Information on Access and Benefit Sharing regarding the Utilisation of Genetic Resources under the European Union Legal Regulation

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1. *Introduction.* The chapter aims to analyse how, in the European legal system, Access and Benefit-Sharing information are exchanged and this could help the implementation of the Nagoya Protocol and its goals, whether data flow could be controlled and whether legal consequences for infringement of rules on information exchange and storage would be more well-defined and reinforced. 'The EU law defines positive duties of behaviours with a focus on information'[1]. However, for genetic resources or associated traditional knowledge which have not been accessed following applicable access and benefit-sharing legislation or regulatory requirements at a national or international level, this 'is not a straightforward prohibition of utilization'[2].

The Nagoya Protocol is an international agreement, which aims at sharing the benefits arising from the utilisation of genetic resources in a fair and equitable way.

Before the Nagoya Protocol, the Convention on Biological Diversity (CBD) was the most widely applied rules for 'Access and Benefit Sharing' (ABS). The Nagoya Protocol on access to genetic resources and traditional knowledge associated with genetic resources complies with Art. 15 of the CBD, which concerns the fair and equitable sharing of benefits (monetary and non-monetary) arising from the utilisation and commercialisation of genetic resources. Such benefits should accrue to the holders of genetic resources and traditional knowledge, particularly indigenous and local communities, from whence the genetic resources have been obtained. Emphasis is also placed on capacity building, particularly in developing countries with a priority on capacity building for women. This may also involve technology transfer. The Nagoya Protocol is therefore relevant to both the private and public sectors, in which it is incumbent upon these organisations to undertake due diligence regarding their own activities relating to genetic resources. D. A. Posey recalls that already before 1990, trading of products made by indigenous person's knowledge and in low-income countries cost around 43 million dollars[3].

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1 GODT G., "The Multi-Level Implementation of the Nagoya Protocol in the European Union", in COOLSAET B., BATUR F., BROGGIATO A., PITSEYS J. AND DEDEURWAERDERE T., (eds.), Implementing the Nagoya Protocol Comparing Access and Benefit-sharing Regimes in Europe, Brill, 2015, Leiden Netherlands, p. 319.

2 Ibidem.

3 POSEY D.A., "Intellectual Property rights and Just Compensation for Indigenous knowledge, Amazonia and Siberia: Legal Aspects of the preservation of the Environment and Development in the Last Open Spaces", in Anthropology Today, 6, 1993, 4, p. 287.

The Multinational enterprises full use of genetic resources and associated traditional knowledge, but the local community and indigenous persons usually did not provide consent and not have a decent remuneration by Multinational beneficiaries of their knowledge. A storm of protest arose from this complex situation (see f.i. Vandana Shiva's movement): the notion of bio piracy emerged to explain - *lato sensu* - the not remunerative appropriation by the Multinational enterprises of biologic and genetic resources and the traditional knowledge mainly in the Southern hemisphere. This situation is new-colonialism economic approach in the Southern hemisphere[4].

As a matter of fact, the approach inside the abusive exploitation of the genetic resources and associated traditional knowledge is unfair, and not ethically correct. This inequity approach is amplified by multinational firms' ability to obtain patent protection or other forms of intellectual property rights (trademark, utility model, short term patent, plant variety right) starting from genetic resources and associated traditional knowledge[5].

The ABS measure is correlated with distributive justice and the principle of solidarity[6], that in the specific case of the framework of the European Union, the former principle underpins the General Principles of European Union law[7]. Within the European Union (EU), the Nagoya Protocol has been spelled out in Regulation (EU) n. 2014/511 and 2015/1866 through which the mechanisms for establishing access and benefit sharing are laid down. In particular, they describe the means by which access to genetic resources and the benefit of their utilisation and commercialisation may be shared.

In the Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization system, the information exchanged and stored by Access and Benefit-sharing Clearing-house (ABSCH) tries to realise the legal certainty and transparency on procedures for access and benefit sharing.

Through a ABSCH, those involved in any aspect of utilising genetic resources (including plant, animal, microbial or other origin containing functional units of heredity but excluding human genetics) may deposit information and connect users and providers of genetic resources and/or traditional knowledge. The ABSCH permits storing and transferring knowledge in which a description is provided along with the source of the genetic resource and whether there are rights and obligations regarding access and benefit sharing. A platform was created for monitoring the utilisation of genetic resources along the value chain, including the internationally recognised certificate of compliance. In the EU legal framework, through the system called Declare, the data and information are submitted to ABSCH.

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4 VEZZANI S., "Il Primo Protocollo alla Convezione europea dei diritti umani e la tutela della proprietà intellettuale di popoli indigeni e comunità locali". In Diritti Umani e Diritto Internazionale, 2007, 1, p. 305-342.

5 SANDBERG A., "Property rights and ecosystem properties", in Land Use Policy, 2007, 24, p. 613-623.

6 CIPPITANI R., La solidarietà giuridica tra pubblico e privato, Iseg srl, 2011, Roma-Perugia-Mexico.

7 COLCELLI V., "The Solidarity Principle in New EU Member States", in PERUGINI C., POMPEI F. (eds.), Inequalities during and after transition in Central and Eastern Europe, Palgrave, 2015, Basingstoke, p. 247-265.

Each Member State shall designate one or more competent authorities to be responsible for the application of EU Law implementing the Nagoya Protocol(see next paragraph 7)[8]. 'The competent authorities shall transmit the information received (….) to the Access and Benefit-Sharing Clearing House, established under Art. 14(1) of the Nagoya Protocol, to the Commission and, where appropriate, to the competent national authorities referred to in Art. 13(2) of the Nagoya Protocol. The national competent authorities shall cooperate with the Access and Benefit-Sharing Clearing House to ensure the exchange of the information listed in Art. 17(2) of the Nagoya Protocol for monitoring the compliance of users'[9].

However, despite the central function assigned by the Nagoya Protocol to the information on ABS, the system realised does not establish assured legal consequences for the user of genetic resources[10] that does not comply with the rules on information exchanging and storing. The development and implementation of ABS regulatory frameworks at the national level will need to ensure that legislative, administrative or policy measures taken are consistent and mutually supportive of other existing ABS instruments. This means that each State has rules on this matter.

In the EU framework, the ABS system is running, but at the moment it is not completely clear what can be done in the case of infringement of the rules on information exchange and storage.

The EU legal system currently does not have a working administrative point for control on information exchange and storage. There are uncertain judicial claims at the EU level and at the national level. Not all the EU Member States who signed the Nagoya Protocol have the legislative, administrative or policy measures necessary for implementing the Protocol.

Thus, to analyse how, in the European legal system, access and benefit-sharing information are exchanged and how this could help the implementation of the Nagoya Protocol, this chapter will be organised as follows: section 2 describes how the Nagoya Protocol or others International Treaty on Plant Genetic Resources for Food and Agriculture apply to genetic resources over which States exercise sovereign rights. Section 3 introduces the EU legal framework implementing the Nagoya Protocol. The meaning of Due Diligence in the contest of the EU law on "Access and Benefit Sharing" is analysed in section 4. Section 5 examines how the relationship between genetic resources and associated traditional knowledge and their utilisation could be addressed by contracts and contractual clauses. Section 6 describes the information flow for ABSCH and its function, as well as the system for storing and transmitting data according to Regulation (EU) n. 511/2014. Section 7 examines when due diligence declaration needs to be requested by national competent authorities, by the European Commission or by the public administrations of Member States in the case of request for market approval or placing products on the market, and the legal consequences for the infringement of the obligation for ABS information. Sec-

8 Art. 6 Regulation (EU) n. 511/2014.

9 Art. 7 Regulation (EU) n. 511/2014.

10 Art. 4 Regulation (EU) n. 511/2014, Point 4: 'user' means a natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources.

tion 8 concludes how it is possible to have rather good control of the flow of information in the EU legal system, if all the public administrations or agencies involved check the ABS due diligence fulfilment.

2. *Benefit sharing: Multilateral international system and the Nagoya Protocol approach.* The genetic resources over which States exercise sovereign rights falls within the scope of Art. 15 of the CBD. Art. 15 of the CBD recognizes 'the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. (…) Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention (…)'[11].

The Nagoya Protocol does not extend to the full jurisdictional scope of Art. 4 of the CBD[12]. 'In addition to the CBD itself, the Nagoya Protocol will become a binding set of norms setting detailed rules on how ABS can be implemented in national legislation'[13]. 'The fact that the CBD and the Nagoya Protocol are two different legal instruments. (…) Art. 4 of the Nagoya Protocol on the relationship between Nagoya Protocol and other instruments only applies in that context and not to the general rules provided by the CBD. Thus the relationship between the CBD and other instruments of international will not be solved directly by the new rules introduced in Art. 4 of the Nagoya Protocol'[14].

That is why an interface between the Nagoya Protocol on ABS and the International Treaty on Plant Genetic Resources for Food and Agriculture of the United Nations Food and Agriculture Organization (ITPGRFA) at the international level exits. The Nagoya Protocol applies to genetic resources, over which States exercise sovereign rights. However, the Nagoya Protocol gives priority enforcement to the specialized legal instruments if they are limited and qualified. This is the case of ITGRFA, just for to the genetic resources covered and for its the purpose[15].

Annex 1 to the ITPGRFA lists crops and forages under the multilateral system for ABS (see next paragraph n. 5). 'Plant genetic resources for food and agriculture' (PGR-

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11 Art. 15 CBD.

12 See CBD, Art. 4 Jurisdictional Scope: Subject to the rights of other States, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, in relation to each Contracting Party: (a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and (b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

13 PERRON F., FREEDOM KAI PHLLIPS J. M., "The Interface between the Nagoya Protocol on ABS and the ITPGRFA at the International Level Potential Issues for Consideration in Supporting Mutually Supportive Implementation at the National Level Fridtjof Nansen Institute (FNI)", in Rep. No. FNI Report 1/2011, Fridtjof Nansen Institute, 2013, Lysaker, Norway, pp. 1-71.

14 Ibidem.

15 See Art. 4 (4) Nagoya Protocol.

FA) means any genetic material of plant origin of actual or potential value for food and agriculture. The list in Annex 1 refers to different taxonomic levels and biology is not a static science. However, 'the list in the Annex gives some legal certainty for which crops are covered, the extent to which wild relatives of cultivated crops are covered introduces a certain level of uncertainty'[16]. Nevertheless, parties to the Nagoya Protocol, in the exercise of their sovereign rights, could decide that certain PGRFA falls within the scope of ITRGFA management and control, even though they are not listed in Annex I to the ITPGRFA.

As a matter of fact, 'with few exceptions there has not been legislation which differentiates between the treatment of genetic resources for food and agriculture and those of other genetic resources'[17]. If a country realised the choice above mentioned the access to plant genetic resources will be realized according to ITGRFA Multilateral System and its Standard Material Transfer Agreement (sMTA), not according to Nagoya Protocol.

3. *Implementing the Nagoya Protocol in the EU legal system.* During 2011, the European Commission adopted the EU biodiversity strategy for 2020, to halt the loss of biodiversity and ecosystem services by 2020. This document is an integral part of the Europe 2020 strategy and the 7th Environmental Action Programme. This implements EU commitments under the CBD.

During 2014, the EU adopted the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from the utilization in the European Union, by Regulation (EU) n. 511/2014. The Regulation (EU) n. 511/2014 rules on 'Access to Genetic Resources and the Fair and Equitable Sharing of Benefits'. It dictates how the Nagoya Protocol is enforced in the EU legal system.

Though, just in the second part of 2015, Art.s 4, 7 and 9 of the Regulation (EU) n. 511/2014 were enforced. The Art.s mentioned above respectively concern the 'Obligations of Users', 'Monitoring user compliance' and checking user compliance. 'Users,' according to Regulation (EU) n. 511/2014, include the natural/legal persons that utilise genetic resources or traditional knowledge associated with genetic resources.

Thus, the Nagoya Protocol is a freestanding legal obligation expressed in the EU legal system by Regulation (EU) n. 511/2014 and the Commission Implementing Regulation (EU) n. 2015/1866 passed on 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) n. 511/2014 regarding registering collections, monitoring user compliance and best practices. The development and implementation of ABS regulatory frameworks at the national level will need to ensure that legislative, administrative or policy measures taken are consistent and mutually supportive with other existing ABS instruments.

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[16] PERRON F., FREEDOM KAI PHLLIPS J. M., "The Interface between the Nagoya Protocol on ABS and the ITPGRFA at the International Level Potential Issues for Consideration in Supporting Mutually Supportive Implementation at the National Level Fridtjof Nansen Institute (FNI), cit.

[17] Ibidem.

As above mentioned, ITPGRFA constitutes a specialised international access and benefit-sharing instrument within the meaning of Art. 4 (4) of the Nagoya Protocol[18], also in the EU legal system (see previous paragraph 2). As matter of fact, in the framework of the EU legal system, 'users acquiring Plant Genetic Resources for Food and Agriculture (PGRFA) in a country that is a Party to the Nagoya Protocol which has determined that PGRFA under its management and control and in the public domain, not contained in Annex I to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), will also be subject to the terms and conditions of the standard material transfer agreement (sMTA) for the purposes set out under the ITPGRFA, shall be considered to have exercised due diligence in accordance with paragraph 3 of this Art.'[19] (see next paragraph 5).

'The Multilateral international system (MLS) is highly relevant for ABS because it is the first sectorial approach to ABS, and could provide useful lessons for the implementation of ABS, including whether and if so, how, sectorial ABS can be dealt with to meet the objectives of the CBD'[20].

4. *The due diligence in the context of ABS.* In the EU legal system, the information flow on genetic resources accessed, the time and place of access and the ways in which the resource may be used are some of the circumstances for complying with the due diligence requirements in Regulation (EU) n. 511/2014 to ascertain the genetic resources and traditional knowledge associated with them.

Due diligence can be defined as an investigation prior to signing a contract, or certain standards of care applying to an act. In tort law, the standard of care is the only degree of prudence and caution required of an individual who is under a duty of care..

In the context of ABS, due diligence means that you did your very best to establish which access and benefit-sharing conditions apply to the genetic resources you wish to access and that you have taken care to meet these conditions[21].

The users exercise due diligence in their own activities linked with genetic resources prior to obtaining 'internationally-recognised certificates of compliance as evidence that the genetic resources covered were legally accessed and that mutually agreed terms were established for the user and the utilisation specified therein'[22], and also national authorities reckoned them. Transferring, keeping, etc. of genetic resources, also for food and agriculture not contained under Annex I of the ITPGRFA, require an internationally recognised certificate of compliance[23].

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18 See, Point 12, Regulation (EU) n. 511/2014.

19 Art. 4 (4) Regulation (EU) n. 511/2014.

20 PERRON F., FREEDOM KAI PHLLIPS J. M., "The Interface between the Nagoya Protocol on ABS and the ITPGRFA at the International Level Potential Issues for Consideration in Supporting Mutually Supportive Implementation at the National Level Fridtjof Nansen Institute (FNI), cit.

21 Art. 3, (4), Regulation (EU) n. 511/2014.

22 Point 21 of the Regulation (EU) n. 511/2014.

23 Art. 4 Regulation (EU) n. 511/2014.

According to point 21 of Regulation (EU) n. 511/2014, 'genetic resources have been accessed by applicable legal or regulatory requirements and to ensure that, where relevant, benefits are fairly and equitably shared'.

If internationally-recognised certificates of compliance are not present, the user has to comply with the *minimum* information required by Art. 17 (4) of the Nagoya Protocol, as specified in Art. 4(3) (b) of Regulation (EU) n. 511/2014. Where no international certificate exists, documents and information have to be verified by the users[24]. Also, the regulation states that users have to declare and provide evidence that they have exercised due diligence when requested.

The requirements of the standard are closely dependent on circumstances. Users obtaining a genetic resource from a collection included in the register of collections within the EU shall be considered to have exercised their obligation of due diligence[25]. A collection that is registered under EU Regulation n. 511/2014 applies standardised procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to third parties for their utilisation in line with the CBD and the Nagoya Protocol; the collection supplies genetic resources and related information to third persons for their utilisation only with documentation providing evidence that the genetic resources and the related information were accessed in accordance with applicable ABS legislation or regulatory requirements and, where relevant, under mutually agreed terms. The request for inclusion of a collection or a part thereof in the register, referred to in Art. 5(2) of Regulation (EU) n. 511/2014, shall contain the information specified in Annex I to Regulation (EU) n. 1866/2015.

5. *Access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation addressed by contracts and contractual arrangements.* The relationship between genetic resources and associated traditional knowledge and their utilisation could be addressed in contracts and contractual clauses. The Nagoya Protocol uses contracts to have mutually agreed terms for sharing benefits with the provider of genetic resources or of traditional knowledge associated with genetic resources. These kinds of contracts – mainly Material Transfer agreements (MTA) – have to set out specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or of traditional knowledge associated with genetic resources. In the EU legal system, according to Art. 3 of Regulation (EU) n. 511/2014, they have also included further conditions and terms for such utilisation as well as subsequent applications and commercialisation.

'Fundamentally Material Transfer agreement (MTA), an is a bailment, that is, a transfer of tangible property without transfer of title. Under such an agreement, the provider could maintain ownership of the property transferred. Transferred property is held by the receiving party according to terms stipulated in a legally binding contract. The contract,

[24] Art. 4 Regulation (EU) 511/2014.
[25] See Point 9, Reg. (EU) 1866/2014.

therefore, governs the transfer of tangible biological materials between two or more parties. In addition to the tangible property rights being owned by the provider, the material(s) may be the subject of a patent or patent application. In this case, the MTA may need to account for the transfer of Intellectually Property rights as well as the transfer of tangible material'[26].

The user shall share fairly and equitably the benefits arising from their utilisation of the genetic resources and traditional knowledge associated with genetic resources, its progeny or derivatives in accordance with the CBD. A non-exhaustive list of non-monetary and monetary benefits is given in the Annex to the Nagoya Protocol.

Mutually Agreed Terms (MAT)are defined also at the EU level by Regulation (EU) n. 511/2014 as 'the contractual arrangements concluded between a provider of genetic resources, or of traditional knowledge associated with genetic resources, and a user, that set out specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or of traditional knowledge associated with genetic resources, and that may also include further conditions and terms for such utilisation as well as subsequent applications and commercialisation'.

Regulation (EU) n. 511/2014 identifies a set of criteria using the identification of the area (country, region, etc.) from which the genetic material used for developing new varieties comes. These criteria will reflect the enforcement of legal rights, the rate of entrepreneurship, the structure of the higher education system, etc. of partner countries of the Nagoya Protocol.

Firstly, contractual arrangements (MAT) should guarantee the effectiveness of legal contracts and technology transfer agreements once the biotech research activity is completed. Second, they have to contribute to develop potential market value of new varieties.

Measurement of returns – mainly monetary – from commercialising innovation will be crucial to identify a fair price to which the new varieties could be sold with particular attention to local communities. One of these criteria is a provision for sharing benefits with the provider of the genetic resources or of traditional knowledge within the contract made for utilisation, subsequent applications and commercialisation of products derived by genetic resources or by traditional knowledge associated with them.

Competent authorities of Member States should check whether users comply with the obligations[27]. This means fair and equitable sharing of benefits arising from the utilisation of genetic resources and traditional knowledge.

Competent authorities could also refer to the Judge of the National and European Union Courts[28]: through the jurisdictional control of the contract for utilisation, subsequent applications and commercialisation of genetic resources and traditional knowledge linked with them, it will be possible to fulfil the goals of Regulation (EU) n. 511/2014. In this case and to better understand what kind of juridical control there could be over

[26] https://www.cbd.int/doc/press/2015/pr-2015-10-07-abs-en.pdf.

[27] See Point 29, Regulation (EU) n. 511/2014.

[28] COLCELLI V., "A Critic Lecture of the EU Two Faced Approach to Biodiversity: Equal Guaranty or Multinational Bioraid? The Importance of a Self-Reconsideration of EU Politics in Biodiversity", in Cerrina Feroni G.,. Frosini L. Mezzetti T. E, Petrillo P. L. (eds.), Environment, Energy, Food Comparative Legal Models For Sustainable Development, Cesifim, 2016, 1, I, Roma, p. 41-53.

the contracts and mutually agreed terms, it relevant settling the nature of the remedies for not fair and equitable contractual arrangements (nullity, voidable etc.), but still now it is not so clear. This situation is intertwined and takes different contours depending on the nature of the interests to be protected. The infringement of EU rules regarding not setting out specific conditions for the fair and equitable sharing of benefits from the utilisation of genetic resources or of associated traditional knowledge in the contract could mean nullity of the MTA[29].

6. *ABSCH: information exchange and storage for facilitating the implementation of the Nagoya Protocol.* The ABSCH is the platform for exchanging information on access and benefit sharing established by Art. 14 of the Protocol, as part of the clearing house established under Art. 18, paragraph 3 of the CBD. By hosting relevant information regarding ABS, the ABSCH offers opportunities by connecting users and providers of genetic resources and associated traditional knowledge.

On 1 October 2015, the first internationally recognised certificate of compliance was issued under the Nagoya Protocol on Access and Benefit Sharing. The permit was issued by India's National Biodiversity Authority, the competent national authority under the Nagoya Protocol. The certificate through the ABSCH serves as evidence of the decision by India to grant access to ethno-medicinal knowledge of the Siddi community from Gujarat to a researcher affiliated with the University of Kent in the United Kingdom. Thus, the researcher can demonstrate that s/he has respected the ABS requirements of India when using this knowledge.

Where an internationally recognised certificate of compliance is not available, other relevant information provided in accordance with Art. 17 (4) of the Nagoya Protocol, as specified in Art. 4(3)(b) of Regulation (EU) n. 511/2014, should be submitted by the due diligence declaration.

In the case of Art. 17(4) of the Nagoya Protocol, the researcher will need in any case provide the following information required by the treaty as a *minimum*: (a) Issuing authority; (b) Date of issuance; (c) The provider; (d) Unique identifier of the certificate; (e) The person or entity to whom prior informed consent was granted; (f) Subject-matter or genetic resources covered by the certificate; (g) Confirmation that mutually agreed terms were established; (h) Confirmation that prior informed consent was obtained; and (i) Commercial and/or non-commercial use.

According to Art. 17 mentioned above, EU Regulation 511/2014, Art. 4, paragraph 3 where no internationally-recognised certificate of compliance is available, the following information and relevant documents are required:

(i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;
(ii) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised;
(iii) the source from which the genetic resources or traditional knowledge associated

[29] Ibidem.

with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;

(iv) the presence or absence of rights and obligations relating to access and benefit sharing including rights and obligations regarding subsequent applications and commercialisation;

(v) access permits, where applicable;

(vi) mutually agreed terms, including benefit-sharing arrangements, where applicable.

However, according to the CBD, an ABS National Focal Point contains information that is relevant to all public institutes, companies and individuals using genetic resources for research and development. It shall provide basic guidance for users seeking access to genetic resources as well as background information on the relevant international agreements, and explains various terms that are often used.

6.1. Declare system and transmission data in the EU legal framework. A due diligence declaration is required (only) for genetic resources or traditional knowledge associated with genetic resources obtained from a party to the Nagoya Protocol that has established relevant access and benefit-sharing legislation or regulatory requirements pursuant to Art. 6 (1) and Art. 7 of Regulation (EU) n. 511/2014. In the EU legal framework, through the system called Declare[30], users request access to the system, submit due diligence declarations and review submitted declarations. Thus, through the Declare system, the competent authority of the EU Member State, approves new submitting organisations, submitted declarations and transmits data to ABSCH. The declaration of due diligence is submitted to the competent authority of the Member State where the recipient of funding is established.

It is relevant to underline point 25 of Regulation (EU) n. 511/2014 which affirms that one suitable point for such a declaration is when research funds are received, and also at the final stage of utilisation. This means at the stage of final development of a product before requesting market approval for a product developed via the utilisation of genetic resources or traditional knowledge associated with such resources, or, where market approval is not required, at the stage of final development of a product before first placing it on the Union market.

Annex II and III of Regulation (EU) n. 1866/2015 are both templates for a due diligence declaration to be submitted at the stage of research funding pursuant to Art. 5(2) mentioned above. Annex II regards the declaration to be submitted at the stage of research funding pursuant to Art. 5(2). The second one (Annex III) is the template for a due diligence declaration to be submitted at the stage of final development of a product pursuant to Art. 6(1).

The time of submission of such declaration may be further specified by the national authorities[31]. Annex II shall be made after the first instalment of funding has been re-

[30] Log-in with ECAS (http://ec.europa.eu/europeaid/funding/about-grants/how-apply-grant/applicant-registration-pador/ecas-registration_en).

[31] Art. 5 of Regulation (EU) n. 1866/2015.

ceived and all the genetic resources and traditional knowledge associated with genetic resources that are utilised in the funded research have been obtained, but no later than at the time of the final report, or in absence of such report, at the project end.

A single declaration may also be made by several users jointly conducting research involving the utilisation of genetic resources and traditional knowledge associated with genetic resources funded by one grant. In this context, a special role should be given to the project coordinator, who should be responsible for submitting the declarations on behalf of the users concerned[32].

The due diligence declaration of Annex III shall only be made once, prior to the first of the following events occurring:

(a) market approval or authorisation is sought for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;
(b) a notification required prior to placing, for the first time on the Union market, a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;
(c) placing on the Union market for the first time a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources for which no market approval, authorisation or notification is required;
(d) the result of the utilisation is sold or transferred in any other way to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c);
(e) the utilisation in the Union has ended and its outcome is sold or transferred in any other way to a natural or legal person outside the Union.

Under Art. 7(2) of Regulation (EU) n. 511/2014, the final stage of utilisation, meaning the stage of final development of a product, should be determined. The stage of final development of a product can be identified with legal certainty as having been completed at the time when either market approval or authorisation is sought or a notification required prior to placing for the first time on the Union market is made or, where neither market approval or authorisation nor a notification is required, at the time of placing for the first time on the Union market.

Over the non-confidential data upload in the Declare system by the genetic resource, data will be under the access from the European Commission, that overviews also of the submitting organisation.

The information provided in the due diligence declarations (that are confidential) is to be submitted by the competent authorities to the ABSCH pursuant to Art. 7(3) of Regulation (EU) n. 511/2014.

7. *Where and who performs the checking on due diligence fulfilment.* As described above, Art. 4 of Regulation (EU) 511/2014 explains which users must comply and fulfil 'due diligence' in their activities linked with genetic resources ascertained. Among them, Art. 4 describes which information users need to seek, keep and transfer to comply with the due

[32] See Point 8 Regulation (EU) n. 1866/2014.

diligence obligation. The latter includes formal documentation from the country where you acquired the genetic resources and information about the genetic resources accessed, the time and place of access and the ways in which the resource may be used. Users shall keep the information relevant to access and benefit sharing for 20 years after the end of the period of utilisation.

There are three moments for prior checking on 'due diligence' and whether or not it was fulfilled by the user: a) in the first instalment of research funding involving the utilisation of genetic resources and traditional knowledge associated with genetic resources, or no later than at the time of the final report, or in absence of such report, at the project end; b) in the event of a request for market approval or c) the placing on the market of products deriving from the utilisation of a genetic resource (see previous paragraph 6.1).

As a matter of fact, according to Art. 5 of Regulation (EU) n. 2015/1866, 'a recipient of funding for research involving the utilisation of genetic resources and traditional knowledge associated with genetic resources shall make the due diligence declaration requested pursuant to Art. 7(1) of Regulation (EU) n. 511/2014 to the competent authority of the Member State in which the recipient is established'. If the recipient is not established in the EU and the research is carried out in the EU, the due diligence declaration shall be made to the competent authority of the Member State in which the research is carried out.

Furthermore, many products in the EU legal system need a request of authorisation for market approval or the placing of products on the market. Anyway, f.i. for placing on the market of plant protection products an authorisation is required. The Regulation for placing Plant Protection Products on the market (1107/2009) lays down harmonised rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the EU.

Food and feed derived from genetically modified organisms are authorised and supervised by a competent authority in the relevant EU country and by the European Food and Safety Authority (EFSA). Regulation (EC) n. 1829/2003 on genetically modified food and feed, lays down rules on how genetically modified organisms (GMOs) and on how genetically modified food and animal feed are labelled. In general, also medicinal products are under a market approval or authorisation[33]. The marketing authorisation holder should submit an application to the competent authorities of each Member State and in the centralised procedure, the applicant applies to the European Agency for the Evaluation of Medicinal Products (EMEA) for marketing authorisation.

In the case for notification required prior to placing for the first time on the Union market, f. i. about food supplements, Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of placing on the market by forwarding it a model of the label[34].

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[33] See, among the others, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; Regulation (EC) n. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

[34] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

A further moment for a prior checking could before European Union Intellectual Property Office, or Community Plant Variety Office or Intellectual Property offices of the EU Member States, despite a coordination between the Regulation itself and the system for the protection of plant variety rights established by European Union legislation is still not present.

Regulation (EC) n. 2100/94 of 27 July 1994 on Community plant variety rights, Regulation (EC) n. 1238/95 of 31 May 1995 that establishes rules for the application of the fees payable to the Community Plant Variety and Regulation (EC) n. 1768/95 of 24 July 1995 for implementing rules on the agricultural exemption built the system for the protection of plant variety rights established by the EU. Anyway, the compliance with EU legislative framework on ABS allows intellectual property rights, valid throughout the EU, to be granted for plant varieties. As a matter of fact, disclosure requirements mean patent (and perhaps also other forms of intellectual property rights) applicants should disclose several categories of information concerning genetic resources, such as the source or origin and evidence of prior informed consent and benefit sharing, when these genetic resources are used in developing the innovation claimed in a patent application.

Due diligence obligation and an internationally-recognised certificate for compliance, as well as full information on genetic material and resources address how to apply for a vegetable patent under the aims of Regulation (EU) n. 511/2014. Without waiting for the Commission implementation how to apply for the vegetable patent under the light of the purposes of the Regulation (EU) n. 511/2014 and Nagoya Protocol, the ABS goals could be realised whether the plant patent is granted if the due diligence is not demonstrable through documentation required for applying for vegetable plants patents.

7.1. Breaching the due diligence obligation: weighing the impacts for users and providers of the lack of ABS information and its formal documents. As a consequence of infringement of paragraphs 3 or 5, Art. 4 of Regulation (EU) 511/2014, the utilisation of genetic resources or associated traditional knowledge shall be discontinued[35]. When the information is insufficient, or uncertainties about the legality of access and utilisation persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation[36].

In the absence of prior informed consent having been obtained in a timely manner, mutually agreed terms having been established, and until an agreement is reached with the provider country concerned, no exclusive rights of any kind will be claimed by a user for any developments made via the use of genetic resources, that is determined to be, or is identified as likely to be, the causing pathogen of a present or imminent public health emergency of international concern. The meaning of health crisis falls under the scope of International Health Regulations (2005), or of a serious cross-border threat to health as defined in Decision n. 1082/2013/EU of the European Parliament and the Council[37].

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35 Art. 4, (2) of the Regulation (EU) n. 511/2014.

36 Art. 4, (5) (6) of the Regulation (EU) n. 511/2014.

37 Art. 4, (8) of the Regulation (EU) n. 511/2014.

In my opinion, with a lack of information, recipients of research funding[38] and user patenting will pay the consequences, over then, of course, the disadvantage for discontinuing on the utilisation of genetic resources or associated traditional knowledge[39]. For instance, on one hand, for EU research funds, we have to take into consideration that 'Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries' is, among the others, one of the main ethical principles established by the EU legal framework related to Horizon 2020. According to Art. 34 (1) of the H2020 Grant agreement, the beneficiaries of an EU project must carry out the action in compliance with: a) ethical principles (including the highest standards of research integrity) and b) applicable international, EU and national law. Thus, non-compliance with the ethical principles, the Nagoya Protocol and Reg. 511/2014, for the grant beneficiaries, means that the grant may be reduced[40], and the agreement or participation of the beneficiary may be terminated[41]. On the other hand, the lack of information and formal documents applying for the vegetable patent would produce a nullity of the bad patent if granted, not taking into consideration information requirements by the Regulation (EU) 511/2014.

8. *Conclusions.* Art. 7(1) of the Regulation (EU) n. 511/2014 makes it clear that a due diligence declaration needs to be requested by the Member States (competent authorities responsible for the application of EU Law implementing the Nagoya Protocol[42]), the European Commission if the money is provided by EU funds and the EU Offices or the public administrations of Member States in the case of request for market approval or placing products on the market. Nevertheless, the agencies for ABS control are not in charge of market approval.

It is possible to affirm that rather good control over the flow information is possible in the EU legal system, if all the public administrations or agencies involved check ABS due diligence fulfilment. Only a crossing flow of information and data among the public bodies involved could build a working system in the EU framework. However, not all the products stemming from research and developing by genetic resources, or associated traditional knowledge are subjected to market approval or authorisation, or they derive from research activity using EU funds.

At the moment, in which the Declare system still does not established, it seems that the providers, the owners of genetic resources and the consumers are not in a position to know who is using research and developing activities[43] before market approval or at

38 Point (25) Reg. (EU) n. 511/2014 /Art. 5 Reg. (EU) 2015/1866.

39 GODT G., "The Multi-Level Implementation of the Nagoya Protocol in the European Union", in COOLSAET B., BATUR F., BROGGIATO A., PITSEYS J. AND DEDEURWAERDERE T., (eds.), Implementing the Nagoya Protocol Comparing Access and Benefit-sharing Regimes in Europe, Brill, 2015, Leiden Netherlands, p. 319, where the author talks about "piggy-back" procedures.

40 See Art.s 34 (4) and 43 Model Grant Agreement.

41 See Art.s 34 (4) and 50 Model Grant Agreement.

42 Art. 6, 9 and 11 Regulation (EU) n. 511/2014.

43 VON KRIES C., G. WINTER G., "Defining commercial and non-commercial research and devel-

the final stage of utilisation of the product (see paragraph 6.1). As a matter of fact, the declaration is not public, as well as data that shall be transmitted by the ABS competent authorities to ABSCH.

It seems that the main mission of the ABSCH provides stronger support for users, than providers. Furthermore, Art. 14 (2) of the Nagoya Protocol describes making mandatory information available in the ABSCH platform: (a) Legislative, administrative and policy measures on access and benefit sharing; (b) Information on the national focal point and competent national authority or authorities (CNA); (c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent (PIC) and of the establishment of mutually agreed terms (MAT). Also, according to Art. 12 (2), Art. 17, (1) (a) (iii) and Art. 22 (6) of the Nagoya Protocol other information made available includes: (a) Measures to inform potential users of traditional knowledge associated with genetic resources about their obligations for access to and fair and equitable sharing of benefits arising from the utilisation of such knowledge; (b) Information provided to designated checkpoints that collect or receive, as appropriate, relevant information related to prior informed consent, the source of the genetic resource, the establishment of mutually agreed terms, and/or the utilisation of genetic resources, including from internationally recognised certificates of compliance (IRCC), where they are available; (c) Information on capacity-building and development initiatives at national, regional and international levels that should be shared through the ABSCH with a view to promoting synergy and coordination on capacity-building and development for access and benefit sharing.

The flow of information available in the ABSCH platform seems to converse with the users more than with providers, stakeholders and consumers and appears to kindly invite the users to respect the ABS system. Providers, stakeholders and consumers, as well as the states that have the sovereign of the genetic resources used, have the possibility to discover the illegal utilisation of genetic resources only accidentally, after products are placed on the market. In this case, the only instruments for contesting the use of the illegal product will be the judicial claim. In EU legal system, thanks to the EU multilevel guaranty system[44], a number of instances for providers, stakeholders and consumers and others private or public persons can bring 'direct action, where appropriate, before the Court of Justice, (…) not intended to create new remedies in the national courts to ensure the observance of Community law other than those already laid down by national law'[45], also if not all the members states still now have ruled the legal measure to comply with Nagoya Protocol.

As a matter of fact, with regard to the EU legal system, individual rights can be effectively protected only if they are used in actions before national courts[46]. It is for 'the legal system of each Member State to determine which court has jurisdiction to hear

opment under the Nagoya Protocol and in other context", in E. CHEGE KAMAU E., G. WINTER G., STOLL P.T., (eds.) Research and Development on Genetic Resources. Public domain approaches in implementing the Nagoya Protocol, Routledge, 2015, London-New York, pp.125-147.

44 FORSBERG T., "Normative Power Europe, Once Again: A Conceptual Analysis of an Ideal Type", in JCMS, vol. 49, n. 6, 2011, pp. 1183-1204.

45 Rewe v Hauptzollamt Kiel (C- 158/80), [1981] ECR, 1805.

46 Theresa Emmot v Minister for Social Welfare, (C-208/90) [1991] ECR, I-4269.

disputes involving individual rights derived from Community law, but at the same time the Member States are responsible for ensuring that those rights are effectively protected in each case'[47].

When the national system of protection cannot guarantee community rights sufficiently, the equipment provided by the EU legal system comes into action. In the system, a uniform network of safeguards for community individual rights (e.g., liability of a Member State, recovery of sums paid but not due, disapplication and obligation to interpret national law in conformity with community law) is provided when the judiciary of a Member State does not safeguard the effectiveness of the protection of community rights. The system does not envision specific or special protection for individual rights but provisions by Member States for effective national legal protection.

[47] Ibidem.