establishment of the Somatic Cell Cryobank is recommended (Groeneveld, E. et al, 2008 [2]). This is a cost-effective ex-situ conservation program. The method to acquire diploid cell material, tissue samples (ear clippings), is easy. The Albanian National Action Plan foresees the establishment of Somatic Cell Cryobank. In order to realize its implementation, it is necessary to clarify, before collection, all issues regarding ownership. The legal and regulatory framework necessary for the establishment of the Somatic Cell Cryobank should contain the entirety of the storage conditions and documentations (storage facilities and rules, data management and documentations, genebank security, special sanitary arrangement and legal issues related to genetic material and data).

Albania has already started the establishment of ex-situ in vivo genetic bank conservation for animal breeds, that are declared at risk of extinction. Actually, there are two herds, with about 60 animals each, with Shkodrane” and “Lara e Polisit” breeds of local goats, that are at risk of extinction. This year it is expected to be created even a small herd with 5 cows and 1 bull of the local breed “Ilyric Dwarf cattle” named “Prespa Cow”. This bank, in legal terms, is a public asset. The animals are purchased from farmers. After this point the animals and their offspring are considered public property. It is important to note, that for the establishment and operation of this bank no legal framework was adopted or drafted. The decision to establish it, as a structural unit inside the Agricultural Technology Transfer Center, Korce, was based on Articles 58, 59 of Law No. 9426 of January 28<sup>th</sup> 2008 “On Livestock Breeding”. In these

conditions, the development of a specific legal framework is necessary that must treat issues related to: (i) status of a National Genetic Bank, (ii) conditions that a species, breed or a local population must meet in order to be part of an ex-situ in-vivo conservation program, (iii) property and animals use rights, (iv) animals inflow and outflow from the genetic fund, (v) veterinary, prophylaxis and sanitary modalities, etc.

### COMPARATIVE ANALYSIS

Differences in the state of legal and regulatory frameworks on AnGR management between developed and developing countries are quite substantial (FAO, CGRFA, November, 2004 [5]). Developing countries often identify a lack of capacity as a major obstacle in the development of legislation and regulatory frameworks. With the absence of adequate human and financial resources and weak institutional and infrastructure development they need to develop legislation based squarely on their needs and possibilities (FAO, CGRFA, November, 2004 [8], FAO 2005 [9]). In Albania, as a developing country, legislation development process in field of ex-situ conservation of FAnGR faces the same problems as those cited above.

In order to constitute good legal basis for development and implementation of conservation methods and use of FanGR, the National legislation should treat, in accordance with the EU regulations and International legislation, issues related to: (i) Ownership and Exclusive Rights in Animal Breeding, (ii) Exchange, access and benefit sharing related to AnGR, (iii) Sanitary and Veterinary Regulations of AnGR, (iv) Information and documentation.

The current Albanian legislation does not fully cover these issues in order to refer to all possible cases. The most treated one are those related to sanitary and veterinary regulations (Law No. 10495, of September 29<sup>th</sup> 2011 "On Veterinarian service") Compared with other countries national legislation (A.M.J. van den Dop [1]; Kompan, D., Cividini, A. [5]; Nikolov, V.<sup>et al.</sup> [6]; Ramljak, J., et al. [7]), the FAnGR Albanian one in general, and in particular the ex-situ conservation legislation for breeds declared at risk of extinction, turns out to be the least developed in the region and beyond.

#### *Bulgarian case (Nikolov, V.<sup>et al.</sup> [6])*

The cryoconservation in Bulgaria is performed only in the AI stations, managed by the

Executive Director of the Executive Agency on Selection and Reproduction in Animal Breeding (EASRAB). The National genetic reserve and the National Genebank are institutionalized.

They are state property and are governed by EASRAB and for this reason are provided with a high security level, including biosafety. The semen in the National genetic reserve and the National Genebank is a state property. It is sold by the National Genebank to farmers and organizations related to the breeding process. The EASRAB goal in the near future is to conserve somatic cells and in the long term perspective oocytes and embryos.

The Bulgarian legislation treats issues related to Property conditions for material acquisition, Gathering of new material, Security of the genetic bank, National Genebank assess, Data management and documentation.

#### *Croatian case (Ramljak, J., et al. [7])*

The legal framework consists of the existing legal frame (>21 laws, orders, acts,...). In legal regulations that will be made it is expected to be included agreements between the owner and the genebank/users. Several possibilities are discussed in order to deal with the ownership (i) can be bought, (ii) be donated, (iii) be under an embargo. The legislation is drafted and the guidelines for manipulation with the genetic material (collection, processing, storage and use of the genetic material) are defined. It already treats issues related to costs of collecting, processing and freezing, rights of intellectual property (Genebank is public property of the State), veterinary/sanitary issues, data protection (the Genebank and Institutions decide which information about stored genetic material shall be available to the public). The Croatian legislation for ex-situ conservation has been developed in accordance with the regulations that are defined by the World Organization for Animal Health (Office International des Epizooties).

#### *Slovenian case (Kompan, D., Cividini, A. [5])*

The most important legal document is: "Livestock Breeding Act (2002)". Chapter 6 of this Act treats issues related to Conservation of Genetic Variability and Genetic Reserves of Farm Animals (Art.66 "Conservation of genetic variability", Art. 67 "Biotic diversity in animal husbandry", Art. 68 "Indigenous breeds"). In 2004 the "Decision on conservation of farm animal genetic resources" was approved. Its Article 41 (Scope of conservation of specific indigenous and other breeds in ex-

situ genebank) states: Genebank (ex-situ conservation) in vitro shall be established for specific indigenous and other breeds classified as critical or endangered pursuant to the provisions of the Regulation concerning genetic reserves.

The Slovenian legislation defines: Genetic reserves are determined by the Regulation on conservation of farm animal genetic resources which determines the preparation of requirements for systematic activities ensuring an overview of the minimum reserves of genetic material for each breed of farm animals

In accordance with the Agriculture Law the Republic of Slovenia shall ensure and maintain genetic reserves for species, breeds and strains of domestic animals in the form of a minimum number of domestic animals, doses of semen, ova or embryos and/or other biological material.

Genetic reserves are determined by the Regulations: (i) Storage of genetic reserves shall provide constant verification of viability. Genetic material needs to be restocked in case of an indication of quality deterioration. (ii) Genetic reserves of farm animal genetic resources important for agriculture shall be constantly monitored and controlled by the Public Service for farm animal genetic resource conservation. (iii) Public service shall prepare at least once a year a report on the state of genetic reserves which shall be decided upon by the Animal Husbandry Council and (iv) The Council shall recommend the Minister the proposals for measures if required.

The actual Slovenian legal framework treats issues related to:

(i) Data management and documentation. All collected data (donor pedigree, amount of semen, and micro location of each sample) are managed by the Public Service (PS) for AnGR. The data are inserted into cryoweb database.

(ii) Genebank security

(iii) Sanitary arrangements/regulations

According to the Regulations on conservation of farm animal genetic resources (Article 20) the genetic reserves by species, breeds or strains of domestic farm animals have to be assured and maintained. The PS has to assure the required amount of the genetic material for genetic reserves. The method of the conservation has to assure the quality of the genetic material. Moreover, the applicability of the genetic material needs to be checked. In case of deterioration suspicions the genetic material has to be restored.

(iv) Legal issues (related to genetic material and data) - Ownership and IP

According to the contract between Insemination Centers and PS for the farm AnGR, the ICs preserves the semen for genetic reserves. The PS is the owner of the preserved genetic reserves in the Genebank. The PS make a proposal about the use of the genetic material, and the approval of the proposal is required from the Minister.

(v) Collecting new material: Articles and conditions in Material Acquisition Agreements. According to the Regulations on conservation of farm animal genetic resources (Article 19) the genetic reserves have to be determined by the type of genetic material. The constituent part of the genetic reserves is the amount of semen for assurance of the reproduction and insemination at critical situations. The amounts of semen have to assure the insemination at least two generations by each breed. There are several types of the genetic material for cryoconservation; semen, oocyte, embryo, somatic cells and DNA. Already valued methods of cryoconservation are preferred.

(vi) Access to Genebank: Articles and conditions in Material Transfer Agreements. Transfer and marketing with breeding material are arranged according to the Livestock Breeding Act (Article 103). The breeding material used for transfer has to be indicated according to the regulations and must have a prescribed Zootechnical document.

#### POSSIBLE MIDDLE-TERMS DEVELOPMENTS OF ALBANIAN LEGISLATION

In the Global Plan of Action for Animal Genetic Resources, FAO, 2007, Ex-situ conservation is one of the priority actions (The storage of genetic material for breeding purposes is common for some commercial breeds, but not in all species. However, for local breeds, the collection and storage of animal genetic material have not been adequate. In such cases, it is important to support planned and targeted collecting of animal genetic resources, and to expand ex situ conservation activities. Strategic Area Priority 3. Conservation, GPA, FAO, 2007 [3])

This priority is also included in the Albanian National Action Plan. In the same way the Albanian government defines the priority of the establishment of the National Cryo conservation Bank for local breeds at risk. This priority cannot be realized due to the Albanian conditions where, experience, capacities, scientific and technical

knowledge and the awareness level of the decision makers and other stakeholders are insufficient. In this scenario, planning and development of a middle-term process is necessary. The main phases of this process could be: (i) preparation of the legal and regulatory framework; (ii) investment for the capacity building in laboratory infrastructure and scientific technical staff; (iii) methodology development for the establishment and functioning of the genetic Cryobank, having regard to the Albanian conditions and in compliance with the guidelines prepared by FAO; (iv) awareness development; (v) encouragement and development of regional and international cooperation as a possibility to generate the necessary funds and the exchange of experience in projects and joint programs framework.

Law No 9426 of January 28<sup>th</sup> 2008 “On Livestock Breeding” and Law “On the Veterinary Service Act” should serve as a legal basis for development of legal issues related to ex-situ conservation programs. The legislative development should create necessary conditions in order to:

(i) Establish and strengthen national facilities for ex situ conservation, in particular cryogenic storage;

(ii) Establish modalities to facilitate the use of genetic material stored in ex situ gene banks under fair and equitable arrangements for storage, access and use of animal genetic resources;

(iii) Develop and implement measures to secure ex situ collections from loss of genetic diversity resulting from disease outbreaks and other threats, in particular by establishing backup samples;

(iv) Develop procedures for replenishment of genetic material taken from gene banks, by systematically developing links with live populations, or establishing in vivo populations of breeds at risk at off-farm locations, such as zoos and parks.

Notwithstanding that Albania is not part of the EU, its legislation should be developed in accordance with that of the EU and the International one. Referring to this request and to other countries experiences, among issues that the Albanian middle-term legislative development shall treat, may be distinguished:

(i) Storage of genetic reserves, monitoring and checking.

(ii) Property rights of the cryo bank conserved material. Agreements between donors (farmers) and cryo bank. Access to gene bank: Articles and conditions in Material Transfer Agreements.

(iii) Collecting new material: Articles and conditions in Material Acquisition Agreements.

(iv) Identification, collection processing and storage of (semen, oocytes and embryo, somatic cell),

(vi) Sanitary arrangements/regulations.

(vi) Data management and documentation.

(vii) Genebank security.

## CONCLUSION

In the region, Albania has the lowest level of ex-situ conservation methods for breeds at risk of extinction. Therefore the legislation in this field is underdeveloped. The existing national legislation provides only general provisions in support of ex-situ implementation methods. The objectives set forth by the Albanian National Action Plan require legislative development in compliance with the EU and international law. This legislative process must start by drafting the legal and regulatory framework in order to establish the national cryo bank and the ex-situ in vivo conservation National Bank for local breeds at risk of extinction.

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