Directorate General for Agriculture and Rural Development

Preparatory action on EU plant and animal genetic resources

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WORKSHOP REPORT

Access to Genetic Resources for Food and Agriculture in the European Union

25-26 February 2016, London

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This Workshop took place in the context of the study launched by DG AGRI of the European Commission called "*Preparatory action on EU plant and animal genetic resources*" which is being conducted by a Consortium of various experts and consultants. The study started in July 2014 for a duration of 2 years, and aims to create an overview of actors, networks, activities and issues regarding conservation and sustainable use of GR in Europe.

A total of seven workshops were planned during the period June 2015 – March 2016. Each workshop was dedicated to specific topics/issues linked to a specific regional context and/or covering sectorial or methodological issues in the field of genetic resources. These workshops covered the four different domains under scrutiny: AnGR, PGR, FGR, and MiGR.

The outcomes of the workshops should provide recommendations concerning approaches and solutions applicable for the conservation and sustainable use of GR, reflecting the objectives and themes of the preparatory action.

More information on the objectives of the study can be found on the study website: http://www.geneticresources.eu.

The Workshop on "Access to Genetic Resources for Food and Agriculture in the European Union" is the sixth of the series.

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1 Introduction

The workshop on "*Access to Genetic Resources for Food and Agriculture in the European Union"* was organized by the Project Consortium in London on 25-26 February 2016. It was prepared by:

- **Bert Visser** (Centre for Genetic Resources, the Netherlands (CGN), Wageningen University and Research, the Netherlands);
- **Julian Jackson** (Department for Environment, Food & Rural Affairs (DEFRA), United Kingdom);
- **Martin Brink** (Centre for Genetic Resources, the Netherlands (CGN), Wageningen University and Research, the Netherlands);
- **Daniel Traon** (Arcadia International, Belgium); and
- **Daniela Biciu** (Cecoforma, Belgium).

The workshop was attended by 35 invited participants from 15 countries, including experts from universities, research institutes, botanical gardens, museums, government departments, international organizations and private companies (see Annex 1 for the list of participants).

The focus of Workshop 6 was to identify and understand access policy development across European Union Member States, and to assess the implications of access legislation in EU Member States for various groups.

1.1 Background

Access and Benefit-Sharing (ABS) refers to the international, supranational and national regulation of access to and use of genetic resources and traditional knowledge, and the sharing of benefits stemming from this use between providers and users. A central international instrument governing ABS is the 'Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization', adopted in 2010 as a supplementary agreement to the Convention on Biological Diversity (CBD). The objective of the Nagoya Protocol is the fair and equitable sharing of benefits arising from the utilisation of genetic resources and associated traditional knowledge. It is aimed at providing a transparent legal framework for access and benefit-sharing, supporting compliance by both providers and users of genetic resources. The Nagoya Protocol rests on three main pillars: measures relating to access, measures relating to benefit-sharing, and measures relating to compliance.

The Nagoya Protocol came into force in the European Union on 12 October 2014, through EU Regulation 511/2014 which applies to all users of genetic resources in the

European Union. However, whereas EU Regulation 511/2014 (which only entered into force on 12 October 2015) gives provisions on compliance, it does not regulate access to genetic resources in the EU, which remains the responsibility of individual member states.

1.2 Issues with respect to access to genetic resources for food and agriculture in the European Union

The issues addressed in the workshop included the following:

1. Access policy developments across EU Member States.
2. The implications that national access regulations in the EU will have on research and development in the EU.
3. Feedback provided to competent national authorities.

2 Agenda of the Workshop

The objectives of the workshop were to raise EU-wide awareness about access measures implemented by EU Member States, including perspectives, motives and expectations behind such measures, and on the resulting obligations and procedures for users in the EU. For this, people working on regulation of access to genetic resources in EU member states (policy makers) were brought together with people using genetic resources or representing user groups.

To achieve the objectives, the agenda presented below was developed. After introductory presentations by representatives of the organizing committee and the European Commission, two main sessions were held, the first on ‘Access legislation in the European Union Member States’ and the second on ‘Implications of access legislation in the European Union Member States’. In each of these two sessions, presentations were given to create a basis for discussion, after which three working groups were formed to discuss the subject in parallel, aided by a number of questions formulated by the organisers. After each session, the conclusions of the working groups were reported in a plenary session, that also provided the opportunity for additional discussion. At the end of the workshop, a final plenary discussion was held, and conclusions were formulated.

Thursday 25 February		
13.00 – 13.30	Welcome coffee	
13.30 – 13.35	• Welcome of participants • Reminder of the objectives of the Preparatory Action • Objectives of the workshop	Bert Visser (CGN, the Netherlands)
13.35 – 13.45	Introduction by the European Commission (DG AGRI)	Sirpa Karjalainen (European Commission, Belgium)
13.45 – 15.25	Access legislation in the European Union Member States	
	• An overview of current initiatives towards access legislation in the European Union Member States (30 min)	Speaker: Fulya Batur (Catholic University of Louvain (UCL) / Arche Noah, Belgium)
	• Regulating access to GR: legislation in Spain and France (2 x 30 min)	Speakers: Alejandro Lago (King Juan Carlos University (URJC), Spain); Patricia Larbouret (Ministry of Agriculture, France)
	• Regulating access to GR: the UK policy (10 min)	Speaker: Julian Jackson (Department for Environment, Food & Rural Affairs (DEFRA), UK)
15.25 – 15.45	Coffee/tea break	
15.45 – 17.00	Working groups discussions (part 1) Identifying and understanding access policy development across EU Member States	Moderators and rapporteurs: *to be decided*
17.00 – 17.30	Reports Working groups	Rapporteurs
	Workshop dinner	
Friday 26 February		
09.00 – 09.45	Implications of access legislation in the EU Member States	
	• Access policy and legislation and EU research projects	Speaker: Licia Colli (Università Cattolica del Sacro Cuore, Italy)
	• Access policy and legislation and transboundary commercial R&D	Speaker: Szonja Csörgő (European Seed Association (ESA), Belgium)
09.45 – 11.15	Working groups discussions (part 2) A. Which implications will national access regulations in the EU have on research and development? B. Which feedback could be provided to competent national authorities?	Moderators and rapporteurs: *to be decided*
in between	Coffee/tea break (coffee/tea available for picking up from 9.45 onwards)	
11.15 – 12.00	Reporting of WG discussions focusing on issues and needs	Rapporteurs
12.00 – 12.45	Final Discussion / Conclusions	All
12.45 – 13.00	Conclusions and next steps	All
13.00 – 14.00	Lunch (optional)	

3 Session 1: Access legislation in the European Union Member States

3.1 'Setting the scene'

Four key presentations were given, after which questions and remarks could be given in a plenary session. Below, a summary of each of the presentations and the questions/remarks is presented.

Presentation 1: Agricultural Biodiversity & the Implementation of the Nagoya Protocol in the European Union (Fulya Batur, Catholic University of Louvain (UCL), Belgium / Arche Noah, Austria)

1. International Law

International law on ABS and biodiversity comprises on the one hand the Convention on Biological Diversity (including the Nagoya Protocol), and on the other the International Treaty on Plant Genetic Resources for Food and Agriculture. The two agreements are mutually supportive. The former aims to counteract biopiracy, covers the conservation, sustainable and equitable use of all biodiversity, and entails bilateral and differential ABS duties (PIC, MAT), whereas the latter aims at increasing food security, focuses on agricultural genetic diversity, and has a multilateral ABS system making use of the SMTA.

2. EU Implementation

The Nagoya Protocol is implemented in the EU through Regulation 511/2014, but this Regulation only comprises compliance measures. It does not set minimum requirements for PIC or MAT, but aims to prevent misuse of genetic resources through a due diligence obligation for users and the establishment of checkpoints. Enforcement of Regulation 511/2014 is decentralised to the country level.

Access is regulated at the member states level, with differences between countries (requiring PIC or not, state or private ownership of GR). Furthermore, a large range of national laws and regulations apply to GR: not only those on access per se, but also those related to nature protection, agriculture, research & development, real & intellectual property, and private international law.

Perceived shortcomings of the EU implementation were reported to be:
- the narrow understanding of applicability and scope;

- light compliance rules;
- difficulties linked to the information flow.

3. Member States approaches

Member state approaches can be analysed with regard to five aspects:
- legal status of GR (regulation of GR and ownership; exercise of sovereignty; treatment of traditional knowledge);
- access to GR (access legislation: Nagoya, national laws; restrained vs. unrestrained; permits vs notifications; protected species);
- benefit sharing mechanisms (legal obligation vs. self-regulation; monetary vs. non-monetary benefits);
- compliance mechanisms (information management; monitoring; checkpoints; sanctions; self-regulation);
- division of ABS competences (vertical division; horizontal division).

Examples of member state approaches:
- Denmark: most complete legislation; no PIC but strict user measures;
- Netherlands: self-regulation; no PIC; extensive use SMTA;
- Greece: access regulated under CBD, but less clear for benefit-sharing & compliance.

4. Conclusions

Common principles:
- civil law principles of ownership predominate, but the possibility exists that a State sovereignty layer is added;
- most EU countries are viewed as users, not providers, and thus access is loosely regulated, but certain countries regulate access more strictly; compliance requirements also vary, even though an EU Regulation exists;
- compliance levels are different for Nagoya access legislation and 'classical'/CBD access legislation.

Difficulties for users:
- to identify applicable laws in a plethora of legal systems (international and national);
- the EU Regulation is of little help (registered collections & best practices), and puts burden on users (even if light compliance).

Presentation 2: Regulating Access to Genetic Resources: the Case of Spain
(Alejandro Lago, Universidad Rey Juan Carlos (URJC), Spain)

This presentation was given by Alejandro Lago in his personal capacity and should not be taken as the official position of Spain.

Natural Heritage and Biodiversity Act

The 2007 Natural Heritage and Biodiversity Act (Law 42/2007) was amended in 2015 (Law 33/2015, into force on 07/10/2015), and now contains the following articles on ABS:
- Art. 71: Access to Spanish Genetic Resources.
- Art. 72: Control of the utilization of genetic resources (GR) in Spain (compliance measures for the national implementation of the EU Regulation 511/2014).
- Art. 74: Control of the utilization of traditional knowledge (TK) in Spain (compliance measures for the national implementation of the EU Regulation 511/2014).
- Art. 80 and 81: Sanctions.

Art. 71 regulates access to Spanish genetic resources (in accordance with CBD, Nagoya Protocol and ITPGRFA), which will be subject (through a bylaw /regulation) to PIC, MAT and access permits. It establishes a simplified procedure for non-commercial research. In case of a change of intent, a new permit is required.

Different competent authorities have been established: the Autonomous Communities (regions) for GR that are endemic to that region; the Central government for Marine GR, GR under the State public domain, GR in *ex situ* collections of State institutions, and GR found in more than one Autonomous Community (region). The National Focal Point is the Ministry of Agriculture, Food and Environment. There will be a centralised system for the notification of access permits to the ABS Clearing House.

Outside the scope are:
- access for taxonomic purposes;
- Plant Genetic Resources for Food and Agriculture (PGRFA) covered by Law 30/2006;
- Fisheries GR covered by Law 3/2001;
- Animal GR for Food and Agriculture covered by specific legislation;

Specific access restrictions may apply for endangered species and protected areas.

Benefits derived from the utilization of Spanish genetic resources will be mainly used for the conservation and sustainable use of biodiversity in Spain (Spanish Fund for the Natural Heritage and Biodiversity).

Draft ABS bylaw

The bylaw (still in draft) regulates access to Spanish Genetic Resources (*in situ* and *ex situ*), control of the utilization of GR and TK in Spain (in compliance with EU Regulation 511/2014), and the Spanish information system on access to and utilization of GR and associated TK in Spain.

Outside the scope are:
- access for taxonomic purposes;
- collection of material and its maintenance in *ex situ* collections with the exclusive purpose of its conservation;
- production and commercialization of forest material covered by Real Decreto 289/2003, when there is no utilization of the material;
- PGRFA covered by Law 30/2006;
- Fisheries GR covered under Law 3/2001;
- Animal Genetic Resources for Food and Agriculture covered under specific legislation.

The competent authority issuing access permits for GR under the authority of the Central Government will be the DG Natural Environment of the Ministry of Agriculture, Food and Environment. Responsible for PIC and MAT are:
- for Marine GR: the DG Coastal and Marine Sustainability;
- for GR that are under the State public domain: the authority that exercises the State public domain;
- for GR in State *ex situ* collections: the State institution that manages the collection;
- for GR found in more than one Autonomous Community (region): the Autonomous Community where access will take place.
Endemic GR of specific Autonomous Communities will fall under the competent authorities of the Autonomous Communities (access permit, PIC and MAT requirements determined by each Autonomous Community).

A distinction will be made between access for non-commercial research and access for commercial research, but in both cases the user is obliged to get an access permit before accessing the genetic resource. This authorization is independent from other permits.

For non-commercial research, the access request form in Annex 1 of the bylaw has to be filled in, with an attached declaration that explicitly states that:
- the user has no intention to utilize the GR for commercial purposes;
- a new access permit for commercial purposes will be requested when there is a change of intent during the utilization of the GR;
- transfer to third parties, if allowed in the terms of the permit, will take place under the same conditions as originally granted;
- the user will provide a written report with the final results of the research to the competent authority that grants the permit.
The authority that grants PIC and negotiates MAT can add specific benefit-sharing conditions, such as duplicates of the samples being deposited into an Spanish *ex situ* collection, or Spanish researchers participating in the research when access is granted to foreign researchers. The authority has a maximum of 2 months to grant the access permit. The minimum content of the access permit is given in Annex 2 of the bylaw.

For commercial research, the access request form in Annex 3 of the bylaw has to be filled in. Guidelines for the negotiation of MAT are under development. The maximum period for granting the access permit is 6 months. The minimum content of the access permit is given in Annex 4 of the bylaw.

A provision is made for access to GR in emergency situations. The declaration of emergency or alert situations could entail an exceptional authorisation of access, on a provisional basis, providing immediate access to the GR. The exceptional authorisation is conditioned to the posterior negotiation of MAT and obtaining the definitive access permit (maximum period of 6 months).

Presentation 3: Implementation of the Nagoya Protocol on Access and Benefit-Sharing (ABS) in France (Patricia Larbouret, Ministry of Agriculture, France)

1. Why regulating access in France?

- France is a very diverse country, also from a GRFA perspective.
- France is both a provider and a user country. A provider country, because it holds a large diversity of *in situ* genetic resources, as well as large *ex situ* collections. A user country, because, for instance, its cosmetics industry ranks 2nd in the world, and agro-food is the no.1 industry in France. Also, much academic & commercial research takes place.
- Regional ABS legislations/regulations already exist for New Caledonia, Polynesia and Guiana.
- Preparatory work has been carried out since 2006, and included studies, dialogue with stakeholders, and voluntary ABS procedures, with more than 40 voluntary requests for PIC and MAT processed since 2010.
- The principles of the French approach on ABS are:
    * a balanced approach between the perspectives of users and collections;
    * a large scope to avoid grey areas for users;
    * a minimalised administrative burden (dematerialized procedure; grouped declarations; approach by 'project');
    * maximised legal security;
    * fair and equitable benefit-sharing, that recognizes existing good practices of users (non-monetary benefit sharing) and is used for biodiversity conservation and sustainable use.

2. Content of the draft legislation

- Drafting the legislation started in 2012. Since June 2014, the draft legislation has been discussed in the two Chambers of Parliament.

- This presentation is based on the draft law still under discussion and possibly subject to modifications.
- The draft legislation is included in a wider draft legislation on biodiversity.

3. General ABS scheme for French GR

- Access measures to GR and TK will apply when the legislation enters into force (except in territories where an access legislation already exists).
- When research is started with genetic resources, a GR declaration has to be made (simple on-line notification). When the objective is 'direct commercial use', a request for authorisation has to be submitted. For starting research on TK, a request for authorisation for TK has to be submitted. The declaration or authorisation receipts are sent to the CHM (with confidential elements excluded), to become international certificates of compliance.
- For GR already in collections (public or private), access measures to GR will also apply when a 'new utilisation' is foreseen.
- GR covered by specific schemes are excluded from the 'new utilisation' provision.
- Negotiations between the user and the CNA on the benefit-sharing proposal should take no longer than 6 months, and the analysis (by the CNA) of requests for authorization not longer than 2 months.
- Access can be denied if the activity or its potential applications risk affecting biodiversity by restraining the sustainable use of the GR or by exhausting the GR.
- Different kinds of benefit sharing are possible (monetary and non-monetary). Monetary benefits will be collected by the future French Agency for Biodiversity, and used for biodiversity conservation and sustainable use.

4. Specific ABS schemes for some GRFA

- Genetic Resources for Food and Agriculture (GRFA) have distinctive features (such as their importance for food security) and need specific ABS schemes, which should facilitated access and exchange. Therefore, in the French draft legislation, access to some GRFA is excluded from the general ABS scheme.
- Six specific ABS schemes are foreseen (but still in preparation), of which five concern GRFA and are to be defined by the Ministry of Agriculture:
    * GR from cultivated plants and wild relatives (based on ITPGRFA, compulsory use of SMTA);
    * GR of domesticated animals (no access measures; AGR are already covered by market and traceability regulations);
    * GR for forestry (master certificate for R&D as well as for marketing; equivalent to a declaration, no authorisation);
    * GR of domesticated and cultivated micro-organisms (working group to be established; objective is a simple scheme to facilitate exchange);

* GR collected by laboratories in the context of prevention, monitoring and fighting against risks in animal health, plant health and food safety (access scheme still to be defined);

- The sixth special ABS scheme concerns GR collected by laboratories in the context of prevention, monitoring and fighting against risks in human health, and is to be defined by the Ministry of Health.
- Some sectors and GR under the competencies of the Ministry of Agriculture will fall under the general ABS scheme, such as biocontrol, veterinary medicine, novel food and bioeconomy.

5. Implementation of the EU Regulation in France

- Titre IV Sub-section 3 and sub-section 4: designation of the Competent Authority; monitoring of user compliance (checkpoints to be specified); checks on user compliance.
- Penalties: proportionate to the infraction (< 1 year imprisonment and a fine < 150 000 €); additional sanctions can be imposed (< 1 million € in case of a commercial use, and an access ban to French GR and TK during < 5 years for commercial use).
- Register of collections: collection holder can ask for registration of collection, or part of it; the French CNA is responsible for initial and regular verification that the collection meets the criteria mentioned in art. 5.3 of the EU Regulation.
- Best practices: recognition of best practices is competence of the European Commission; France encourages its users to develop and implement best practices.

6. Conclusions

- ABS and GRFA in France: a key issue for the Ministry of Agriculture, Agrifood and Forestry.
- Specificities of the sector need to be taken into account at national and European levels, taking into consideration international agreements (ITPGRFA, UPOV) and specific work (CGRFA).

As for the Preparatory Action:

- A network of experts in the ABS/GRFA field needs to be built, to facilitate the implementation of the NP in Europe, with experts from the Members states, the Commission level, and European networks (ECPGR, ERFP, EUFORGEN).
- Possible tasks: finalisation on the Guide on the scope of the EU Regulation; preparation of the sectorial Guides in 2016; exchanges on national access regulations (preparation and implementation); and exchanges on the implementation of the EU regulation.

Presentation 4: Regulating Access to Genetic Resources in the United Kingdom (Julian Jackson, Department for Environment, Food & Rural Affairs (DEFRA), United Kingdom)

There are no "domestic access and benefit sharing legislation or regulatory requirements" in the UK. So, there is no requirement to seek Prior Informed Consent (PIC) from the UK Government.

Why isn't the fact that there is no PIC requirement in the UK simply published? Article 6 of the Nagoya Protocol applies to those seeking to exercise sovereignty, but there is no obligation on Parties not asserting sovereignty to do anything or publish anything.

Who Governs Access in the UK? Defra is responsible for ABS, but access is largely a devolved matter. In theory, the 4 countries forming the UK (England, Wales, Scotland and Northern Ireland) could pursue separate access policies, but also the Crown Dependencies (Guernsey, Isle of Man, Jersey), the 13 Overseas Territories and the two Sovereign Base Areas.

Other legal issues to be taken into account:

Property
- Permission is required from the "owner" of a genetic resource.
- In England, Wales and Northern Ireland, the owner of *in situ* plants, microorganisms and domesticated plants and animals is the landowner.
- You cannot "own" a wild animal other than game or fish (unless you are the Queen, who owns the whales, sturgeons and untagged swans).

Access
- Permission is required from the landowner for physical access for collecting specimens.
- Mapped areas of mountain, moor, heath, downland and registered commons allow public right to roam, but not to collect (Countryside and Rights of Way Act 2000).
- HM Land Registry indicates owners in England and Wales, with Scotland and Northern Ireland having separate registers.

Protected species
- Protected sites, SSSI/Natura, RAMSAR.
- Wildlife and Countryside Act (includes Schedule of protected species; licences granted for collection of protected genetic resources from Natural England or Countryside Council for Wales).
- Habitats Directive.
- CITES/CMS.

International Law
- UNCLOS (requirement to notify countries of intention to undertake 'marine scientific research', this is done through diplomatic request to the FCO).
- Antarctic Treaty (Madrid Protocol; permit system).

Health and Safety
- Health and Safety at Work Act (1974).
- Control of Substances Hazardous to Health (2002).
- The Carriage of Dangerous Goods (2009).

The UK has commitments under the CBD, ITPGRFA and ECPGR to provide access to PGRFA. *Ex situ* collections are held in decentralised genebanks in various institutions across the UK, funded in different ways. As for *in situ* PGR, 15 priority sites have been recommended for CWR genetic reserves. The Nagoya Protocol has just been ratified (on 22 February 2016).

3.2 Working groups

Three working groups were formed to discuss the subject, aided by pre-formulated questions. Each working groups discussed the same questions. The conclusions of the working groups were reported during a final plenary session, and listed below.

Working Group 1 (rapporteur: Jens Weibull)
Identifying and understanding access policy development across EU Member States *1a. Are more access measures currently foreseen in EU member states, in addition to France, Hungary, Italy and Spain and? Is it known what these measures look like?* • Germany, Finland, Sweden: no access legislation; In Finland, Sami traditional knowledge will be regulated. • Croatia: some regulations on native plants and some collections. • Italy: work is in progress; non-Annex I species are subject to on-going discussions, which are still not resolved; the idea is to use SMTA for all, but hesitation about putting into the Multilateral System (MLS). *1b. Which motives have led to access measures in EU member states?* • Motives for introducing access legislation (e.g. Spain and Italy): national sovereignty; 5-10 access requests per week (so they are sought for!); can be looked upon as ecosystem services that are being paid for. • Motives for no access legislation: practical reasons (Finland) • All environmental measures are born nationally, no common source of money. *1c. Will exemptions for access to plant genetic resources for food and agriculture (PGRFA) be introduced in the national measures above, what about other GRFA?* • Can this be foreseen?

- Should/could they be introduced at all?
- For sustainable agriculture, more crops as well as control measures must be considered than those presently used for 'food security'.
- There are already exemptions for pandemics.
- Spain: we want to be able to give immediate access, but there will still be a benefit-sharing obligation, which could very well be non-monetary.

1d. In this respect, what would be the scope of PGRFA (which type of material will be included in the scope, which not)?

- Croatia: we would like same access to all PGRFA, but not for not native CWR.
- Sweden: Nordic countries give access to all PGR in the public domain under the SMTA.

1e. Will exemptions apply to PGRFA held ex situ only, or also to PGRFA occurring in situ? (Will approaches differ for material on private land and public land)

- No exceptions in countries without access legislation.

1f. Will different access measures also apply to collections not under the management and control of government and in the public domain?

- Can state sovereignty extend to private collections?

1g. Are the compliance measures as set out in EU Regulation 511/2014 also applicable for genetic resources accessed from other EU member states?

1h. If registered collections are established in EU member states with access regulations, will they still fulfil the 'due diligence' requirements on behalf of their users?

Other remarks

- About intent: discussion about changes of intent; where to draw a line? Commercial vs. non-commercial research? The complex issue concerning access vs. patents and commercialisation. Is this only a European Union problem?
- Basic research leading to commercialisation? What is the aim at the onset?
- Important to see the whole picture! Will my research lead to a product on the market?
- Distinction between commodities and genetic resources (e.g. exciting mould on apple).
- Important to try to clarify grey areas between the Nagoya Protocol and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).
- How will we deal with different interpretations of the implementing EU guidelines? After all it's all about national sovereignty and interpretation – not an EU problem.
- Discussion on SMTAs and the traceability of origin of varieties; big companies vs. SMEs and obligations put on them.

Questions/remarks in plenary session

- Non-annex 1 crops cannot be placed in the Multilateral System (MLS) of the ITPGRFA.
- The comments by Alejandro were made on a personal basis, they do not automatically form the official position of Spain.

Working Group 2 (rapporteur: China Williams)

Identifying and understanding access policy development across EU Member States

1a. Are more access measures currently foreseen in EU member states, in addition to France,

Hungary, Italy and Spain and? Is it known what these measures look like?

- Greece has existing legislation, as we have heard.
- Denmark has legislation, as we have heard.
- Poland is not going to regulate access.
- Sweden probably will not regulate access.
- Latvia unlikely to introduce access legislation.
- Many MS have existing legislation regulating access, for instance for Protected Areas. Do existing laws under the CBD count as access legislation under the Nagoya Protocol, or do member states have to specifically list these as implementing the NP – for instance by registering pre-existing legislation on the ABS-CHM, for example. The Greek law for instance, predates the NP and will need to be updated to be fully compliant. This should be clarified in the EU ABS Guidelines.

1b. Which motives have led to access measures in EU member states?

- Did France conduct a cost benefit analysis before designing legislation, or was it more politically motivated? In the case of France it was a government position to implement in this way. An impact assessment was carried out in 2013 to look at impact and costs in the different sectors. In fact, it was a clear political decision to preserve TK and biodiversity in overseas territories. Now we are trying to decide who will be the Competent Authority.
- In the UK conscious decision not to regulate access. The UK would not want to preclude Overseas Territories or devolved territories to come to a different decision.
- In Sweden we don't have the kind of diversity we would expect to benefit from or would justify a costly and complicated set of laws and regulations. However, both UK and Sweden said an in-depth cost-benefit analysis had not been undertaken, so this assumption was not based on genuine evidence, and a different decision could be taken in the future.
- Italy: Italian group members did not know full details, but speculated on a rough cost-benefit analysis; complex access regulation not deemed worth it.

1c. Will exemptions for access to plant genetic resources for food and agriculture (PGRFA) be introduced in the national measures above, what about other GRFA?

- In France there are some key sectors, clearly in the scope of the Nagoya Protocol, that are well-defined and already have their own well-run systems (e.g. domesticated animals, cultivated plants, forest genetic resources), so that it seemed more rational to exclude these sectors.
- In France at the moment, the biocontrol industry is silent. Why is this? Is this industry simply not aware of what is going on and that they could be caught? Awareness raising is happening.

1d. In this respect, what would be the scope of PGRFA (which type of material will be included in the scope, which not)?

- Crop Wild Relatives – are any countries developing legislation on this? In the UK there is no access legislation to cover CWR of Annex 1 material. Do we need this? We don't have a policy. Do any other countries? Sweden: CWR are mostly growing in situ, on private land. What should we do with respect to access to these? In the UK you could quite easily break the spirit of the IT by collecting CWR and asserting rights over them. In Denmark there is free access to CWR. In Sweden there is a right to roam/all man's rights law, so theoretically CWR could be freely collected.
- Animals and livestock – as food demand is increasing, all the major species should be kept out of the NP and EU Regulation, or regulation in general; there should be free access to increase ability to improve food production (Italy). Access to livestock is governed by private law in most MS. Or, in many cases, regulated by sector legislation and guidance. Farmers are used to having significant freedom to exchange genetic resources.

- France – horticultural crops and textiles out of scope/in exemptions list. The ITPGRFA apples to food and agriculture. If just for agriculture, e.g. for textile or ornamental horticulture, we still think free access, but we don't know whether to use the SMTA in this case, if for non PGRFA uses.
- Also, plant genetic resources not used for plant breeding (these may be covered by other schemes in any case).

1e. Will exemptions apply to PGRFA held ex situ only, or also to PGRFA occurring in situ? (Will approaches differ for material on private land and public land)

- Under French legislation no distinction is made between access from *ex situ* and *in situ*.

1f. Will different access measures also apply to collections not under the management and control of government and in the public domain?

- This question is about encouraging private individuals to put their collections in the multilateral system.
- In France, all genetic resources will be subject to French state sovereignty, unless captured by a specific scheme. In the UK it is the opposite!
- There are clearly different approaches to getting access from public or private land. Even without specific access legislation, there is likely to be a difference. Where there is no access legislation, each *ex situ* collection is likely to have its own system of access.

1g. Are the compliance measures as set out in EU Regulation 511/2014 also applicable for genetic resources accessed from other EU member states?

- Yes, of course, if they are utilised in the EU.
- In some MS there will be more obligations for compliance than in others.

1h. If registered collections are established in EU member states with access regulations, will they still fulfil the 'due diligence' requirements on behalf of their users?

- This depends on where the genetic resource has been accessed. Are the registered collections granting access to the MS genetic resources, or managing genetic resources accessed from, for instance, non-MS? The answer will be different depending on where the material has come from, and what the access legislation is, and when access took place.

Other remarks

- In Switzerland users who want pre NP material are encouraged to go back to the country of origin of this material for access, rather than getting it from an *ex situ* collection in Switzerland.
- Twenty year record keeping was questioned: beyond twenty years, can you claim ownership/rights etc. over anything you want?!

Questions/remarks in plenary session

- The approach mentioned for Switzerland (encouragement of users who want pre NP to go back to the country of origin of this material for access) is also followed by Kew.
- CWR found *in situ* may also be included in Annex 1 of the ITPGRFA.

Working Group 3 (rapporteur: Gerard Verkleij)

Identifying and understanding access policy development across EU Member States

1a. Are more access measures currently foreseen in EU member states, in addition to France, Hungary, Italy and Spain and? Is it known what these measures look like?

- The Hungarian representative in this discussion group noted that a working group has started in 2015. The idea is to develop one legislation for access and user compliance, the obligatory part of which has been finished and entered into force. Meanwhile, a discussion on access measures started again, and that it should be focussed on certain sectors. For PGRFA, nature conservation is leading the discussions, while another department is the focus for food and agriculture, and communication needs to be improved. Hungary is not very open to benefit-sharing under the ITPGRFA, although it is a party to it. Most gene banks are not very keen on the Multilateral System, and are more likely to lean towards ABS under the CBD/NP. To conclude, access will be regulated and detailed measures will be set in place, but it is not yet clear what these measures will entail nor when exactly these will be finalized. TK is unlikely to be regulated by Hungary in the future.
- Problems caused by the division of responsibilities between departments of agriculture and environment regarding ITPGRFA and NP are also experienced in other countries. Means of integrated implementation are needed.
- As was also mentioned in the session on national access implementation, in many Member States (MS) no list of plant genetic resources is available to function as the Annex I for the ITPGRFA. For GRFA the situation is complicated, as often more than one ministry is involved.
- Reaching a balanced implementation of access measures is a learning process for most MS and could benefit from the exchange of information between MS. This latter point could be improved in the opinion of several members of this discussion group.

1b. Which motives have led to access measures in EU member states?

- Spain has an advanced access legislation: what was the rationale behind this? Juan Fajardo pointed out that Spain sees itself primarily as a provider country being a very biodiversity-rich region (*in situ* GR), and also as a user country. Public genebanks are held by public bodies and institutes, which have to manage them in compliance with the EU Regulation and the national ABS law; often they do not regard themselves as the legal owners of these collections.
- Hungary also sees itself as both a user and a provider.
- Physical specimens and natural information (genetic information) are regulated in some MS, as it is easier to manage objects than information.

1c. Will exemptions for access to plant genetic resources for food and agriculture (PGRFA) be introduced in the national measures above, what about other GRFA?

- For France and Spain the situation is clear. Hungary may treat PGRFA separately, but at present, it does not know yet.

1d. In this respect, what would be the scope of PGRFA (which type of material will be included in the scope, which not)?

- What are the arguments for and against treating *in situ* GR under the Nagoya Protocol or under the ITPGRFA? It is noted that treating all GRFA in the same way would be simpler for the users.
- In Germany no access legislation will be set in place, but still special genebanks for PGRFA have been set up, also for the purpose to control the wild relatives (they have been actively put under the IT). So, not only Annex I species but also others that are

used for several other purposes.

1e. Will exemptions apply to PGRFA held ex situ *only, or also to PGRFA occurring* in situ*? (Will approaches differ for material on private land and public land)*

- Spain is uncertain about *in situ* / *ex situ* GR, particularly in the context of wild relatives. At the moment, even *in situ* material is transferred through the same route as the *ex situ* material. This makes it simpler for the users, but also ensures that everything is held as vouchers by the national gene bank.
- What constitutes a Crop Wild Relative (CWR) is fairly well known. Spain has a list at least for some crops, and Annex 1 includes guidance. However, it is not entirely clear for all crops. Names are not harmonised across MS. If access to a CWR is different to that to other plants, then there needs either to be a list or a set of guidelines to enable rapid decision-making as to which route to use. Although the SMTA was primarily developed for Annex I crops, the SMTA can be used for any other crop CWR if the provider wishes this. There are several studies and lists produced that indicate which wild GR (so, *in situ*) are closest to *ex situ* GR. Proof that wild GR can be used for crop production are documented. If the difference between *in situ* and domesticated GR is not so clear this can be a complicating factor (some domesticated GR are very similar to wild GR). An exercise conducted in the Netherlands identified around 300 wild relatives of domesticated crop species.

1f. Will different access measures also apply to collections not under the management and control of government and in the public domain?

- Collections outside the control of the government or public domain would probably in most cases not be governed by access measures, but this may depend on the state, and the applicable requirements from the EU Regulation.
- Collections are not always clearly public or private. In Spain no special rules for private collections exist (so, outside scope (?), but in France such collections are within scope.
- Collections are varied in holdings, staff and capacity for administrational tasks. Some collections may have difficulties assessing requests for access. Currently the level of ABS implementation and knowledge in these collections is also varied. Small collections are sometimes more keen on knowing and better informed what the requirements are. How can a small collection adequately implement ABS when it lacks the necessary resources? The SMTA system of the ITPGRFA is not so complicated and can be dealt with adequately in most collections.

1g. Are the compliance measures as set out in EU Regulation 511/2014 also applicable for genetic resources accessed from other EU member states?

- In other words: can an EU MS be a provider country? Yes.

1h. If registered collections are established in EU member states with access regulations, will they still fulfil the 'due diligence' requirements on behalf of their users?

- If a collection situated in an EU MS with regulated access is providing GR originating from that country, with PIC and MAT (as a recognized competent authority on behalf of the country), the additional status as a registered collections is of no real additional importance. This is only of relevance when the GR provided by that collection originates from another country than that where the collection resides.
- Note also that when users within a MS that regulates access utilise GR from within that state, they are also in the scope of the EU Regulation.

Other remarks

- Organisational issues exist for countries which include regions with different access measures. Some countries, like Spain, have autonomous regions regulating access to their (endemic) genetic resources, under the overarching ABS law for Spain as a whole.

Greenland is territory of Denmark, while Denmark does not rule over Greenland. It was noted that Greenland will have access legislation, but Denmark not, which may cause some difficulty in executing the tasks of publishing national records in the ABS Clearing House, which in this case would have to be done by a national authority of Denmark.

- Have MS carried out impact assessments in the decision-making process on whether or not to introduce access legislation (Spain, for instance)? Was some balancing exercise done (cost/benefit)? The size of crops may differ a lot and thus their weight in this balance. Sometimes it is difficult to predict what will be important in future and what not (think of the example of *Brachypodium* in Spain, which seemed small and insignificant in the beginning).
- The relevance of access in practice, i.e., the amount of access events actually occurring, is important for deciding on whether it is actually worthwhile to come to legislation – besides formal law, guidelines can help and may be sufficient.

Questions/remarks in plenary session

- With respect to the question if the EU Regulation is applicable to MS that have regulated access (1g): all EU citizens are obliged to comply to the EU Regulation, even if they live in a country which is not yet a party to the NP. However, the EU Regulation is not applicable to access regulations of in countries that are not parties to the NP.

4 Session 2: Implications of access legislation in the EU Member States

4.1 'Setting the scene'

Two presentations were given, followed by questions and remarks, in a plenary session. Below, a summary of each of the presentations and the questions/remarks is presented.

Presentation 1: Access Policy and Legislation and EU Research Projects (Licia Colli, Università Cattolica del Sacro Cuore, Italy)

The question to be addressed in this presentation is "How is the European ABS Regulation going to affect EU research project activities?", or, in a wider perspective, "How is the ABS Regulation going to affect research in the EU?".

1. The IMAGE Project

As a case study, the IMAGE (Innovative MAnagement of GEnetic resources) project was presented, a project with 28 partners (including SMEs and NGOs) from 12 EU and 5 non-EU countries, with the following aims:

1. to enhance the use of genetic collections and to upgrade animal gene bank management;
2. to develop genomic methodologies, biotechnologies, and bioinformatics for a better knowledge and exploitation of animal genetic resources.

2. IMAGE and the EU ABS Regulation

ABS is explicitly addressed in several Work Packages of the IMAGE project.

- WP1, Task1.3 *Implementation of access and benefit sharing regulation*:
  "…this work will contribute to development of standard Material Transfer Agreement and Mutually Agreed Terms in T2.3. The survey will also evaluate awareness regarding the procedure to register gene bank collections in the Commission's register and training needs in the ABS for gene banks managers, to inform work T7.5 and T7.6.";
  "The ABS issues will constitute a part of the comprehensive, detailed gene bank survey planned in T2.1";
  "A second survey will determine ABS provisions in the national legislation developed to implement the Nagoya Protocol and EU Regulation 511/2014. The survey will address both access requirements and potential benefit sharing provisions, especially in the context of utilisation of genetic resources from ex-situ collections…"
- WP2, Task T2.1 *Inventory and mapping of European animal genetic collections and their specific characteristics*:
  "Task 2.1 will also provide a detailed analysis of ABS related practices, in close collaboration with Task T1.3"
- WP2, Task T2.4 *Economic analysis of gene bank development and use*:
  "Variation between countries in their genebank status/funding and ABS legal framework may also be relevant for the economic analysis and will be taken into account"

It is also stated that: "In case animal DNA samples would need to be provided by a non-EU country, they will be provided in agreement with the ABS rules of the country of origin. They will remain the property of the country of origin". IMAGE also involves Egypt and Morocco, but "the work plan does not include the use of biological resources from these countries. Yet, both countries will benefit from training programmes and guidelines to establish their national gene bank, respectively."

3. Impact on participating research institutions

- Procedures on access, use, supply (define who decides on samples management (receipt, transfer etc.); policy for change of use).
- Regular training (researchers, administration, legal offices, visiting scientists).
- Database and sample storage system.

- Tracking system (internal use, transfers; use unique sample identifiers).

4. Impact on project budget

- Monetary and non-monetary benefits for sample providers.
- Training of personnel on ABS.
- Setting up of database and storage systems to trace and track samples.
- External legal advice.

5. Impact on competitiveness of European research

- Delayed onset of research because of additional paper work burden.
- Lack of reactivity in case a new use for a given resource is foreseen, or in case additional resources become necessary in the course of a project: need for re-negotiation.
- Unfair competition between EU and US (not part of CBD).
- Research results obtained inside EU could be more easily exploited outside EU, e.g. in non-CBD countries.

6. Impact on the efficacy of livestock research efforts

- Too restrictive access laws in relevant countries may lead to the lack of characterization of their resources or limit the extent of future research, just to avoid the burden of paper work.
- On the positive side: provider countries become able to characterize their own resources and may become full partners of EU research (e.g. the case of Columbia within the IMAGE project).
- Researchers will have to find a balance between good scientific plans, the number/identity of partners involved, and overall costs of ABS compliance.
- National laws are often more demanding than the EU Regulation, especially the date of application is crucial (e.g. resources collected before 2014): uncertainty on how to proceed in case information on the origin of a sample is lacking.
- As a consequence, old but highly valuable resources may become unavailable for research: risk of destruction of old resources ("why should we continue to keep them?").

7. Conclusion

Freely accessible livestock genetic resources would be best. If that is not the case, at least:
- facilitated access for non-commercial research on animal species relevant for food production (in particular if local scientists are involved in the research);

- availability of a specialized international instrument like the ITPGRFA for livestock species?;
- exclusion of information available in molecular databases from the EU ABS Regulation and national laws (at least for non-commercial use);
- extensive consultation between national authorities and local scientists before national access laws are finalized;
- livestock sector specific guidance developed by the EU?

Questions/remarks

- It is not realistic to expect the Nagoya Protocol to be amended. As for new (ITPGRFA-like) instruments, it was remarked that nobody is waiting for another 7 years of negotiations to come to an IT for livestock. However, ABS issues can be introduced into the Global Plan of Action (GPA).
- The introduction of standard contracts and 'common practices' is recommended to facilitate exchange.
- There was some surprise that things are working well in the project, as it is complicated to work with Colombia in ABS matters. LC answered that there is no genetic resources transfer with Colombia planned in the project.
- The question was asked if there are already examples available of access in the IMAGE project, but so far there have been no experiences.
- In the private AGR sector the interest in access issues is limited at the moment, but it may grow in the future.
- The example was mentioned of a project with goats and sheep in Kenya, where ABS issues may pose a challenge.
- The needs mentioned are similar to those for museums. The development of guidelines, best practices and tools would be useful to help users to know what to do, and providers to know what users need.

Presentation 2: Access Policy and Legislation and Transboundary Commercial R&D (Szonja Csörgő, European Seed Association (ESA), Belgium)

1. About ESA

ESA represents the European seed industry in contacts with the European institutions and international organizations, and maintains contacts with a wide range of actors in the fields of agriculture and biotechnology. It informs, represents and lobbies on all seed-related issues, including seed marketing, IPR, access to genetic resources, and plant/seed health. Its members include 38 national seed associations, 40 companies, and 29 seed-related businesses.

2. The context – why access to genetic resources is key?

Plant breeding involves landraces/wild material, genebank accessions and commercial material, in a multiyear process of selection, recombination and evaluation. Thousands of genetic resources from around the world may be used to arrive at one new variety. Therefore, facilitated access to all genetic material is key and has to be safeguarded. With respect to access, two parallel but mutually exclusive regimes exist: a general regime (CBD and Nagoya Protocol) and a special regime (ITPGRFA).

3. Overview of approaches to access

ESA has done an internal survey on national ABS legislation to which ESA members active in different European countries have provided information. Based on this internal survey, the European countries can be divided into five groups with respect to the legal situation regarding access:
- no information available (Latvia, Lithuania, Luxembourg, Malta);
- introduction of access rules is considered (Belgium, Cyprus, Estonia, Hungary, Ireland, Portugal, Slovenia);
- draft access rules in discussion (Bulgaria, France, Italy);
- access rules in force (Croatia, Greece, Norway, Spain);
- no access rules apply (Austria, Czech Republic, Denmark, Finland, Germany, Netherlands, Poland, Romania, Slovakia, Sweden, Switzerland, United Kingdom).

With respect to approaches to access measures, the main distinction is that between declaratory systems (Belgium), authorization systems (Bulgaria, Croatia, Greece, Italy, Spain), and mixed systems (France).

4. Key elements of access legislations

- The scope of access rules should be clear, limited and apply only to genetic resources that are accessed post Nagoya.
- Access rules should in any case not cover GR governed by the MLS of the IT PGRFA, and commercial varieties that are used as GR in further breeding.
- With respect to rules on benefit-sharing, clarity and legal certainty (e.g. provisions in the law) are appreciated; the MAT should comprise reasonable terms, not only monetary benefit-sharing should be considered, and a clear cut-off point to benefit-sharing obligations should be accepted. An example of clarity is the New Brazilian law, which states that 1% of net sales have to be paid to a dedicated fund. It was underlined, however, that 1% is an extremely high figure, so from that point of view it is not the example to follow.

5. What impact access legislation may have on innovation / R&D in breeding

- Complicated, costly and lengthy procedures (ABS laws are different in every country; PIC/MAT negotiations are necessary; external help may ne needed). So, part of the R&D budget has to be allocated to ABS checks, and less budget is available for innovation. This may favour bigger companies and result in further market imbalance.
- Accumulated obligations (several hundreds of GR may be used in the breeding of only 1 variety, and the number of GR with ABS obligations will become higher and higher). If there will be no clear cut-off point to obligations, this will result in material heavily encumbered with ABS obligations and limitations. This may result in a reduced use of genetic variation for further breeding, and cause a drawback for innovation.
- Possibilities for abuse (no transparency in bilateral negotiations on MAT; restrictive clauses on access; restrictive clauses on further use of a product obtained or requirement for subsequent user to restart negotiations). So, access measures may be abused by some players to restrict use of their material.
- Less biodiversity will be used in plant breeding and will be available from plant breeding. This is contrary to the goals of the CBD/Nagoya Protocol.

Access legislation may also be a success, for all, if access is granted, via a clear and easy procedure, and on reasonable terms. For the providing country, this will mean that resources will be used and benefits will be shared; for the commercial user, this will contribute to its innovations; and for society as a whole this will mean a greater product diversity and quick answers to new needs and challenges. Thus, it will serve the objectives of the CBD/Nagoya Protocol.

Brazil is an example of a country that changed its access measures significantly and made access easier (from an authorization system to a registration system). The reason for this change was that in the old system the procedure to obtain authorization was too complicated, resulting in very few authorizations issued, many abandoned initiatives, less R&D and less use.

6. Conclusions

- The aim should be to ensure access to all GR for further breeding.
- Based on experience order of preference is:
    1. no access rules;
    2. SMTA for all crops;
    3. declaration / registration system;
    4. authorization system.
- Any system needs to avoid cases where no follow up is given to requests.
- Any system must be clear and easy and must lead to results.

Questions/remarks

- It was remarked that the requirement in the New Brazilian law to pay 1% of net sales can be burdensome. EU member states should think well before introducing such a requirement, because it could stifle innovation.
- There could be a need for a network of users, like the network for regulators as expressed earlier. Currently there is no formal network. ESA talks with other private sector users, but the links with the public sector are less strong.
- Getting access in developing countries may be difficult. In India, for instance, it is very difficult.
- It was remarked that if commercial varieties will be exempt of the EU Regulation, the cut-off point problem mentioned in the presentation would be solved.
- According to some, the breeders' exemption in Plant Breeders' Rights (i.e. that breeders can use protected varieties for creating new varieties) is already a form of benefit-sharing.
- It was remarked that some of the problems mentioned in the last two presentations have already been solved, and that there is a need to move from generalities to more precise details.
- It was commented that US companies are ready to comply with access regulations, even though they are not obliged to (as the US is not a party to the CBD and Nagoya Protocol). Why is this awareness of international obligations not present to that extent in the EU? How much has the plant breeding sector contributed to the benefit-sharing fund of the ITPGRFA so far? Regulators are ready to look for solutions that work for everyone, but companies should accept that they should share benefits ("We are desperate to solve the access problems; are you desperate to share benefits?"). In reaction, it was mentioned that the lower level of awareness has to do with the fact that the number of companies in Europe is higher than in the US (and their size on average much smaller), and that the awareness in Europe is improving. Regarding contributions to the benefit-sharing fund of the Treaty and the willingness to share benefits, it was argued that the plant breeding sector is not unwilling to share benefits at all, and it was underlined that much benefit-sharing is being done by the sector, often in the form of in-kind contributions.

4.2 Working groups

Three working groups were formed to discuss the subject, aided by pre-formulated questions. Each working groups discussed the same questions. The conclusions of the working groups were reported during a final plenary session.

Working Group 1 (rapporteur: Michele Bozzano)
Question 1 **Which implications will national access regulations in the EU have on research and development?**

- Users of genetic resources will need to improve tracking systems; the key is information.
- Transaction costs are crucial (can be reduced by standardisation and online procedures).
- Networking platforms (such as ECPGR and EUFORGEN) at the EU level, for science-policy interface and for sharing experiences (between countries) and understanding, are to be recognized and supported.
- The need to register collections. There is much interest for registering, but there are still a lot of questions.
- At the moment, there are no real implications for Animal Genetic Resources (commercial breeding and reproduction), because imports are possible from a limited number of countries only, due to veterinary rules. In the EU member states, commercial breeding is often exempted from access regulations.
- Implications for Plant Genetic Resources and Forest Genetic Resources GR & FGR including implications on internal market
- Delays in research.
- Stakeholders need to be aware of differences between member states.
- Users will need to adjust to a new situation: from no regulation to new regulation.
- At the moment, users face a lack of knowledge and expertise.

Question 2
Which feedback could be provided to competent national authorities?

- National Focal Points should inform stakeholders in the EU about access legislation in their countries.
- Awareness raising is important.
- The ABS Clearing House should be reliable.

Questions/remarks in plenary session

- Some participants are disappointed that there is no coordinating body providing information on access policies of all EU member states. The International Chamber of Commerce (ICC) may perhaps fulfil that role? Perhaps countries could publish draft legislation on the ABS Clearing House, so that information is available at an earlier stage. Others think that it is sufficient that the ABS Clearing House offers the opportunity for member states place their legislation and measures there.

Working Group 2 (rapporteur: David Cary)

Question 1
Which implications will national access regulations in the EU have on research and development?

1a. What are the implications of access measures in EU member states for different stakeholder groups, including users of plant, animal and microbial genetic resources for food and agriculture, as well as forests genetic resources?

- Different access rules across different EU Member States.
- Sector Guidance is important for this.
- ABS Forum helpful.

- ABS Clearing House exists, but there is still a lack of information; it should be developed further.
- Recording of MS positions is needed: is this a role of the European Commission? Most countries have some website information on access.
- It will be a continuous process, with reviews and possible changes after lessons learned.
- Awareness raising for sectors is needed.
- Sector experience is that access regulation is at a very early stage and not presently workable, but this will develop with time and experience.

1b. Are there additional policies besides ABS, which impact on access to GRFA? Which bottlenecks may arise?

- Phytosanitary measures.
- In Italy there are EU and national laws, but also authorisations are required at regional level for access to and collection of samples.
- No private ownership of GR.
- Research at EU level, e.g. Horizon 2020, has to deal with procedures for public/private funding of R&D.

1c. Does the absence of an access policy (clear access policy) cause problems?

- Access is unsure if there is no law, particularly for sectors less represented and unsure of the mechanisms.
- Lack of clarity of the extent of usage of GR without further negotiation of access with landowners etc.
- Different terms and conditions.
- A single access point has advantages, but is not possible in all MS.

1d. How might these bottlenecks be solved?

- Do not place general notifications on the ABS Clearing House whilst the situation is still unclear, but raise awareness at the national level, for major stakeholders and for minor stakeholders who are the least aware.
- Legal uncertainty is problematic and has led to different interpretations.

Question 2
Which feedback could be provided to competent national authorities?

2a. Which implementing measures may resolve or alleviate potential negative effects of foreseen access measures?

- Needed is a legally non-binding box to tick for countries not currently requiring access.
- Netherlands NFP website quite helpful.
- The use of Best Practice models, flow-charts, checklists, etc. These could be placed on the ABS Clearing House website.
- Look at the impact of placing uses under the scope and then giving clear advice of any decision
- Clear advice on the interim position regarding access whilst the law is being enacted, such as ‘free access’, ‘advice that access will be retrospective’, etc., like Brazil.
- Make sure that positive effects of compliance are communicated to stakeholders

2b. What would be the role of CNAs, national Focal Points (NFPs) and monitoring agencies in guidance of EU users accessing genetic resources from EU members states establishing access measures?

- Provide as clear as possible information.
- In Italy, the role of the NFP is not always simple, because legislation is still in draft format. Can information be given whilst procedures are still going on?
- In Germany, NFPs have built up a nice webpage with 40 Q&As in German only; the

information will need to be at least bilingual.
- Information in Finland will be in 3 national languages and English.
- France will have 3 CNAs; Germany: 1 CNA and 2 assisting; Italy: 1 CNA for granting, but many for monitoring; Netherlands: 1 CNA and one agency for monitoring.
- Member states should declare benefits and a clear analysis of goals, benefits etc. would be a bonus. Australian example is a very good one not monetary but knowledge of what happens with their biodiversity.
- Plant GR examples are more numerous than for animals in conservation. Wildlife conservation could benefit.
- Regulators and ministries: awareness raising, authorisations, enforcement! Need to know the extent of their own roles!
- Issues with SMEs and their access to information and advice need special attention.
- The intention of the CBD and Nagoya Protocol is not to decrease biodiversity in EU companies.
- Be more friendly to your users.

Questions/remarks in plenary session
- With respect to question 2b: CNAs have not yet been designated in France.

Working Group 3 (rapporteur: Chris Lyal)

Question 1
Which implications will national access regulations in the EU have on research and development?

1a. What are the implications of access measures in EU member states for different stakeholder groups, including users of plant, animal and microbial genetic resources for food and agriculture, as well as forests genetic resources??
- Problem of researchers: lack of knowledge and information about regulations.
- It will become more costly for researchers to obtain access.
- It is sometimes unclear to people which regulations apply.
- It will require additional time to put things in order to ensure research can be carried out, which may result in being too late for funding opportunities. NFPs need to react quickly.
- Some problems arise from the lack of awareness of the Nagoya Protocol among scientists, and there may be too little awareness in government of the issues that affect researchers. It is important to identify who needs to do something about this. It can be done by scientists informing and training their peers. For this, they need to have both information from governments and the ability to provide input.
- Some examples exist of sectoral associations and networks developing information, advice and best practice.
- Plant breeders' organizations are trying to help members set up systems, noting that different entities have very different processes in a place already, so single solutions may not be appropriate.
- It is still very much work in process. This means that there is still a strong degree of uncertainty.
- It is important that at government level all ministries are involved and communicate well with each other, and that government engages all stakeholders as soon as possible. There is a need to help collections organise. The need for funding was not necessarily seen in impact assessments.
- Larger organisations may find it easier to adapt than smaller ones. Would be helpful to

have funding from EU to support smaller enterprises. LIFE+ is probably still in place and may offer opportunities. This may be too difficult for a small organisation but a consortium might apply.

1b. Are there additional policies besides ABS, which impact on access to GRFA? Which bottlenecks may arise?

- The ITPGRFA with its Annex 1 is a specialised instrument. For GR outside Annex 1, the situation is more complex and there may be no added value in using the SMTA. Different countries have different opinions on the use of the SMTA.
- Intellectual Property (IP).
- Native traits and patents: this problem must be addressed by MS, but it would be helpful to have this addressed at EU level.
- Bilateral free nets on this could militate against plant breeders exemption.

1c. Does the absence of an access policy (clear access policy) cause problems?

1d. How might these bottlenecks be solved?

- Again a communication issue within countries at ministry level.

Question 2
Which feedback could be provided to competent national authorities?

2a. Which implementing measures may resolve or alleviate potential negative effects of foreseen access measures?

- Model contractual clauses may help in the management of obligations of benefit-sharing and to raise trust.
- Issue of 'misuse' of bilateral negotiation raised earlier; a code of conduct may address this.

2b. What would be the role of CNAs, national Focal Points (NFPs) and monitoring agencies in guidance of EU users accessing genetic resources from EU members states establishing access measures?

- It is hoped that that implementation will be accompanied by training and awareness raising by authorities
- In Belgium, Louvain has trained NHM and other scientists on laws and how to address them.
- Policy in Wageningen is aimed at scientists, including visitors. Particularly the big users can set up effective policies, processes and tools.
- There is an important role for national focal points in making national stakeholders aware (if they know who they are, and many do not).
- Solving the problems cannot be left to a single DG but mainstreaming across stakeholders at this level would be beneficial. The relevance of ABS to a wide range of activities across the EU needs to be better appreciated and articulated. This must be reflected in appropriate awareness raising and funding for projects.
- Such mainstreaming would also be important at the MS level, so that different ministries can be informed effectively.
- Sectoral guidance documents will be prepared, based on stakeholder involvement. Sector experts will create first drafts. Government departments will be involved when the first draft is discussed.
- Hobby gardeners are also a stakeholder group, and setting up workshops to reach stakeholders at this level would be helpful, Funding to address this is also important.

Other remarks

• It takes time to develop sufficient awareness, acceptance and understanding.
Questions/remarks in plenary session • There were no questions nor remarks.

5 Discussion, conclusions and recommendations

In the final plenary session, some remaining issues were discussed, and conclusions/ recommendations were formulated.

Discussion

1. Is there a possibility of better taking into account the position and limited capacity of SMEs in the EU Regulation? Best practices and registered collections were meant to partially address this. Perhaps by developing model contracts in relation to access regulations? Trade organizations for SMEs exist and should be involved. Some sectors are lacking umbrella organizations (e.g. biostimulants), so that individual companies are left to themselves. Awareness in some sectors particularly needs to be raised. What can the European Commission do? Are there EU funding opportunities for proposals on capacity development regarding the implementation of ABS measures?
2. In Spain, an minimal approach has been chosen, so that not only large companies can handle the new situation (e.g. model contracts as part of guidance). In France, model contracts are foreseen as well.
3. The benefits of the implementation of the Nagoya Protocol need to be better communicated to stakeholders. Often the Protocol is still seen as an additional burden.
4. The differences in awareness raising between EU Member States should be limited, there should be consistency and a level playing field between Member States.
5. How can you become a EU-registered collection? Do all samples need to conform? No: it is also possible to register only a part of a collection.
6. Some participants request NFPs to create a coordinating information point on access regulations in EU Member states, possibly at the EC level. Others argue that this role is foreseen for the ABS Clearing House Mechanism. Information on ongoing legislation processes is needed as well. Networking between stakeholders (e.g. this workshop) partly provides for this.
7. Can NFPs confirm the absence of access requirements in a uniform way?

8. It would be better if the ABS Clearing House would have some standard questions answered in English for each country. In this regard, there are standard forms to be filled in, so the possibility exists, but the CBD secretariat cannot force countries to include all information. Neither does the CBD secretariat have the resources to have all legislation translated into English. Make clear what you want to see improved on the CHM! If there is no access law, you need info on civil law (property law), info on relevant civil law on the ABS-CH would be helpful. However, according to others, this might be confusing. The WIPO website may be consulted for legislation.

Conclusions/recommendations

1. Access legislation is coming into place, and cannot be ignored. This message should be conveyed to users in MS.
2. Awareness-raising is central in further work.
3. The balance between smaller and bigger players/sectors and the need for creating a level playing field needs further attention.
4. Regulators need to communicate why access is regulated in their country.
5. The important role of European Networking programmes on genetic resources (i.e. ECPGR, EUFORGEN and ERFP) should be recognized.

ANNEX 1: List of participants

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ANNEX 2: Presentations

On the CGN website dedicated to the workshop, pdf-files will be made available from all presentations (after approval from the European Commission):

http://www.wageningenur.nl/en/Expertise-Services/Statutory-research-tasks/Centre-for-Genetic-Resources-the-Netherlands-1/Centre-for-Genetic-Resources-the-Netherlands-1/Show-1/Workshop-Access-to-Genetic-Resources-for-Food-and-Agriculture-in-the-European-Union.htm