CAPACITY BUILDING NEEDS FOR COMPLYING WITH THE REGULATION NO. 511/2014 – PECULIARITIES FOR AGRICULTURE

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Abstract

Romania is a European Union (EU) country with a biological diversity in situ as well as ex-situ due to collections of microorganisms, plant and animal species. However, due to this peculiarity for Romania the implementation of the 3rd objective of the Convention on Biological Diversity (CBD), remain a great challenge. In 2014, the "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity" (Nagoya Protocol), entered into force. Romania signed the Protocol and if ratifying it for the future, will have the chance to implement the 3rd objective of the CBD. Moreover, this activity may be further supported when Romania will comply with the Regulation (CE) no. 511/2014. The purpose of this article is to analyze our country institutional capacity's needs for harmonizing at the general level the implementation of this Regulation. Attention is paid to peculiarities of the country to implement Article 4 of the Regulation, on user compliance measures. The conclusions of this study support the idea that Romania has the capacity to implement and enforce this Regulation. All national authorities must join together for further developing required national procedures. Relevant for Romania are procedures development that are related to access to genetic resources as well as for defining traditional knowledge to users of the third countries. Recommendations are made on access to human resources and for developing innovative financial mechanisms.

Key words: access for benefit sharing, biodiversity conservation, agro-biodiversity, capacity building, Regulation 511/2014

INTRODUCTION

Romania with a rich biodiversity (i.e. species and habitats) is comprising native common such as plant animals macromycetes as well as new strains of microorganisms [40; 45], endangered and endemic species of plants [11; 22] and animals [7]. All these species, due to their genetic material and biomolecules may be defined as resources for further new economic uses and therefore they may become subjects of access for benefit sharing (ABS) if they are accessed by users of a third country. This action may be granted for non-commercial research but when it is proved to become relevant for commercial use, the users need to comply the third objective of the Convention on Biological Diversity or CBD [42]. This is connected for the EU countries to the provisions of Art. 4 of the "Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union" (Regulation). The 3rd objective of the convention supports the development of innovative financial mechanisms that are supporting biodiversity conservation and its sustainable use [6; 25]. In other words, if the use of information inherited by a native living organism, may become a subject of financial gain the third Party have to payback the country of origin. In 2010 it was adopted the Nagoya Protocol and the Regulation entered into force in 2014, thus Romania must implement all required legal provisions for both [9], also considering the Council Decision 93/626/EEC [1; 14]. Therefore, all the European Union (EU) member states must harmonized procedures develop complying to the Protocol on one hand and to the Regulation on the other hand. Romania ratified the CBD based on the Low no. 58/1994. The Romanian Ministry Environment is the competent authority for biodiversity conservation. Other three legally binding agreements are already officially adopted under CBD and all of them are recognized in the context of the EU such as the following: the Cartagena Protocol on Biosafety (i.e. Cartagena Protocol that entered into force in 2003), the Nagoya Protocol (i.e. Nagoya Protocol entered into force in 2014) Nagoya-Kuala and the Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol (i.e. Nagoya-Kuala Lumpur Supplementary Protocol entered into force in 2018). These three new instruments create the international legal framework for harmonizing measures for full implementation of the CBD [31]. For the EU countries by implementing the Nagoya Protocol become a challenge [39] as there is a need for harmonizing legal procedures for all 28-member states. The scope of this article is to emphasize the needs of Romania in capacity building terms, especially regarding the obligation for users related to the access wild biodiversity and traditional knowledge (TK) related to of Art. 4 of the Regulation, Chapter II, user compliance [2].

MATERIALS AND METHODS

This paper follows the capacity building evaluation model for needs and gaps based on a top-down approach [24] and clearly define the central subjects of ABS in accordance with the provisions of Nagoya Protocol and requirements imposed by the "Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union" [3].

RESULTS AND DISCUSSIONS

Building institutional capacity. At the national level of any country, the process of

implementing subjects new legislative generally requires proactive measures for creating connections on an existing basis. Furthermore, there is a need for supporting the implementation of win-win solutions by accessing mainly long-term memory at the institutional level [20]. Such an approach will also access the executive longterm memory that comes with an existing trained human resource and will contribute to the further information management on each subject, including cross-cutting issues [18]. Three different subjects of the Regulation are defined in the Art. 1 and are according to the objective of the CBD: genetic resources or GRs (i.e. genetic information), associated TK (i.e. the knowledge of rural communities in case of Romania) and benefit arising from their utilization (i.e. defining financial mechanisms needed for complying with the third objective of the CBD).

After 1980 progress was recorded for developing all kind of biotechnology branches based upon bioprocesses that can access cell factory for making them more consistently, cheap, accessible and fast technologies [29]. This was the very first stage proving that the genetic information of living organisms is an interesting subject in financial terms. A schematic representation of biotechnology fields as well as the main public authorities having interests for our country is described in Fig. 1.

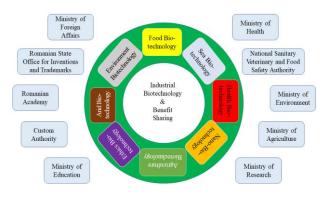


Fig. 1 Research domains and public authorities dealing with different domains of biotechnology as well as with ABS and or TK (Original).

Industrial biotechnology today, in their efforts for patenting life for commercial use, is accessing metabolomics as well as synthetic biology and associated TK depending on the final product [30].

In this context, it is relevant to mention that in paragraph 3 of the Preamble of the Regulation it is underlined that major stakeholders are accessing either GRs either TK. paragraph is in line with Art. 8 j of the CBD. In this regard, for the scientific monitoring of biodiversity, the Romanian Academy through the Commission for Nature Monuments Protection should be involved as a major stakeholder for validating accessing to GRs at the national level (i.e. in situ and ex situ). In 1992 the CBD through the provisions of Art. 4, biodiversity is defined as a heritage of the country jurisdiction [9] and they are already defined as a scientific competent authority working under the Bern Convention. The sovereign rights of the states and parties to the CBD are completed by the provisions of paragraph 6 of the Regulation [36]. However, Romania as a future Party to the Nagoya Protocol should take into consideration how to grant access to GRs for a third Party. This may be complicated further if proves that implies the connectivity to local knowledge or TK of rural communities. One compulsory obligation of the signatory Parties to the Protocol is to report how the Protocol is implemented. The reporting in Romania should be managed by the competent authority for environment as a national focal point. In 2016 parties sent the 6th national report according to the requirements imposed by the Conferences of the Parties. As one of the main subjects of the Protocol is the access on GRs, the management of the subject needs to be addressed by competent authorities already working on biodiversity conservation considering examples of Norway, Brazil or European Union [32]. In this regard, the competent authority for environment should manage the subject and the implementation of the Regulation (Fig. 1-3). The need of experience implementing similar in procedures into the competent authority for environment may be supported by the competent authority for agriculture and namely by the Gene Bank of Suceava as the national focal point of the "International

Treaty on Plant Genetic Resources for Food and Agriculture, or Plant Treaty". Today the Gene Bank from Suceava has the expertise to apply the Standard Material Transfer Agreement or SMTA. This mechanism is working under Multilateral System and up today in Romania have been recorded 3303 accessions to different plant GRs by the Gene Bank from Suceava [4]. A comprehensive paper describing the SMTA implementation was published 12 years ago [10] and Romania may further access the Gene Bank from Suceava for further developing procedures and expertise implying capacity building [13].



Fig. 2 Treaties and Romanian authorities dealing directly or indirectly with the scope of Nagoya Protocol (Original).

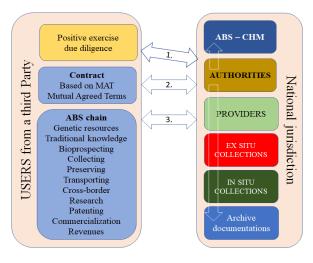


Fig. 3 ABS communication scheme between users and authorities in three stages: 1) the user should prove due diligence according to paragraph 1 of art. 4 of the Regulation; 2) contract signing based on mutual agreed terms and 3) procedures development according to the ABS chain at the national level (Original).

In this regard, it is recommended the close cooperation between the two national focal points. However, Nagoya Protocol is closely interacting with different other international agreements. Thus, aside other biodiversity conservation agreements (i.e. the "Convention on International Trade in Endangered Species

of Wild Fauna and Flora" or CITES and the "United Nations Convention on the Law of the Sea" or UNCLOS) are other adopted under health (i.e. the "Pandemic Influenza Preparedness" or PIP, and the "Framework for the Sharing of Viruses and Access to Vaccines and Other Benefits", World Organization for Animal Health or OIE) [19; 21] trade (i.e. the "Trade-Related Aspects of Intellectual Property Rights" or TRIPS) and the UN World Intellectual Property Rights Organization or WIPO [34].

Therefore, capacity building for new subjects should be started by applying a top-down approach to address all competent authorities working in this case under all potential types of biotechnology, as well as all associated stakeholders having interests in the domain especially for commercial-use biodiversity such as GRs or/and related TK (Fig. 1). Paragraph 18 of the Preamble of the Regulation states that each of the Parties must promote and encourage research with noncommercial intent. However, according to Brundtland Report adopted in 1987, the research should generate knowledge and be a catalyst for developing innovative financial mechanisms for sustainable development. This is not against the scope of the EU Regulation and is only for clarifying the momentum between research commercial intent and with commercial intent

Under the umbrella of the Romanian Academy, the Commission for Nature Monuments Protection should cooperate with other scientific commissions working under different authorities such as the Ministry of Health (i.e. GRs of human health importance), Ministry of Agriculture (i.e. GRs for food and agriculture), Ministry of Research and the Romanian State Office for Inventions and Trademarks. The scope of such a cooperation is to clarify procedural issues related to patenting the access to GRs originating from our country's jurisdiction on one hand and for preventing biopiracy on the other hand [33]. authorities Consequently, the generally responsible for the CBD implementation need

to cooperate with those dealing with the scope

ABS capacity building and biotechnologies.

of TRIPS and WIPO [44]. Among the major stakeholders are the Romanian State Office for Inventions and Trademarks [41] and the Ministry of Research. We add, the Ministry of Agriculture through the Gene Bank from Suceava [27] and the State Institute for Variety Testing and Registration [38] that have appropriate knowledge of closely working with TRIPS, WIPO, UPOV and Plant Treaty (Fig. 2). The competent authority for environment needs to network with the abovementioned authorities for implementing this Regulation.

The research, either public or private of a third party, is the central stakeholder for accessing GRs and/or associated TK. To fully understand how should be further developed unique procedures the competent authority for environment in Romania should cooperate closely with other competent authorities (i.e. for foreign affairs, internal agriculture, research, affairs, education, health) and the Romanian State Office for Inventions and Trademarks. All these stakeholders should be part of capacity building development especially due to research project implementation when they involve third parties. Also, the Romanian Academy through the Commission for Nature Monuments Protection plays already a key role under the current regulatory framework for wild biodiversity conservation [5; 8; 28]. The main concern of the Regulation related to the maintenance of wild GRs of national jurisdiction is that they need working in situ conservation measures. In this case, the Romanian Academy needs to closely work with a network of Scientific Councils including those for protected areas. The wild biodiversity and TK will become a central subject of interest for future strategies of developing the management plans in protected areas too. Furthermore, the custodians of protected areas should be part of stakeholders. Their major scope will be focused mainly on implementing procedures related to permit issues for bioprospecting in the wild for all types of research. However, a holistic national survey regarding TK related to GRs will be required, at least upon the implementation of the Regulation. We mention that such studies and researches regarding the TK related to wild biodiversity are already published for South - East Transylvania [15; 16; 17].

In case of ABS related to patenting products of biotechnologies covering health (i.e. human, animal and plant health), the ABS National Focal Point will closely cooperate with other two institutions. Thus, for human health, they will cooperate with the Ministry of Public Health already running databases under the European Medicine Agency or EMEA and for animal and plant health with the National Sanitary Veterinary and Food Safety Authority (ANSVSA) which is responsible for connecting with DG SANCO at the European level. Both national focal points need to be involved in capacity building developments under the ABS mainly due to pathogens of public concern to the health of human beings, animals or plants [9]. In all cases GRs are subject of trade as species, specimens or simply compounds or products and the ABS national focal point need a cooperation with specialized offices working under the Custom Authority of the all country. In this case, identified stakeholders need to be part of ABS procedures development for all chain (Fig. 3). Users compliance. According to Art. 4 paragraph 2 of the Regulation it is stated that the transfer and use of GRs and TK knowledge will be in accordance with "mutually agreed terms" (or MAT) to sign a specific contract with the user. Romania needs to develop such legal procedures and all users need to exercise due diligence to ascertain that GRs and TK associated with the first which they utilize have been accessed in compliance with the national legislation based on paragraph 1 of Art. 4. To note the paragraph 5 of the preamble defined the TK in line with the provisions of Art. 8 i of the CBD.

In line with Art. 4 of the Regulation and connected to wild biodiversity we need to take care of the preamble recommendations stating that all native GRs need to be maintained *in situ* conditions and therefore the future strategy of biodiversity conservation need to address the Millennium Development Goals too. Such an aim will need to further integrate innovative financial mechanisms into all

economic sectors that are dealing directly or indirectly with the sustainable use of biological diversity. In this case, protected areas management structures need to closely work with the Romanian Academy's scientific commissions as well as with the Ministry of Economy.

Based on this approach we mention that the competent authority for environment from Romania has a long-term capacity of working on international and European databases related to GRs if considering the Convention on International Trade in Endangered Species of Wild Fauna and Flora or CITES and Biosafety under Cartagena Protocol biosafety. Therefore, to complete the development of national procedures connectivity to the CITES database as well as to the Cartagena Protocol need to be evaluated. The access to in situ GRs can be realized based on bioprospecting or/and collecting from the wild protocols that should be part of a contract based on MAT. The procedure should relate to CITES and non-CITES permits' procedures when the user belongs to a third party. The monitoring system for collecting and transferring genetic material up to patenting and trade of final product/service should be in place in close connection with other research institutions.

The full implementation of the provisions of Art. 4 paragraph 3 needs an appropriate communication system development and the communication future ABS should transparent, based on the provisions of Preamble of the Regulation, paragraph 10, to ensure the needed trust of cooperation between Parties. Also, integrating local communities the future ABS in communication system is relevant for all stakeholders when accessing GRs as such or by using the local or TK. Moreover, in the Preamble of the Regulation paragraph 15 it is underlined the need to clarify derivatives term under the ABS Protocol which is different compared to the CBD and Cartagena Protocol on Biosafety. However, the term includes biological compounds that may result in the action of the secondary metabolism and may not be directly connected to the codons of the deoxyribonucleic acid [26]. Based on this it becomes clear that it will be more difficult to accept wild PGRFA not listed in Annex I of the Plant Treaty to not be a subject of the future ABS regulatory framework of our country. In this regard, we mention that the development of terminology, processes, and concepts may rise more barriers in smoothing the future implementation of the Regulation [12].

In line with the same paragraph 3 of Art. 4 of the Regulation each of the countries need according to paragraph 16 of the Preamble of the Regulation to raise the attention on microorganisms and mainly on viruses that may be produced as well as on access to vaccines for human and animal health such as the PIP framework [23]. For all the abovementioned cases, the users must apply, keep and even transfer to subsequent users the internationally recognized certificates of compliance and information related to MAT that are relevant and fall under the scope of further ABS monitoring system [37]. As mentioned above, such an expertise already exists in Gene Bank from Suceava working under the Multilateral System.

Archiving ABS documentation will be compulsory at the EU level as the European Commission will establish and maintain a register of collections within the Union according to Art. 5 of the Regulation. Moreover, all users are obliged to maintain for 20 years at least documentation after the year of their utilization according to paragraph 6 of the same article. The ABS Clearing-House mechanism is compulsory to be implemented. The term user is also defined under the paragraph 17 and this should be consistent with the definition of utilization of GRs as it is in the Nagoya Protocol (Fig. 3).

However, for wild PGRFA that are closely connected to the Plant Treaty implementation, the Gene Bank from Suceava need also to be involved. Users accessing and acquiring wild PGRFA others than those adopted in the list of species of Annex I of the Plant Treaty may become the subject to the terms and conditions of the standard MAT for the purposes set out under this treaty or not depending on the signatory Party. These users according to the EU Regulation, shall be

considered to have exercised due diligence in accordance with paragraph 3 of Art. 4.

Thus, for Romania, a major subject of a debate should be wild PGRFA that are not listed in Annex I of the Plant Treaty.

We add herewith the TK that is not mentioned in the Plant Treaty, but it is defined by the CBD, Nagoya Protocol and the Regulation.

Therefore, in paragraph 4 of Art 4. of the Regulation it is not imposing to the member states to expand the mentioned list of species. This makes possible discussions to be conducted on this issue: if Romania will expand or not the list of Annex I of the Plant Treaty or simply is imposing to the user to comply with the provisions of paragraph 3 of the Art. 4 of the Regulation. We mention that in the Preamble of the Regulation, paragraph 12, it is stipulated the need for harmonizing the existing system working under the Plant Treaty such as the Multilateral System with the future working on a complimentary basis. This controversial issue is also outlined in Preamble of the Regulation in paragraph 13 where it is stipulated that PGRFA, not listed in Annex I of the Plant Treaty should be treated under the Multilateral System. We mention that here it is the case of wild PGRFA as well as related TK and differences between EU members states related to biodiversity may be. However, now it is still possible that each of the countries will decide on their own. In this regard, it is compulsory to harmonize for long-term effects under economic predictions the connectivity between the Romanian competent authority for environment and the Gene Bank from Suceava, in its capacity of the national focal point under the Plant Treaty as well as the Patenting Office.

The case study of collections is presented in paragraph 7 of Art. 4 of the Regulation opening the possibilities for the countries to consider as owning GRs with different origins if they can prove that they entered the country before 1992 with the adoption of the CBD [43]. According to paragraphs 27 and 28 of the Preamble of the Regulation, collections, and collectors from the wild are to be defined. Standards should be applied for the EU recognition of collections. Thus, Romania

may provide to users the full access to all GRs from the wild as well as from public collections (i.e. microorganisms, plants, animals as species or specimens). The Botanical Garden Association expressed their interest for supporting the implementation of the Nagova Protocol. This is an opportunity for creating innovative financial mechanisms for further using biological diversity under the third objective of the CBD.

All potential pathogens are accordingly regulated in the provisions of paragraph 8 of Art. 4 of the Regulation and they should comply with the EU regulatory framework. A control ABS system should be in place and work for the implementation of the recommendation of paragraph 19 of the Preamble where it is stated that due to ethical issues the Regulation will not include access to human GRs.

For fully implementing the provisions of art. 4 of the Regulation all users need to comply the due diligence that is imposed to all potential users and applicants. Each of the Parties develop should appropriate diligence according measures to the business environment and by considering already working best practices. Of high interest will be users form non - parties' countries that intent to apply for ABS.

CONCLUSIONS

Regulation (EU) No 511/2014 will become a real challenge for the Romanian authorities to be implemented. It is compulsory that all relevant stakeholders to get together and discuss, based on the ABS chain, the substance for procedures development in harmony with those already existing or to develop new other. Scientific advisory bodies should be involved for developing appropriate procedures when setting MAT for contracting the access on GRs, and/or TK. The user compliance procedure for Romania will be harmonized in the EU context. However domestic procedures should be evaluated for cost-efficiency and revenue supporting biodiversity in Romania. The main principle guiding capacity building

implementing this Regulation is that of sustainable development and accordingly innovative financial mechanisms should be in place. This should include the re-definition of rural communities, local knowledge and TK related to the conservation and sustainable use of biodiversity. Romania has the capacity to fully implement the Regulation 511/2014.

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