

BEST PRACTICES IN THE EUROPEAN COUNTRIES FOR COMPLYING THE NAGOYA PROTOCOL

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Abstract

By adopting the Nagoya Protocol, the international community is responding to the 3rd objective of the Convention on Biological Diversity (CBD). It refers to the fair and equitable sharing of benefits resulting from the biodiversity use and it is the intention of the parties to the CBD to create innovative financial mechanisms working for its conservation. For the regional level the EU adopted the Regulation (CE) no. 511/2014 for providing the harmonizing framework in the implementation of the Protocol. For the year 2017, 15 Member States' reported to the Secretariat of the CBD on the state of implementation of the Protocol on voluntary basis. The purpose of this article is to identify best practices in managing new topics for Romania in this field, such as synthetic biology, digital sequence information, biopiracy related to patenting, traditional knowledge and local communities for further development in agriculture. These subjects have also been addressed during the meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA 22) which take place in 2018. Relevant stakeholders for Romania were identified and they should be involved in the general debate on these subjects. The national consultancy is of utmost importance for developing the legislative framework in Romania by taking into account the financial costs of implying the full implementation of the Nagoya Protocol.

Key words: *synthetic biology, biopiracy, best practices, digital sequence information on genetic resources, traditional knowledge, local communities, Nagoya Protocol*

INTRODUCTION

Biodiversity is at the heart of world economy since the origin of humankind and starting with 1992, the year of the Convention on biological diversity (CBD) adoption, it is more than ever acknowledged the relevance of its impact on our sustainable development [15]. After 1992 a myriad of subjects and their attributes or characteristics have been identified and defined for supporting our future sustainable development. Among these subjects, agro-biodiversity as a concept was under constant negotiations and new attributes were given in direct connection with bio-economy. Interconnecting biodiversity with socio-cultural and economic values was very well captured in the text of the Convention [39]. If species and ecosystems were easy to be evaluated, for genetic resources took almost 18 years up to the momentum when the Protocol was adopted [27]. The Protocol is interconnecting a broad range of research fields and it is supporting among others the

conservation of traditional knowledge (TK) as a cultural value related to indigenous local communities (ILCs) or local communities (LCs) in line with Art. 8 j) of the CBD. TK is relevant for agriculture development. This can be also associated to local knowledge in case of rural communities. This knowledge is relevant for biodiversity conservation as well as access to genetic resources. We further need to define TK in our regulatory framework.

Principles, defining global legal frameworks, under which national regulatory frameworks for Nagoya Protocol implementation can be developed are already setting all over the world innovative financial mechanisms in scattered and different maturity grade. Not all screened countries were ready after 2010 to foster the development of their own regulatory framework for implementing the Protocol. However, the experience in different subjects generated by the Protocol can be identified almost in all studied countries at a certain extent depending on their political vision.

European Union (EU) was a leading group for finalizing the negotiation and adoption of the Protocol. Thus, in the regional context Romania as well as all Member States should implement the Protocol in a harmonized way. At the EU level, it was adopted the Regulation (EU) No 511/2014 (Regulation) for harmonizing among the EU member states the implementation of the Nagoya Protocol. As the process is too complex it was needed to develop and adopt another supplementary legal act namely the Regulation (EU) 2015/1866 for laying down detailed rules regarding the register of collections, monitoring user compliance and best practices. Standards and standardization process were needed for harmonizing the data collection from all member states. The level of compliance of the Member States towards the requirements imposed at the global level can be understood by accessing the portal of Access and Benefit-Sharing (ABS) Clearing-House (ABSCH) [2]. After three years of entering into force of the Protocol (i.e. 2017), all parties were invited to first report its implementation. 15 national reports and one of the EU have been submitted to the ABSCH by 2017. Generally, the EU countries do not encounter important problems in reporting together the implementation of the Nagoya Protocol [1].

For the national level, there are no harmonized access measures established at the EU level, especially due to different regulatory frameworks working for example for patenting as well as under the regulatory framework for intellectual property rights. Another issue is related to defining and harmonizing the checkpoints on the ABS chain of activities at the EU level. Based on the Regulation a major check-point is defined in the Art. 4 of the Regulation. Other checkpoints can be depicted when considering gathering due diligence declarations. Such declarations are meant only when on the market will be placed products after accessing genetic resources and associated (TK). These issues related to checkpoints were first mentioned in 2011 [10]. Romania as Member States into the EU makes efforts in complying the provisions of the Protocol as well as of the

current EU Regulatory framework. However, the novelties of the subject in managing certain subjects defined by the Protocol are delaying the taken into action at the national level. The scope of this article is to emphasize best practices related to specific subjects encountered during the Nagoya Protocol implementation for all the 15 Member States that reported to the ABSCH to provide a better understanding regarding the expertise needed for experience exchange inside the EU. The targeted subjects are as following: synthetic biology (SB), biopiracy, TK and LCs in close connectivity to agriculture development. These subjects are matters international negotiation for further developing procedures and they were intensely discussed during the 22nd meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA 22) from 2-7 July 2018 followed by the meeting of the Subsidiary Body on Implementation (SBI 2) that took place between 9-13 July 2018 [3].

MATERIALS AND METHODS

This paper follows a top-down approach [24] to identify and discuss potential subjects relevant for our country in the implementation of the “*Nagoya Protocol Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization*”. The Protocol implementation is harmonized at the European Union level between the members states based on 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*”. The identified subjects are discussed for the 15 EU countries that reported to the Secretariat of the ABSCH for emphasizing their expertise. The identified countries are as following: Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Malta, Netherland, Poland, Slovakia, and Cyprus. The identified subjects

are as following: SB, biopiracy, TK and local communities. Such subjects need to be addressed appropriately by the national legislation in harmony with the EU Regulatory framework. In this regard we mention that according to the Regulation (EU) No 511/2014 the key elements needing a major attention were clear: a) the legislative frame for the user's compliance (Art.4), b) the way defined to register and access the collections (Art.5), c) the focal points with the list of the competent authorities of the Member State (Art. 6), d) the monitoring of the user compliance (Art. 7) and e) surveillance (check) on user compliance (Art. 9). All these regulatory issues should be included in a chain Plan-Do-Check-Act as in a Deming wheel which transposes a quality management method PDCA in this case applied to the genetic resources [43]. According to the provisions of paragraph 2 of the Preamble, Art. 5 and 8 of the Regulation, "*all members states must provide information for voluntary tools, namely registered collections and best practices, to assist users in complying with their due diligence*" and these obligations are framed under the provisions of Art. 4. To support this approach the EC published a portal for providing complete information regarding the ABS regime also based on public consultation published in 2016 [31].

RESULTS AND DISCUSSIONS

International aspects. Among the concluding remarks of the SBSTTA, working under the CBD, it can be underlined the strong development of SB such as: broadening the organisms that can be modified, the access to new tools and technologies, the novelty in environmental risks associated with living modified organisms release. Also, it is imposed the development of tools dedicated to detection and monitoring into the environment of organisms, component derived thereof and products of SB. Such measures should be followed by new risk management rules and procedures. The impact of SB on economic growth should be connected to environmental protection to be in line with Brundtland Report [9]. Some of the above-mentioned

subjects discussed by SBSTTA are already addressed by experts from the European Union countries. Thus, these countries will be analysed in this paper as potential sources of expertise to be accessed for Romania when should consider capacity building needs in this area. In this regard, new potential resources belonging to genetic resources that may be interesting for agriculture should be further discussed.

European Union designated the European Commission (EC) as the regional focal point for reporting at the regional level the status of implementation of Nagoya Protocol. We underline that the philosophy of the European Union is that countries have sovereign rights over their own genetic resources found on their territory. This will imply all genetic resources (i.e. the access to DSI and biomolecules as new resources) found *in situ* or into *ex situ* collections. For this the economic principle according to which any benefit arising from their access should be shared in a fair and equitable manner with the country providing these resources, is applied [10; 37].

Austria it is recognized among the leading countries relevant in the long process of negotiation for adopting the Protocol, and based on their report published in 2017 the Division on International Environmental Affairs of the Federal Ministry of Agriculture, Forestry, Environment and Water Management is in charge with its implementation at the national level, in the European and international contexts. According to their report harmonizing between the nine regional regulatory frameworks is the most challenging from administrative point of view. TK was not a subject of the current regulatory framework like all western European countries. Among the major goals of Austria, we may mention their interest in tracking patents such as that related to antiparasitic compounds extracted from the African plant species *Aframomum aulacocarpos* [30]. Companies in Austria are also interested in accessing digital sequence information (DSI) related to genetic resources [25].

Belgium nominated at the federal level the General Directorate for Environment of the Federal Public Service of Health, Food Chain Security and the implementation falls under the Federal, Regions and communities' levels. The authorities published a national study which underline that the implementation of the Protocol should be realized step-by-step, gradually based on a proactive approach [12]. Belgium proves it's interested in speeding the implementation of the Regulation [44] and promoting SB in different universities such as Ghent University [21]. An excellent review regarding DSI and SB was published by Belgium experts during 2013 in close cooperation with Norway [46].

Bulgaria nominated the competent authority for environment as the ABS National Focal Point NFP, responsible for managing due diligence declarations of users. This is closely working with competent authorities for agriculture and economy. At least one case is documented for Bulgaria that already applied a specific procedure of the Protocol: Prior Informed Consent (PIC). This was related to procedures developed for an animal case, in to generate Internationally Recognized Certificate of Compliance (IRCC) [25]. Bulgaria developed also a penalties system for non-compliance cases that should be a valuable expertise [35].

Czech Republic. The Ministry of the Environment as well is the ABS NFP. They are advanced in creating and developing their national framework for Nagoya Protocol implementation. Thus, starting with 2015 researchers studied ways and means to comply with Nagoya Protocol provisions regarding the use of microorganisms and in this case the use of bacteriophages for antibiotics production [4]. The use of quinoa (*Chenopodium quinoa* Willd.), for food production in European countries including the Czech Republic, was already documented for Nagoya Protocol compliance considering that the species is originating from South America and is not listed under the Plant Treaty [7].

Denmark proved a great leadership in implementing the negotiation and adoption of Nagoya Protocol aside Germany, France,

Netherland, UK, Finland, Austria, Belgium, and other European members states [22]. A significant contribution to the development of the Nagoya Protocol's text was given by these EU countries aside Norway [38]. Based on these authors their interests are major and their concerns were mostly oriented to share the benefit arising from the ABS. As an NFP was nominated the Danish Environmental Protection Agency working under the Ministry of Environment and Food. According to the national legal framework, Denmark requires first a notification system implementation for ABS. At the very general level all users are required to send a standard notification to competent authority when they are bioprospecting for sampling Danish genetic resources especially for clarifying their intention in the scope (i.e. non-commercial and potential commercial use). By applying the due diligence principles regarding the former experience in ABS, Danish legislation is forbidding the access to users not complying this requirement. Also, they take care of defining the TK in connection to the ABS by applying the same principle. They are using in the estimation of the penalties and fines the potential economic benefits that may arise through the violation of the legislation in a similar way with Malt, Bulgaria, Portugal for the EU and Norway and Switzerland [35]. In this regard, the users not complying with the current regulatory framework can be even imprisoned for two years. Well defined are the checkpoints of the ABS chain that are relevant for the monitoring system as a basis for enforcement of the ABS regulation. Danish experts extended their knowledge and expertise to other countries such as Australia [35] or India [34]. The interests of Denmark are also well related to patenting as they revised the patenting legislation with specific provisions regarding the disclosure of genetic resources in patent applications like Norway or Sweden. Denmark and Sweden rank higher among the EU counties for patenting [38].

Estonia. The competent authority for environment as well is the NFP for the Nagoya Protocol. The legal framework was assessed for collecting from the wild [23]. The

cooperation in the Baltic Sea with Nordic countries will make easier the process of harmonizing the implementation of the Regulation [19; 45]. The cooperation between the competent authority for environment with those of agriculture, education and research provides new insights for the vision of the country for crops and livestock improvement for the future.

Finland is part of the leading countries for the negotiation and adoption of the Nagoya Protocol as well. The direct connection between the Finnish Environment Institute, Natural Resources Institute and the competent authority for environment shows the strong orientation and clear vision towards focusing on research and education up to SB [6] and beyond [42] for accessing genetic resources outside the country as well.

France is one of the best examples in the negotiation for the Protocol related to biodiversity not established in Europe but belonging to countries from the EU. The interest of France is also grounded by its contribution to the Nagoya Implementation Fund managed by the Global Environment Facility (GEF) together with Norway, Switzerland and Japan [28]. Their interests go for patenting life for plants, animals, medicine, and research as well [11]. Excellent knowledge is recognized in the domain of biopiracy, in some case studies related to TK and the ABS generally [8; 5]. In this regard, it should be underlined that TK related to genetic resources was recognized in French Guyana and not in France up to 2014 [13]. Also, in France, it is established a close cooperation between Ministry for an Ecological and Solidarity Transition and the Ministry for Higher Education, Research and Innovation. French and Belgium experts published a review related to SB and its economic impact during 2016 [14].

Germany as a leading EU country in the negotiation and implementation of Nagoya Protocol has established new procedures published also in English on the website of the Federal Agency for Nature Conservation closely working with the ministerial division entitled *Competent National Authority for the Nagoya Protocol*. In Germany it was only

recognized the *access to genetic resources*, and TK was not considered into the domestic legislation up to 2014 [29]. Germany has now an extensive expertise on legal issues related to biopiracy and patenting. One famous case is related to a patent based on the access to *Pelargonium sidoides* by a German phytopharmaceutical company in 2010 [29]. New concepts and innovative future development strategies are defined for the promotion of domestic bio-economy and conservation [32].

Hungary is trusting the National Inspectorate for Environment, Nature and Water with the Nagoya Protocol issues based on the first interim report published in 2017. Hungary developed already controlling activities in different ABS checkpoints and is granting access to all genetic resources for research [40]. Hungary may provide expertise for TK conceptualization and integration into the domestic legislation based on the first judgment case recorded in 1997 of intellectual property rights: Gabcikovo-Nagymaros, Hungary versus Slovakia [33].

Malta through the Plant Health Directorate was also involved with other countries in developing collection standards under the Plant Treaty [17]. Malta was also involved in the conceptualization of the CHM under the United Nations in 1967 [18] and has interests in research developments.

Netherlands is recognized internationally for their active involvement in the negotiation of the Nagoya Protocol. They are implementing the Protocol with the support of the competent authority for economic affairs, revealing among lot of countries their willingness to fully implement the sustainable principles defined by the Brundtland Report in 1987. Netherlands showed its interests in developing specific domestic legislation for access of all genetic resources and furthermore, broadened the group of experts providing expertise on the subject [12; 28]. It is worthy to mention the proactive governmental policy document *Sources of Existence* adopted in 2002 which encompasses a policy of free access to all genetic resources occurring in all Dutch. They also defined the bio-cultural heritage in direct connection with LCs and their efforts in the

conservation and breeding. The ownership towards their local genetic resources it is well established based on the Dutch Civil Code. The today interest in implementing the ABS regime is going behind plant pathogens [36], bio-control [26] human and animal health [25].

Poland is represented in the Nagoya Protocol implementation by the competent authority for environment and developed procedures to develop research in the domain [16; 41].

The Slovak Republic nominated as a national focal point the Slovak Environmental Inspectorate and developed expertise in biopiracy and research [20].

Cyprus is running ABS procedures through the Department of Environment from the competent authority covering agriculture, rural development and environment. Among other different countries, Cyprus was already assessed for capacity building related plant bioprospecting from the wild [23].

Romania. The national focal point for Romania is nominated for the competent authority for environment and for the implementation of the Regulation was nominated the National Environmental Protection Agency. However, the ABS regulatory framework is not yet published on the websites and do not generated the report to the CBS-CHM. Romania do not reported under ABSCH for 2017. The conclusions of a forum run by the EC and implying 25 major stakeholders supported in 2016 the development of guidelines documents. 10 of these were governmental bodies and 15 belongs to industry and non-profit organizations. For 7 organizations there exists no membership for our country or organizations from our country and most of them may fall under agriculture interest for the country. At least 12 other organizations include our country either as public or private organizations. The list may provide an image of the type of stakeholders that need to be addresses on the subject in our country to further define the checkpoints relevant for the country (Table no 1).

By analysing the list of stakeholders, and some of the above-mentioned expertise already proved at the EU members states, it

can be considered the need to further continue documentations related to some subjects. Only the University of Agricultural Sciences and Veterinary Medicine from Bucharest represented their interest for the topics proving their major impact in this domain. This expertise may be broadening in the network of the same type of public universities.

Related to biopiracy and intellectual property rights protection we need to take into consideration the need to further evaluate the impact of SB and DSI on the appropriate implementation of the Nagoya Protocol.

Table 1. EU Forum Participants and identified potential Romanian stakeholders

Crt. no.	Forum participants
1	<i>Arche Noah</i> through ADEPT Foundation
2	<i>Association of the European Self-Medication Industry</i> through RASCI Romanian Association of the Self-Care Industry
3	<i>BGCI (Botanic Gardens Conservation International)</i> through the Association of Romanian Botanic Gardens (AGBR)
4	<i>DNR (German League for Nature)</i> through 2Celsius
5	<i>EU Specialty Food Ingredients Group (AMFEP/EFFCA)</i> through: Alinda Ro srl, Azur SA and Frutarom Etol Ro SRL. <i>DuPont</i> through Pioneer Hi-Bred Seeds Agro SRL and <i>DuPont Romania S.R.L.</i>
6	<i>European Association of Bio-Industries</i> through companies having branches in Romania
7	<i>European Federation Pharmaceutical Industries & Assoc.</i> through pharmaceutical industry associations in Romania
8	<i>European Forum of Farm Animal Breeders</i> – not yet accessed.
9	<i>European Regional Focal Point for animal GR</i> through the University of Agronomic Sciences and Veterinary Medicine Bucharest
10	<i>European Seed Association</i> through AISR (Romanian Seed Industry Alliance) and AMSEM (Romanian Association of Breeders, Producers and Traders of Seed and Propagating Material)
11	<i>FoodDrinkEurope Group</i> (incl. COFALEC and EFFA) through ROMALIMENTA – Romanian Patronal Federation from Food Industry
12	<i>International Biocontrol Manufacturers Association</i> - not yet accessed.
13	<i>International Chamber of Commerce</i> – through - ICC Romania.
14	<i>International Federation for Animal Health</i> - not yet accessed.
15	<i>International Fragrances Association/UNITIS</i> - not yet accessed.

Source: original table based on the information available at <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=31024&no=3>

The future vision of national public research needs to take into considerations these subjects that are valuable for patenting and furthermore to be integrated into the next economic policy vision at the European and

global level. It is also relevant to discuss other subjects of socio-cultural importance such as TK and local communities. If TK is not yet defined by our current regulatory framework it can be further considered for its relevance to be defined as a subject related to genetic resources in the context of biological diversity conservation and mainly connected to rural communities and further agriculture development. Moreover, it should be analysed for further possibilities to connect local knowledge to the cultural identity that it is recognized according to Art. 6 of the Romanian Constitution. This would be the very first step ahead to link LCs to the proper implementation of art. 8 j of the CBD in our country to ensure for long term the conservation and sustainable use of biodiversity. Thus, TK and LCs may be defined for the first time for their integrative role for the support of biodiversity conservation and sustainable use. The presence of competent authorities for international affairs and economy would be of utmost importance in understanding the value of ABS as well as of funding new innovative financial mechanisms for agriculture especially.

CONCLUSIONS

Implementing in Romania the Nagoya Protocol is not an easy exercise. A series of subjects such as SB, DSI, biopiracy as well as TK and LCs need to be analysed and defined for the peculiarities of the country. It can be considered that an enormous amount of scientific literature was already published and covers these subjects that have been addressed also for the 22nd SBSTTA meeting and the 2nd SBI meeting under the CBD. At least 15 EU countries reported to the ABSCH during 2017 and each of them may provide excellent expertise in all identified subjects. In terms of capacity building, most of the countries included the Ministry of Agriculture among the major stakeholders aside Ministry of Environment. Therefore, agriculture should occupy a central role in Romania for further development and implementation of Nagoya Protocol. Countries such as Austria, Belgium,

Denmark, Finland, France, Germany and Netherlands may provide excellent expertise in further developing domestic regulatory acts connected to implementing the Protocol as well as on SB and all related subjects. Also, Bulgaria and Hungary may provide their experience in biopiracy as well as in ABS checkpoint development under the current regulatory framework. An appropriate regulatory framework may be further developed with the full support of all stakeholders. Some of them are already identified and others are easy to be invited for an ABS forum on the subject. For the future, it will be relevant to analyse subject by subject all recommendations adopted under SBSTTA negotiations for their country's economic impact, capacity building needs, the socio-cultural impact for further harmonizing the implementation of the Regulation 511/2014 at the EU level. Furthermore, by taking into account the relevance of these subjects under the EU biodiversity conservation policy vision it should take care of information control and validation in order to increase data management quality as a step by step process under continuous development.

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