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Risk-mitigation for projects that rely on genetic resources from multiple sources: a project planner's decision-making tool

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EUCLEG - Breeding forage and grain legumes to increase the EU's and China's protein self-sufficiency. The strategic goal of EUCLEG is to reduce Europe and China's dependency on protein imports by developing efficient breeding strategies for the legume crops of a major economic importance in human food and animal feed. Large genetic diversity panels are studied in a range of field and controlled conditions and extensively genotyped. Markers associated to traits are identified and the potential of genomic selection to increase genetic gain is measured. The objective is to improve diversification of crops, crop productivity, yield stability and protein quality of both forage (alfalfa and red clover) and grain (pea, faba bean and soybean) legumes. This project is coordinated by INRAE (France).

www.eucleg.eu

www.inrae.fr

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INTRODUCTION

The purpose of this decision-making tool, is to help research and development (R&D) project planners mitigate the risk of project setbacks or failures, as a result of not being able to access genetic resources and related research inputs, to use them as needed for project purposes, or to disseminate research products derived from their use. It is intended primarily for planners of projects that rely on accessing, pooling and sharing a diverse portfolio of genetic resources from multiple sources in different countries and continents; projects for which the risks are substantially increased, in proportion to the diversity and number of sources of genetic resources they rely upon.

This tool responds to the fact that - as a result of an increasingly complex mix of social, political, technological and legal developments - there is a very real risk that potential providers of genetic resources (including research partners) will be not be willing or able to make them available for use in research projects.

Understandably, many scientists and research managers are not fully aware of these risks, and are therefore surprised when they start to encounter challenges after their projects are funded and initiated: challenges that can require them to alter or terminate planned activities, to find and work with alternative genetic resources and partners, and to suffer delays and added costs.

This tool is designed to raise scientists' awareness of the risks involved, so they can take them into consideration in the earliest stages of project planning.

It sets out questions that scientists need to ask themselves as part of the process of assessing the risks to their own plans under development, and lists optional strategies and 'go/no go' decision-making points to help with mitigating those risks in the project planning stages.

Influence of combined social, political, technological and legal developments

The combined social, political, technological and legal developments that have contributed to the current state of uncertainty and unpredictability concerning the availability of genetic resources, is already well documented (Safrin 2004, Halewood 2014, and others), so we include only the briefest description here. Biotechnology breakthroughs in the 1980s, combined with expanded intellectual property protections, raised concerns about the different ability of developed and developing countries to benefit from the use of genetic resources. One response has been to promote international rules for access and benefit-sharing which promote national sovereign control over genetic resources.

Despite the fact that the international community has, in recent decades, been able to agree upon a number of international conventions concerning intellectual property protections and access and benefit-sharing , legal certainty and predictability concerning availability and use genetic resources has not, in general, been increased. Indeed, in some ways, it continues to decrease. This is both reflected, and perpetuated, by the fact that shortly after most of these international conventions were adopted, international processes were launched to review and revise them (or develop new international laws), driven by dissatisfaction with their impact and/or by new technological developments that threaten to make them obsolete.

Recent breakthroughs in genome sequencing and high throughput phenotyping, combined with gene editing and gene synthesis technologies, are exacerbating concerns that commercial users can profit from the use of genomic sequence data, without having to share benefits under the existing framework of international access and benefit-sharing agreements, but still have the possibility of enjoying intellectual property protections for those inventions.

The result is a new generation of what continue to be heated contested negotiations in multiple international fora about technology, equity, intellectual property and access and benefit-sharing.

One knock-on effect of this international level dynamism, is that many countries' national laws are also in a state of flux. This is partly due to the fact that it usually takes several years for national systems implementing international agreements to be put in place. But it is also a function of the fact that, because of lingering dissatisfaction and uncertainty in the overall balance of rights and obligations that have been struck to date across the international legal framework, many contracting parties are reluctant to invest resources in developing implementing measures.

Alternatively, some countries have adopted new implementing measures 'on paper', but they are delaying making requisite investments to make them fully operational until the outcomes of ongoing international discussion and negotiations are clearer. Of course, many countries have made requisite investments to make their national laws and regulations functional, certain and predictable, but is sometimes hard 'from the outside' to distinguish between them. All of this, of course, contributes to a lack of clarity and predictability for researchers and other genetic resources users about the rules and conditions that apply to owning, controlling, accessing and using genetic resources and associated information in different countries.

While less politically contentious, internationally coordinated and nationally implemented systems to prevent the spread of diseases through the transfer of biological materials, can also have major impacts on researchers' ability to access genetic resources.

In this decision-making tool, we will include consideration of risks associated with the operation of national systems pertaining to plants in particular, i.e., those which implement the International Plant Protection Convention.

The structure and logic of this decision-making tool

Section 2 of this tool, immediately following this introduction, presents 4 successive stages in the life cycle of a typical large research and development project that involves accessing and pooling genetic resources and related information and technologies from multiple sources. For each of those stages, we list the risks to the project and to the subsequent take-up of the project's results.

In ***Section 3***, we focus on the policy and legal issues that that are associated with accessing and using genetic resources and related information and technologies, that can contribute to the risks.

For each of these policy and legal issues we include:

1. the questions that research planners need to address to evaluate the extent of the particular risk, taking into consideration the state of laws and policies in the countries where partners are located, where research and development activities are carried out, and ultimately, where research products will be disseminated, including the manner in which these laws and policies can affect (positively or negatively) those risks.

2. tips for addressing those risks at the planning stage of the project.

Section 4 proposes overall strategies that project planners can adopt as part of their risk-mitigation efforts.

The EUCLEG project

The Horizon 2020-funded project "Breeding forage and grain legumes to increase the European Union's (EU) and China's protein self-sufficiency" (EUCLEG project) has involved 37 participants from more than 10 countries (both EU and non-EU). It has relied on the sharing and characterization of wide collections of genetic resources of the target crops (alfalfa, red clover, white clover, pea, faba bean and soybean) for identifying valuable trait variation to be introduced into current elite material used in breeding programs.

One of the research packages built into the EUCLEC project from the very beginning, involved monitoring the impacts of genetic resources-related policies at institutional, national and international levels on project activities. This has facilitated more systematic, project-wide reflection on these issues than is often the case, where policy challenges are experienced as an incident of practical project administration. It is not the purpose of this decision-making tool to enter into details of challenges encountered during the EUCLEG project. Those are documented elsewhere (Bedmar et al. 2020). That said, the experience of the EUCLEG researchers has allowed the project to identify the main legal and policy-related issues that individual researchers, research organizations and research consortia face when acquiring, sharing and using germplasm, related information and technologies in the first place; and then generating and disseminating research results based on genetic resources and related information and technologies. It has also allowed the project to explore ways to anticipate and address policy and legal issues at early stages, in order to ensure compliance, minimize inefficiencies and avoid restrictions to the dissemination of research results, including in the form of new commercial products.

This decision-making tool builds on the EUCLEG project experiences, aiming to provide guidance to researchers who embark in similar research projects and consortia, funded by the H2020 programme and other funding programmes and donors.

POTENTIAL RISKS OVER AN R&D PROJECT'S LIFECYCLE

Assembling the research inputs, including genetic resources

Risk: Project partners are unable to acquire genetic resources and other research inputs from provider organizations within or outside the research consortium.

Contributing factors:

- Potential providers' feeling that the project will not generate sufficient benefits for them
- Access and benefit-sharing laws
- Political sensitivities around the sharing of genetic resources
- Intellectual property rights over the genetic resources, related information and technologies
- Provider partners do not actually have the authority or legal right within their organization to share the research inputs
- Phytosanitary regulations

Data exchange within the project

Risk: Project partners do not share with one another the data and information they have generated.

Contributing factors:

- Lack of commitment with the project's goals
- Unclear rules about data ownership and data sharing

Disseminating the research results

Risk: Project partners are not willing or able to share or disseminate the project's results.

Contributing factors:

- Restrictive conditions in the agreements under which the genetic resources and other research inputs were acquired
- Disagreements concerning control and dissemination of research results

Product development and commercialization

Risk: Potential users of the projects' results face challenges to take up the research results and to use them for the development of commercial products.

Contributing factors:

- The conditions under which the research inputs were acquired limit commercial users' ability to use them for producing marketable products
- Users cannot show ABS due diligence
- Benefit-sharing obligations become too heavy a burden for commercial users

ADDRESSING RISKS AT THE PLANNING STAGE OF AN R&D PROJECT

Dealing with issues related to the access to genetic resources and the sharing of benefits arising from their use

Introduction

- If you embark on a research project with activities that depend on the access to and use of genetic resources coming from different countries and organizations, you will surely have to address questions around who has the right to control access to genetic resources, who can use them, and who can benefit from the results of the research.

- Laws regulating the access to genetic resources and the sharing of the benefits arising from their use (ABS) are designed to address these issues. There are two types of ABS frameworks: under bilateral frameworks each transfer is negotiated bilaterally between the provider and the recipient; under a multilateral framework everyone agrees that every transfer will be subject to the same set of rules, which are negotiated in advance. The International Treaty on Plant Genetic Resources for Food and Agriculture (the Plant Treaty) establishes a multilateral system for the exchange of a set of plant genetic resources to be used for research, training and breeding in food and agriculture.

- Despite efforts made by the international community and by countries to put ABS systems in place, many research organizations are based in countries where there is still much tension around the sharing of genetic resources, and mistrust and discomfort among researchers. In some countries, national ABS laws have established long and cumbersome access procedures that researchers often find difficult to navigate. For these and other reasons, it may happen that the provider organizations that you would like to engage in your project, feel reluctant to provide samples of the genetic resources they hold, or that they try to impose restrictive conditions that limit project partners' ability to use the genetic resources for the purposes of the project, to disseminate the research results, or to employ them in the development and commercialization of products at the end of the R&D chain.

- In an increasing number of countries, as a result of the implementation of the Nagoya Protocol on the Access to Genetic Resources and the Sharing of the Benefits Arising from their Use, systems are being put in place for monitoring if users have obtained the permits required by the national laws and regulations of the provider countries. In the European Countries, the EU ABS Regulation 511/2014 on compliance measures for users sets up the overall monitoring framework in EU countries. According to this Regulation, project partners that are based in the EU need to demonstrate that they have acquired the genetic resources in accordance with applicable laws. Otherwise, they may not be able to obtain funding, disseminate the research results (including in scientific journals), obtain intellectual property rights over them, and exploit them through commercial products. In addition, not being able to demonstrate due diligence may put these partners' reputation at risk, and may generate mistrust among their collaborators and donors.

Project partners cannot obtain the genetic resources necessary for the project (1/3)

Are the provider organizations from which the project partners expect to obtain the genetic resources interested or motivated to provide access?

- If not, are there benefit-sharing options that may encourage the provider organizations to change their perception and become more inclined to provide the genetic resources?
- If so, what kinds of benefit-sharing are the organizations interested in?
- Can the project afford them?
- If not, can alternative providers of the same genetic resources be considered?
- If not, can you revise the project's plans so that it does not depend on those particular genetic resources?

TIPS

ABS rules were developed largely in response to a sense (particularly among countries that are often historical 'providers' of genetic resources) that more, and more creative benefit-sharing from R&D projects is necessary. So it makes sense to build serious consideration of benefit-sharing into your project plans. You can consider, among other measures, greater involvement of that organization in the project, participating in the identification of research priorities, getting funding for R&D activities that is part of the project, sharing ownership in, or getting priority access to, research results, capacity building and technology sharing, a share in royalties from downstream licensees of project outputs, maybe even agreements for research collaboration beyond the project.

One of the criteria for choosing research partners and potential providers of genetic resources and related information can be organizations' reputation for providing access to germplasm, and their experience and agility in dealing with germplasm requests. If you don't think the benefits you can offer through the project can overcome their demonstrated past reluctance, it is important to recognize that up front, and make other plans.

For plant genetic resources available through the Plant Treaty's multilateral system, access and benefit-sharing terms are already 'pre-agreed' by contracting parties in the form of a Standard Material Transfer Agreement (SMTA). In theory, if materials you want are included in the multilateral system, then you should be able to get facilitated access to them under the SMTA. The challenge here is that it can be hard for the project partners to know for certain if a particular plant genetic resource for food and agriculture (PGRFA) is actually available through the multilateral system, or if it falls under some other national regulatory framework.

Risk

Project partners cannot obtain the genetic resources necessary for the project (2/3)

Can the potential provider organizations obtain permission to give access to the genetic resources?

If not, is it because the applicable laws regulating the access to genetic resources and the sharing of benefits arising from their use (ABS) are unclear, or the access procedures long and cumbersome, or simply not operational because implementing systems are under-resourced?

If so, can the project afford to spend the time and resources necessary for obtaining the access permits?

If not, can alternative providers of the same genetic resources be considered?

If not, can you revise the project's plans so that it does not depend on those particular genetic resources?

If not, is it because the organization originally acquired the genetic resources subject to conditions that restrict their transfer to further users?

If so, can the project partners go to the original providers and obtain the genetic resources under more permissive conditions?

If not, can alternative providers of the same genetic resources be considered?

If not, can you revise the project's plans so that it does not depend on those particular genetic resources?

TIPS

Here, the focus is on the national laws and not on the provider per se. The provider may be willing to provide the resource, but not be able to get permissions at all, or in a timely manner, from the competent national authorities. In order to understand the difficulties, become familiar with access and benefit-sharing rules in the potential providers' countries (including those of planned partners). Your potential partners are a good place to start asking for feedback about the national laws. In addition, for information about national ABS laws implementing the Convention on Biological Diversity (CBD)/Nagoya Protocol, you can consult the ABS Clearing House, which provides information about national ABS regimes: https://absch.cbd.int/. You can also get in touch with national ABS authorities (also listed in the ABS Clearing House) and request guidance. As far as whether or not materials are available under the Plant Treaty's multilateral system, you can ask the potential providers. Another potential source of information is the Plant Treaty National Focal Point, who is listed on the Plant treaty website at http://www.fao.org/plant-treaty/countries/national-focal-points/en/.

One of the criteria for choosing research partners and potential providers of genetic resources can be the clarity of their country's national ABS regimes and whether the process for obtaining access permits seems friendly, for example by providing simplified procedures for the acquisition of genetic resources for research purposes.

Project partners cannot obtain the genetic resources necessary for the project (3/3)

Will provider organizations require monetary benefit-sharing?

If so, can the project afford the required payments?

- If not, can they be negotiated?
  - If not, can you consider alternative providers?
    - If not, can you revise the project's plans so that it does not depend on those particular genetic resources?

If not, does the project want to voluntarily assume some form of monetary benefit-sharing?

TIPS

Learn about partners and providers' policies and practices in relation to monetary benefit-sharing: What rates they apply for monetary benefit-sharing; when the obligation to make payments as monetary benefit-sharing is triggered (e.g. when using the genetic resources, when disseminating the research results; when commercializing research-based products); and what reporting conditions they require to monitor compliance with monetary benefit-sharing obligations.

Monetary benefit-sharing obligations have not only financial implications, but they may also imply transaction costs derived from the need to track, trace and report how the genetic resources have been used, the extent to which they have contributed to commercial products, and the revenue portion that is allocated to benefit-sharing. Evaluate the financial and transaction costs at the planning stage, and their potential implications for the project partners and for the actors you want to see using the project's research results.

Put in place mechanisms to ensure that project partners pass onto commercial users the benefit-sharing obligations that will be triggered at the commercialization stage. One clear case is the monetary benefit-sharing obligation under the Standard Material Transfer Agreement of the International Treaty on Plant Genetic Resources for Food and Agriculture. This SMTA requires companies to pay a percentage of the monetary benefits obtained from the commercialization of new varieties that incorporate any level of the germplasm they received with the SMTA, whenever the new varieties are not available for further research and breeding. If project partners have obtained genetic resources through the SMTA and they pass research results which incorporate these genetic resources to commercial actors who will exploit them commercially, they have to make sure that they pass on the benefit-sharing obligations of the SMTA onto the commercial actors.

Even if genetic resource providers do not require monetary benefit-sharing, the project partners could agree to assume payments on a voluntary basis, or to require commercial users to assume the payments. There may be strong reasons for doing this, for example to provide incentives for the provider organization to facilitate access to their genetic resources, to reinforce collaboration with the provider organization, to improve the reputation of the project and the project partners, and to facilitate progress towards the project's objectives.

Project partners cannot disseminate the research results derived from the use of the genetic resources

Will provider organizations try to impose conditions that may limit project partners' ability to 1) share the data generated by the research with other project partners; and 2) disseminate the research results (data, methods, genomic tools, improved lines or strains) in the ways envisaged by the project?

- If so, can the conditions be negotiated?
  - If not, can you consider alternative providers of genetic resources?
    - If not, can you revise the project's plans so that it does not depend on those particular genetic resources?

TIPS

Evaluate the potential conditions that providers of genetic resources may try to impose. For example, if project partners are obliged to get approval from the providers before sharing the research results with other project partners or with potential users, the transaction costs will increase considerably at the dissemination phase. If the providers ban the sharing of the research results with certain users (for example companies who may exploit the project's products commercially), the range of actors who can benefit from the project may be seriously restricted.

Target commercial users cannot exploit the research results

Will provider organizations try to impose conditions that may limit the ability of your target commercial users to exploit the research results?

- If so, can the conditions be negotiated at the time of assembling the genetic resources?
- If not, can you get some assurance that there will be a constructive negotiation down the road, once the research results demonstrate market potential?
- If not, can you consider alternative providers of genetic resources?
- If not, can you revise the project's plans so that it does not depend on those particular genetic resources?

TIPS

Map and characterize the commercial actors that you want to see using your research results (e.g. breeding companies). Some may be already partners in the project. Understand the conditions that would make it difficult for them to convert the project's research results into commercial products. For example, limitations to sell the products in relevant markets, restrictions to claim intellectual property rights over the products, or requirements to share a substantial proportion of royalties or other benefit-sharing conditions that they consider unduly onerous.

If you can't secure freedom to operate for your commercial target users at the time of assembling the portfolios of the genetic resources, you can try and come up with a strategy to facilitate the negotiation between the relevant providers or partners and the relevant commercial actors once it becomes clear that certain research results have a market potential.

Try to define the outer limits of negotiable conditions with potential partners and providers, in order to minimize the risk of them introducing conditions that will in practice make getting project deliverables scaled up and out impossible.

Project partners cannot demonstrate ABS due diligence

Will project partners and further users of the research results be able to demonstrate that the genetic resources used in the project were obtained in accordance with applicable ABS laws?

- If so, what proof of compliance will they have to present?
- Do project partners have the requisite proof, or can they acquire it?
- If not, can the project afford the consequences of not demostrating compliance?
- If not, can you revise the project's plans so that it does not rely on genetic resources for which project partners cannot show due diligence?

TIPS

Become familiar with the requirements of the ABS checkpoints in the countries where you and your target users will operate. Checkpoints are required by the Nagoya Protocol on ABS for all its member states, and have the objective to monitor if users comply with the ABS requirements imposed by the provider countries. Checkpoints may include ministries of research, funding agencies, intellectual property offices and public agencies for the registration of new commercial products. Proof of due diligence required by the checkpoints may include international certificates of compliance, access permits and and material transfer agreements.

Set up a documentation system that helps you keep records of project partners' acquisitions, and of the conditions that apply to each genetic resource used in the project.

Be prepared to share the necessary documentation with users of research results who may need to show due diligence when conducting further research or developing and commercializing products. Checkpoints may also want to see proof that you received materials under the SMTA. While germplasm transfers under the multilateral system is not within their jurisdiction, it may be that the only way they can know this is the case is to see proof you obtained it under an SMTA.

Acquiring research inputs that are subject to intellectual property rights

Introduction

- The research project may need to use genetic resources, related information, technologies, methods and other inputs that may be subject to intellectual property rights. In fact, with the raise of intellectual property protection in biotechnologies in general, and in technologies dealing with plant, animal an microorganisms used in agriculture in particular, it is likely that many research projects will be interested in using proprietary technologies in their activities.
- Genetically modified plants and animals, breeding methods, traits, genomic tools and other research resources can be subject to patents. Obtaining the licenses for using them in the project can be time consuming, and expensive. If you are planning to use cutting-edge biotechnologies, most probably you will have to deal with inventions that are subject to multiple patents, or acquire complementary technologies, each of them subject to its own patent. This increases the challenges involved in obtaining the necessary licenses.

- Plant varieties subject to plant breeders' rights (PBR, or plant variety protection rights - PVP) that have been granted by countries who operate under the UPOV Convention can be used for further breeding by crossing and selection, and the resulting varieties can be commercialized without any obligation to seek the permission from the PBR holder. However, in practice, PBR owners may feel reluctant to provide access to their protected varieties to researchers who are based in countries where the varieties are not being commercialized if they suspect that the recipient organizations may subsequently use the varieties not only for further breeding, but also for multiplication and commercialization, without obtaining the necessary licenses.

- Fears can arise also at the time of disseminating the research results, and the commercial products derived from the project: project partners and commercial users may not want to release their proprietary technologies (including plant varieties and animal breeds) in countries where they feel that their property rights won't be enforced, so others can simply access the materials on the open market and use them to enter into competition with the owner.

Project partners cannot obtain genetic resources and related technologies necessary for the project

Does the project need to use genetic resources and related technologies that are subject to intellectual property rights?

If so, are the holders of the protected technologies willing to provide them to the project?

If yes, can the project afford the costs (financial and transaction costs)?

If not, is there a way to decrease the costs (e.g. engaging IPR owners as project partners; using alternative, substitute technologies that can be organized under more favorable terms)?

If not, is it because of the intellectual property holder's own business strategy?

If not, is it because the intellectual property holder is afraid of misappropriation by some of the project partners?

If so, is this fear well founded?

If not, can the project address possible misperceptions?

If yes, perhaps there is nothing the project can do. Can the project find another partner or provider?

TIPS

Identify the research inputs that are subject to intellectual property rights in the countries where the project will operate and seek legal advice on the time and resources that you will need to invest in order to obtain the necessary licenses.

Evaluate the project's chances of acquiring patented technologies in a timely manner, taking into consideration the fees to be paid, the transaction costs, the research consortium's ability to negotiate the licenses, and the benefits the project can realistically generate for the patent owner in return (in addition to the fees; e.g. reputation, access to cutting-edge technology and information, possibility of long-term collaboration with other research organizations).

Investigate the intellectual property right culture within the partners' organizations, and study the legal framework and enforcement mechanisms in the countries where research partners will be working with the protected materials. Assess whether the fear of misappropriation is founded, and explore ways to guarantee and reassure the providers of proprietary materials and technologies. There may be cases in which getting meaningful protection in the country concerned will be impossible. If intellectual property protection is crucial for key project partners, you may want to decide to work somewhere else.

Project partners cannot disseminate the research results derived from the proprietary genetic resources and related technologies

Will providers of genetic resources and related technologies that are subject to Intellectual Property Rights try to impose conditions that may limit project partners' ability to disseminate the research results in the ways envisaged by the project, and their take up by further users, including commercial actors?

- If so, can the conditions be negotiated?
- If not, can you consider alternative or substitute technologies?
- If not, can you revise the project's plans so that it does not depend on those proprietary technologies?

Project partners and target commercial users do not want to disseminate research results and derived commercial products

Are project partners and target commercial users reluctant to disseminate results and products over which they intend to claim intellectual property rights?

- If so, is it because they are afraid that their intellectual property rights won't be respected and enforced in some of the project's target markets?
  - If so, is this fear well-founded?
    - If not, can the project address possible misperceptions?
      - If yes, is there anything the project can do?

TIPS

Study the legal framework and enforcement mechanisms for intellectual property rights in the countries where you want to see the project results converted into commercial products, possibly subject to property rights. Assess the risk that the new products be misappropriated, and the extent to which misappropriation can represent a big disincentive for project partners and target commercial users.

Introduction

Researchers involved in the project may assume that they have the legal authority to commit their organizations to share genetic resources with the other project partners, and later in the project, when the time arrives to send the genetic resources, they may find out that they don't have such rights. In order to avoid this situation, you and your research partners must verify your own capacities and rights to make legally binding agreements on behalf of your organization to share germplasm. This verification should take place at the planning stage, and certainly before committing to contribute the selected genetic resources to the project.

Project partners cannot provide access to genetic resources they hold and that are necessary for the project

Do the individuals you are engaged with in planning the project have the authority to agree, on behalf of their organizations, to share genetic resources for the project purposes?

- If not, is there an institutional policy that prevents them from obtaining authorization?
  - If not, can they obtain the authorization from the relevant managers?
    - If not, can alternative providers of the same genetic resources be considered?
      - If not, can you revise the project's plans so that it does not depend on those particular genetic resources?

TIPS

Confirm that individual researchers from different organizations involved in your project have the authority to make legally binding undertakings to provide germplasm or related information on behalf of their organization. If they do not, get such assurances from people in their organization that do have such authority; before project planning and partnership formation processes are complete.

Dealing with phytosanitary regulations

Introduction

- Phytosanitary regulations restrict or prohibit the importation of certain plant species, or products of these plants, so as to prevent the introduction or spread of plant pests or pathogens that these plants may be carrying. These regulations can have a big effect on the actual movement of samples across countries and regions.
- Certain plants and plant products entering the European Union must have an import permit issued by EPPO and a phytosanitary certificate guaranteeing that they are properly inspected; free from quarantine and any regulated pests, and in line with the plant health requirements of the EU as per conditions given in the import permit. The exporting country's national plant protection authorities issue the phytosanitary certificates. Once in the EU, a plant passport may replace the phytosanitary certificate for imported plants, plant products and other objects, for movement within the EU region.

Plant protection agencies in exporting countries may have limited capacities to issue phytosanitary certificates with sufficient declarations demanded by the importing country, and/or plant protection agencies in importing countries may not consider the phytosanitary certificates issued by certain countries reliable or sufficient. These limitations can delay or block the movement of genetic resources among providers and recipients in your project. EPPO authorities could hold the material for further inspection and testing. This could result in a substantial delay in accessing the material, and potential loss of the material found to be contaminated with pests. Overcoming these potential challenges requires advance planning and advance action (3 to 12 months ahead depending on the species; vegetatively propagated germplasm requires long time than the seed crops). In addition, you must take into consideration the costs associated with the phytosanitary controls, as well as possible additional tests required in certain countries. For example, some countries may require tests for checking presence of genetically modified organisms (GMOs).

Project partners cannot obtain genetic resources necessary for the project

Are the samples of genetic resources that you want to assemble for the project subject to phytosanitary requirements?

- If so, do project partners and other potential providers have capacities to issue bonfide phytosanitary certificates?
  - If not, can alternative providers of the same genetic resources be considered?
    - If not, can you revise the project's plans so that it does not depend on those particular genetic resources?

In addition to a phytosanitary certificate, what other regulator documents may be necessary? (e.g., customs clearance; declaration of GMO status)

- Can provider organizations and project partners provide all the necessary documentation?
  - If not, what alternative options can be considered?

How long does the import process normally take? How much do the procedures cost?

- Can the project afford the expected costs and delays?
  - If not, can you revise project plans in order to avoid import of genetic resources in the most problematic countries?

Will GMO testing be required?

- If so, can the provider organization carry out the testing?
  - If not, can alternative provider organizations be considered?

TIPS

Become familiar with phytosanitary requirements in the countries where you need to send or receive the material, and anticipate possible problems and delays at customs. Identify the quarantine pests and the regulated non-quarantine pests that may affect the import of samples your project plans to use. Bear in mind that phytosanitary requests change in response to the emergence of new pests and diseases, and new methods for controlling them. And that it sometime occurs that out of an abundance of caution, some countries require proof of absence of diseases that are not known to affect the genera or species in question.

Keeping up to date on international, regional and national requirements in relation to the species you work on will help you avoid surprises. You can check the EU websites for these purposes: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R2031-20191214; https://eur-lex.europa.eu/eli/dir/1992/103/oj.

Be prepared for GMO controls, particularly if the project works with plant, animal or microorganism species for which GMO varieties, breeds and strains have been approved and are already commercialized in the provider organization's country, and banned in the recipient organization's country. The rules of the exporting and the importing country may require that the provider organization demonstrates that the presence of GMO plants in the sample is below a certain threshold. This requires rigorous, certified testing of the whole sample.

Defining common strategies for results' dissemination and exploitation

Introduction

- Your project results may include information (e.g. phenotypic and genotypic data), genomic tools (e.g. expressed sequence tags-ESTs, molecular markers, genetic maps), bioinformatic tools (e.g. software, algorithms), research and breeding methods, and improved varieties, breeds or strains.
- The success of your research project will be determined by the extent to which the project partners and your target users take up these research results and use them in their own work, either directly, in the form you release them, or for further research, and for the development of new products such as new plant varieties and animal breeds.

- Partners' preferences in relation to the dissemination of the results can affect how project partners share information they have generated with one another, and how they disseminate the research results. Some partners may be bound by institutional policies that require them to treat the results of their research as public goods, unless particular circumstances recommend putting restrictions on their availability. Other project partners may have the freedom, and the preference, to treat the project's results as proprietary technologies and control their use through license agreements. Some project partners may prefer to share the research results with any interested user, while others may wish to provide exclusive rights over the research results to selected users. The donor or funding agency may impose its own conditions on product dissemination and exploitation.

- Unless the project partnership agrees on a common approach and all project partners commit to it at the planning stage, conflicts might arise, and the dissemination of the project's results may be compromised.

Project partners do not share or disseminate research results as envisaged by the project

Do project partners agree with dissemination principles that best support the project's mission and objectives?

- If not, can you include flexibilities and exceptions that will accommodate partners' concerns and preferences without compromising the project's mission and objectives?

TIPS

Identify divergences in the consortium members' views on how the products should be disseminated, and assess the different options, from open access to exclusive and restrictive licenses. Do this assessment bearing in mind the project's mission and objectives, the funding agencies' requirements and the partner organizations' policies and preferences.

Consider possible exceptions, embargos and flexibilities that the project partners can subject themselves to in order to accommodate their preferences and needs within the overall dissemination principles. For example:

1. The research consortium can agree to provide access to research data in an open and free manner, but the timeframe may be subject to certain flexibility. For example, exclusive rights over the data can be recognized for data generators over a limited number of years, or until the data are published in a scientific publication.
2. The research consortium can agree to provide access to the research results through exclusive or semi-exclusive licenses (provided that this is allowed by the donor and in line with the project's objectives), but some exceptions to the exclusivity approach can be recognized. For example, project partners can be permitted to reserve themselves the right to make the results available to particular types of users (e.g. public research organizations) and for particular uses (e.g. non-commercial research for food and agriculture, or for the benefit of 'resource poor farmers', or for 'humanitarian purposes').

Negotiate and agree on a common dissemination approach at the project's planning stage, and spell it out in the partnership agreement. This will provide certainty to the project partners on a crucial aspect, and will help to avoid frustrations and negotiations at a later stage.

Willingness of organizations to align to a pre-determined dissemination approach (for example, open and free access to research results) may be one of the criteria for selecting the project partners.

OVERALL STRATEGIES FOR MINIMIZING RISKS

Start preparing early

As soon as possible, and ideally before the project starts, begin negotiating the agreements about who will contribute what to the project, and under what conditions. Additionally in the early planning stage, discuss and agree on the principles that will govern the dissemination of the project results, and possible exceptions to the general dissemination strategy.

Starting early will give you time to negotiate with partners and potential providers, address requirements derived from national ABS laws, and explore options to address partners and providers' possible reluctance or discomfort when sharing genetic resources and related information. This will also enable you to avoid situations in which a project partner or a provider unexpectedly rejects a request to provide germplasm it has originally committed, and which is necessary for the project's activities, as well as situations in which project partners deny access to data they have generated throughout the project to other project partners, or try to impose restrictions on the dissemination of research results based on their own institutional policies and practices.

Define your red lines

Anticipate situations you cannot accept. For example: the procedures for obtaining genetic resources takes longer than X months; the conditions imposed by the provider organization are too restrictive and will limit the project's activities and objectives; the provider organization does not give permits in written form, or does not provide legal certainty otherwise.

Consider standardization of terms and conditions for the acquisition of genetic resources

At the planning stage, project partners can agree on the text of a common material transfer agreement (MTA) that will be used for all the transfers of germplasm within the project and which spells out the conditions that are acceptable for all project partners, from permitted uses to benefit-sharing arrangements.

Be conscious of partner's different preferences, and understand that some partners may need to include different or additional conditions for sharing particular samples. These conditions may have been imposed by the original provider of those genetic resources, they may come from national ABS rules, or they may be required by the provider partner's policies. The consortium must find the balance between setting common standards and respecting individual needs. For example, some partners may feel reluctant to share improved lines they have developed unless the material transfer agreement makes it clear that the samples cannot be used for purposes beyond the project, and particularly for seed multiplication and distribution.

If you are dealing with plant genetic resources for food and agriculture, you will have to use the Standard Material Transfer Agreement of the International Treaty on Plant Genetic Resources for Food and Agriculture for all transfers of plant germplasm that are included in the Plant Treaty's multilateral system of access and benefit-sharing (MLS) (you can learn about collections/accessions that are included in the multilateral system at http://www.fao.org/plant-treaty/areas-of-work/the-multilateral-system/collections/en/; Genesys https://www.genesys-pgr.org/ Eurisco https://eurisco.ipk-gatersleben.de/). If the PGRFA used in the project are not already included in the multilateral system you can nonetheless considering voluntarily using the SMTA for such transfers in the project if partners agree, and providers in each case have the legal right to do so.

Assess the possibility of obtaining permits at two stages

Providers of genetic resources, information and technologies may be willing to provide access to their inputs under simple terms, and in a quick manner, if these are going to be used only for research purposes. In this case, providers usually impose the condition that if the resources, knowledge or technology is subsequently used for the development of commercial products, the user will have to obtain a new agreement with new terms and conditions, often pertaining to benefit-sharing arrangements. This two-step approach (i.e. first agreement for research purposes, and second agreement for product development) may be appropriate for your research project, since it minimizes transactions costs when acquiring genetic resources, information and technology, the value of which (for the development of commercial products) is still unknown. Once research results demonstrate where the market potential is, project partners or commercial users can go back to the original providers and negotiate a new agreement for the commercial exploitation of the selected genetic resources, information, technology, etc.

Consider open access for disseminating the project results, and particularly data

Ample access, sharing and use of information (including phenotypic and genotypic characterization data) are considered the fuel for the furtherance of plant and animal research and breeding. Some of the biggest information platforms and databases, research consortia and research organizations have embraced the principle of providing free and open access to the data they generate and host. If your research consortium is publicly funded, you may need or want to apply this same approach to most of the data you will generate. In fact, some large funding programmes and agencies such as Horizon2020 require projects to implement open access.

Open access does not necessarily mean absence of terms and conditions. If data are made available on existing databases, data access and use conditions of such databases will apply. Project partners will need to be aware of this from the beginning of the project, since this will influence the conditions they can or cannot accept from providers of research inputs.

If the project sets up its own database, you may consider that certain conditions are met by data users in order to:

- protect the public nature of the data (for example intellectual property rights over the data or over data and products derived from the original data could be restricted);
- recognize the source (for example attribution could be required); and
- increase legal certainty around data usage. National laws, institutional rules and obligations acquired through contracts (e.g. access agreements obtained with original providers of the genetic resources and related information) may also require partners in the research consortium to include certain terms and conditions for the use of data.

You need to be aware, as noted in the introduction, that there is currently disagreement in a number of international fora concerning the governance of genomic sequence information, particularly if and how monetary benefit derived from the commercial use of such information should be shared. As a result, this is a sensitive issue and should be explicitly discussed and agreements reached about how the project will share genomic research data.

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