IMAGE
Innovative Management of Animal Genetic Resources

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IMAGE

Innovative Management of Animal Genetic Resources

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TOPIC: MANAGEMENT AND SUSTAINABLE USE OF GENETIC RESOURCES

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DELIVERABLE D8.2 :
Compliance to the EU regulation 511/2014 for access and benefit sharing related to the use of genetic resources

Abstract: The project will use DNA samples for the molecular characterization of gene bank collections. This research activity constitutes utilization of genetic resources according to the Nagoya Protocol. This deliverable describes the procedure for compliance to the Nagoya Protocol for access and benefit-sharing (ABS).

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Contributors: INRA, SGGW
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[1] **PU** Public (must be available on the website)

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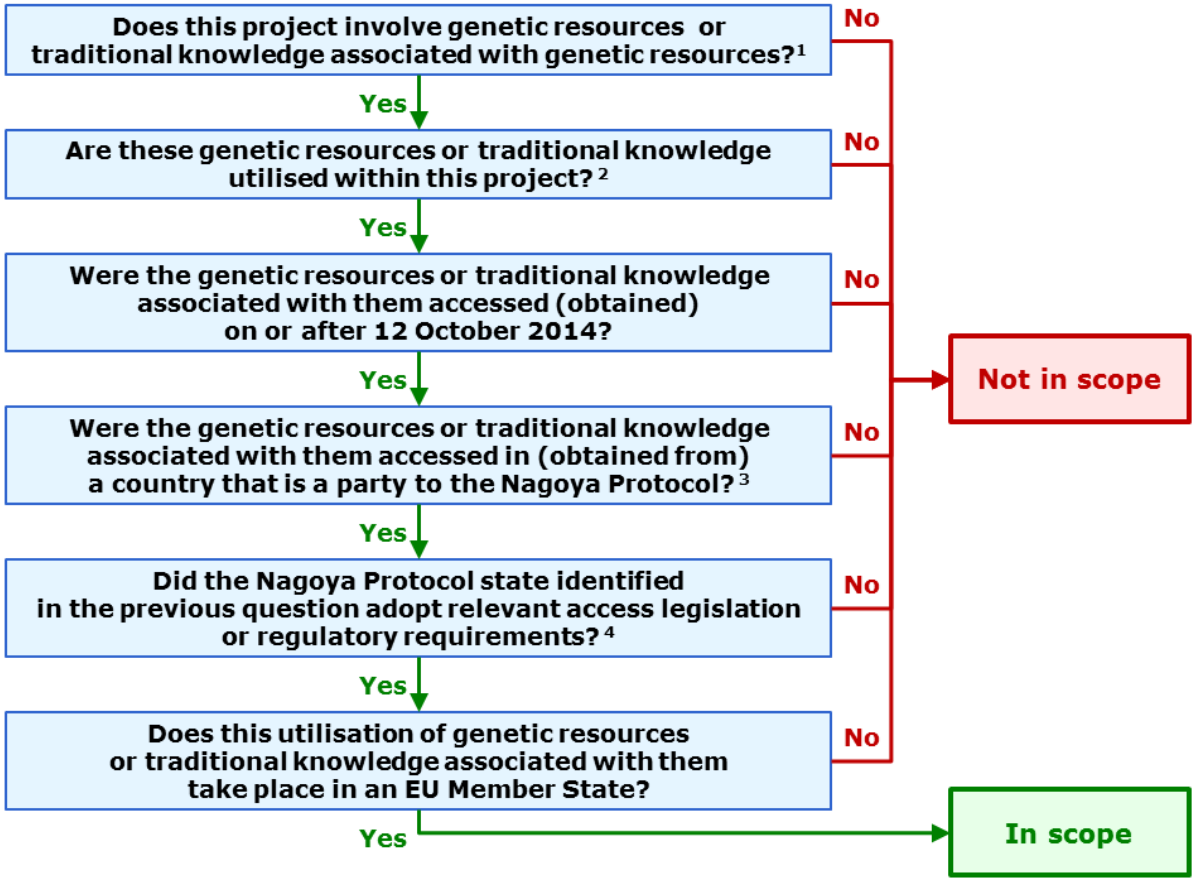
Executive Summary

Background	The IMAGE project is funding research on animal genetic resources that may fall within the scope of the Nagoya Protocol. The DNA samples are provided by partners of the project, who are located in different countries. Each country has the sovereignty on its genetic resources and therefore can decide on access measures. The EU ABS regulation 511/2014 sets the procedures to check that users in its Member States are complying with the Nagoya Protocol in their research & development activity.
Objectives	To comply with the EU ABS regulation for all activities of IMAGE pertaining to the use of genetic resources. To explain how a due diligence declaration will be made.
Methods	The nature of the research planned is analysed in order to decide whether it constitutes a 'utilization of genetic resources' according to the Nagoya Protocol (cf. Article 2). The national measures for legal access to genetic resources are retrieved from the ABS CH of the CBD (https://absch.cbd.int/). The ABS decision tree provided on the participant portal online manual is applied in order to determine whether the use of genetic resources made in IMAGE falls under the scope of the EU regulation or not, on a case by case basis. If the answer is yes, due diligence declaration is required by EU ABS regulation. In case a country is not party at the Nagoya protocol but regulates the access to its resources, then it is necessary to comply with the national regulations.
Results & implications	The sequencing and genotyping of DNA samples planned in WP4 constitute a 'utilization of genetic resources' as defined in the Nagoya Protocol. The use of gametes and embryos planned in WP3 and WP6 is aimed at testing laboratory procedures or a breeding method, and does not constitute a utilization of genetic resources. Regarding the country of origin of the DNA samples, four cases are encountered: Case 1: country is not a party to Nagoya Protocol Case 2: country is party but has no access measures Case 3: country is party and has access measures, but these do not involve domestic animals Cases 1 and 2 are out of the scope of the EU regulation but national specific requirements have to be considered for Colombia and Switzerland. Case 3 is in the scope but no certificate is required for access to domestic animal resources. A regular monitoring of national legislations will be done by the coordination of IMAGE since new national laws may be adopted.

1. Decision tree to comply with EU ABS regulation



2. Use of DNA samples for sequencing or genotyping within IMAGE

Work planned

- Task T4.2: Additional sequencing and genotyping of selected resources
  Task leader Inra; Duration M6 to M36

  The following activities are planned:
  - High density genotyping data for 100 Holstein individuals from European countries; high or medium density genotyping data for 330 Colombian cattle; 15 whole genome sequence from a rare cattle breed from Spain, 5 whole genome sequence from 4 local cattle breeds from Colombia.
  - Sequence data of 100 sheep and genotyping data of 350 sheep of different European origin, both local and selected breeds.
  - Sequence data of 100 pigs of 7 different local breeds.

- Sequence data of 300 chickens from local chicken breeds from European countries

Thus genetic resources, i.e. DNA samples, are used.

Some of these DNA samples have been collected (accessed) after October 12, 2014.

No use of traditional knowledge is planned.

The sequencing and genotyping will be performed in three EU member States: France (INRA partner, sequencing), The Netherlands (WU partner, genotyping) and Italy (UCSC).

- Task T4.5: Design of cost-efficient genotyping assays for large scale characterisation across breed/species

  Task leader: WU; Duration M24 to M36

Subsets of 60K SNPs will be chosen for each of the major species currently found in European Gene banks. A new multi-species SNP chip will provide a more cost effective and more rapid assay than sequencing.

The use of the multi-species genotyping assay(s) provides a cost-effective tool that can be applied to a large number of individuals by any gene bank, for the purpose of rationalising and evaluating collections. Based on information stemming from WP2, a sample of collections will be genotyped with the aim of: i) validating the procedures designed in WP4; ii) aiding the rationalisation of collections as envisioned in WP2. This will result in genotype data for 1000 additional chicken, 1000 pigs, and 1000 sheep, for the same 'one for all' chip.

Genotyping will be performed under the responsibility of partner WU, but the genotyping platform has not yet been chosen. The DNA samples to be genotyped have not yet been chosen. Some may be collected specifically for IMAGE, others may be in collection already before October 12, 2014.

Country of origin of the genetic resources and associated conditions

Since the priorities for large-scale characterizations will not be decided before M24, the list of samples to be genotyped for task 4.5 and the list of provider countries are not yet available. Consequently, Table 1 is listing all the countries participating into IMAGE and the legal measures for access to genetic resources from these countries.

The information has been retrieved from the ABS CH (https://absch.cbd.int/). It must be noted that information on this site is not always up to date and additional information had to be retrieved from other sources for some countries, (legal documents made public by Colombia, Switzerland, France).

All EU Member States have to implement the EU ABS regulation directly and most countries have already developed a national legislation in this respect (indicated as "National Legislation to implement EU ABS Regulation" in table 1), except Austria and Italy which just have the transcription of EU ABS regulation.

Country	Party at the Nagoya protocol	ABS legislation in place	Provisions for regulation of access and benefit sharing	International Recognized Certificate of compliance
Argentina	Yes	No, just a focal point	none	none
Austria	No	EU ABS Regulation only	none	none
Colombia	No	Yes: national law	Yes	None described in the CH ABS
Egypt	Yes	No, just a focal point	none	none
France	Yes	National Legislation to implement EU ABS Regulation	Not for domestic animals	None issued yet
Germany	Yes	National Legislation to implement EU ABS Regulation	none	none
Hungary	Yes	National Legislation to implement EU ABS Regulation	none	none
Italy	No	EU ABS Regulation only	none	none
Morocco	No	In preparation	none	none
Norway	Yes	Yes: a national law	Not for terrestrial domestic animals	None issued yet
Poland	No	National Legislation to implement EU ABS Regulation	none	none
Spain	yes	National Legislation to implement EU ABS Regulation	Not for domestic animals	None for domestic animals
Switzerland	yes	Yes: national law	a registration system	None issued yet
The Netherlands	yes	National Legislation to implement EU ABS Regulation	none	none
UK	yes	National Legislation to implement EU ABS Regulation	none	none

Procedure to comply with the EU ABS legislation

Three cases are encountered:

Case 1: country is not party to Nagoya

Austria, Colombia, Italy, Morocco, Poland

There is no due diligence declaration to show compliance to the EU regulation but we must check whether these countries have an ABS law.

This is the case of Colombia which regulates access to its genetic resources :

https://www.google.ca/search?q=columbia+ABS+legislation&oq=columbia+ABS+legislation&aqs=chrome..69i57.8971j0j8&sourceid=chrome&ie=UTF-8

"In implementing the general provisions of Decision 391, the Colombian government identified the Ministry of Environment, through the 1997 Resolution 620, as the national authority entitled to grant access to genetic resources. In 2007 Resolution No.1393 established that the Direction of Permits and Environmental Licenses will be the competent for the approval or rejection of ABS applications as well as for the signature of the ABS agreements.[1] The main steps for access include: the filling of an application; its study and approval or rejection by the national authority; and, in the case of approval, the access contract. "

For IMAGE, CORPOICA will contact the national authority in order to fill in the application and a material transfer agreement will be signed between Inra and CORPOICA before the reception of the DNA samples. The approval of the Colombian authority will be necessary for this MTA to be signed and will be provided by the Colombian partner as an annex to the MTA.

Case 2: country is party but has no access measures

Argentina, Egypt, Germany, Hungary, The Netherlands, UK

Case 3: country is party and has access measures, but these measures do not require a certificate in the case of the utilisation of genetic resources planned within IMAGE

For France, Norway, Spain :

There is no access measure for genetic resources from domestic animals.

In the case of France, the access to genetic resources for domestic animals benefits from a special measure under the authority of the ministry in charge of Agriculture which does not require a certificate of compliance.

In the case of Spain, the access to genetic resources is regulated for resources sampled in the natural environment (Patrimonio Natural y de la Biodiversidad), and domestic animals are not included.

For Switzerland,

This country requires registration in the case of market development, and registration is voluntary in the case of research without commercial development, as described on https://www.admin.ch/opc/en/classified-compilation/20150120/index.html, section 3 art. 8 :

[1] *On accessing genetic resources in Switzerland, the user must record and retain and following information and pass it on to subsequent users:*

a.-the name and address of the user;
b.-description of the genetic resource or subject matter and its utilisation;
c.-date on which and location where the genetic resource was accessed;
d.-in the case of direct acquisition of the genetic resource from a third party: the name and address of this person and the date of acquisition;
e.-in the case of the transfer of genetic resources: the name and address of the subsequent user and the date of the transfer.

[2] *If the name and address of the person under paragraph 1 letter d are subject to trade secrecy, this information need not be passed on to subsequent users.*

[3] *The user must notify the FOEN (*Federal Office for the Environment*) of the information specified in paragraph 1 before market approval or, if such approval is not required, before the commercialisation of products developed on the basis of utilised genetic resources.*

[4] *Notification may also be given voluntarily, in particular if no commercialisation is intended.*

[5] *The user receives a register number as evidence of the notification and, on request, an attestation to the effect that the Swiss provisions on access and sharing of benefits have been complied with.*

[6] *The information specified in paragraph 1 must be retained in accordance with the requirements set out in Article 3 paragraph 5 and be made available on request to the implementing authorities.*

[7] *Genetic resources in respect of which the information specified in paragraph 1 has already been recorded and made available to the FOEN in global form in connection with a different procedure are exempt from the notification requirements under paragraph 3.*

The Swiss partner EPFL participating to WP4 will consult the FOEN to enquire whether a voluntary notification is needed for the access to DNA samples from swiss farm animals in the case of the research plannes in IMAGE.

Cases 1 and 2 are out of the scope of the EU regulation.
But a specific procedure has to be respected for Colombia and for Switzerland.

Case 3 is in the scope but no IRCC is required for domestic animal resources.

It should be reminded that this is the current situation of ABS legal measures, but countries currently not having access measures may be preparing some. Thus, a regular monitoring of national legislations will be done by the coordination of IMAGE with the help of partner SGGW on the basis of the survey conducted within WP2. In any case, at the time of access, the partner providing DNA samples will check with the national focal point of his/her country whether new legal measures are in place.

3. Use of germinal cells, embryos or entire individuals

Germinal cells and embryos from domestic animal species are used in WP3 of IMAGE, but the objective is to improve a technological procedure (freezing procedure, fertility assessment) and not to characterize the genetic resources which are used to test and validate a procedure. This does not constitute 'utilization of genetic resources' in the frame of the Nagoya Protocol (see Article 2 of the Nagoya Protocol) and is out of scope of the EU regulation.

Whole animals (chickens) and embryos are used in WP6 of IMAGE to test the introgression procedure of a major gene into a commercial line. The objective is to demonstrate the feasibility of an introgression method and is using DNA genotyping on early chicken embryos. Since the aim is not to characterize the genetic resources but to test a procedure, this does not constitute 'utilization of genetic resources' in the frame of the Nagoya Protocol and is out of scope of the EU ABS regulation.