

PUBLIC CONSULTATION ON THE IMPLEMENTATION AND RATIFICATION OF THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY

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QUESTIONS

The Commission invites answers to the following questions:

The Nagoya Protocol contains detailed provisions on ABS, PIC and MAT which will need to be complied with by users and providers of genetic resources upon entry into force of the Protocol.

As a general point, the implementation of the Protocol should be undertaken based on the principle that utilization of genetic resources for research and development is generally of benefit to society-at-large. Unless ABS rules are clear, transparent and facilitative of Article 15 of the Convention on Biological Diversity, the objective of the Nagoya Protocol will not be achieved and genetic resources will not be utilised for the benefit of biodiversity and society.

1. What are the concerns of stakeholders with respect to the new legal situation that will result from entry into force of the ABS regime established by the Protocol? Do they anticipate any significant changes or problems?

1. ***Lack of legal certainty:*** For users of GRs it is of utmost importance that any national rules and obligations (adopted in the implementation of the Protocol) create legal certainty concerning ABS. This requires clarity regarding the key definitions and the circumstances in which users and providers have obligations. In addition, national rules implementing provisions of the Protocol should minimize administrative burdens and be simple and practical for users - including small and medium-sized enterprises - to comply with. It would be better to apply easily manageable and, preferably, already existing regulations with which companies, even small or medium-sized companies, can comply in most routine cases without any added administrative requirements.

The scope of the regime must be clarified in the sense that its norms should:

- Regulate exclusively those acquisitions of GR which have taken place after the NP's entry into force in the provider country; and
- Exclude from its application certain genetic resources such as human genetic resources.

Going more into detail of the specific measures, it is crucial that the regime :

- Provides that all requirements for access are contained in legislation and regulation;
- Provides for fair and timely application procedures;

- Minimizes transaction costs;
- Does not interfere with intellectual property or other regulatory systems.

2. *Lack of clarity regarding use of GRs without permits in a compliance system (Article 15):* The provisions regarding the obligation of Parties to check compliance of users with the PIC and MAT requirements as established by the ABS rules of other Parties are in themselves a challenge and it will be important to see how they can work in practice when it comes to implementation. Furthermore, it also has to be clarified that the non-existence of information on PIC and MAT does not imply lack of compliance with national ABS rules. A large proportion of GRs in use would have been acquired prior to the NP, and so the NP does not apply. Moreover, once the NP is implemented at the national level, several Parties have stated that they will choose not to condition access on PIC and will not issue permits. It remains a question how any checkpoint will deal with these situations.

3. *Checkpoints lead to administrative burdens (Article 17(1)):* As under current EU legislation no such checkpoints exist, it will be a new legislative and administrative burden for users of GRs.

As stated in NP Article 17(a)(iv), any checkpoint "must be effective"; to be effective any checkpoint should be clearly designated, easily accessible and not unduly burdensome for users. The purpose of a checkpoint is to support compliance by the relevant parties engaging in an ABS agreement through monitoring and enhanced transparency. It should also not create trade barriers nor interfere with other legal/administrative/regulatory processes, such as intellectual property systems, product approvals, or customs clearance. Importantly, any checkpoint should not be seen as a "policing" mechanism.

4. *A Global Multilateral Benefit-Sharing Mechanism is not needed (Article 10):* The Protocol foresees an obligation for Parties to consider the need for and modalities of such a mechanism. ICC however does not see a need for such a mechanism and is concerned – from the way the article is worded and was negotiated – that if Parties would see such a need, that provisions could be set up in such a way as to create obligations for situations which fall outside the scope of the CBD both temporally and geographically. ICC disagrees with this approach. (see enclosed ICC paper on the GMBSM)

- 5. *Supply chain liability:*** Many industries' supply chains are very long. One ingredient may go through numerous suppliers before reaching the final, finished product manufacturer. Therefore, it is highly challenging for third parties (e.g., intermediate suppliers and finished product manufacturers) to trace PIC and MAT back to the original point of access. If the burden of compliance is placed on finished product manufacturers, then they will in turn demand compliance from their suppliers. From experience, we believe that many – if not most – suppliers would not be able to verify PIC and MAT back to the original point of access. Thus such an obligation could have an immense chilling effect on innovation and new product development and potentially putting suppliers who cannot verify PIC and MAT out of business.

For the company acquiring genetic resources, the transfer of the genetic resource to the company's material stock marks the beginning of the industrial value creation process. A single company is not necessarily in a position to discover and exploit all value creation potential on its own. Any multiple value creation for a genetic resource may take place both inside and outside the acquiring company, which has a significant influence on the implementation regulations for the practical handling of genetic resources.

Implementation of Article 15 (Compliance) should therefore recognize the reality of lengthy supply chains and the fact that several different participants may be involved in the process of creating value from genetic resources.

- 2. Would you expect a positive or negative economic impact in your particular sector from an entry into force of the NP in the EU? If yes, please specify.**

YES	NO
X	<input type="checkbox"/>

The potential impact of the implementation of the NP will largely depend on how this is undertaken.

If the implementation results in a regime which promotes wider sustainable use of genetic resources and increases confidence in the way that access and benefit-sharing are taking place then its impact could be positive, but it is critical that this is done through solutions which encourage investment.

A negative economic impact can be expected from additional administrative requirements related to access to, and subsequent use of GRs, as companies will have to deploy more financial, personal and time resources into these activities. The additional expenses for doing business should be fair and reasonable to justify the likely increased cost to the consumer. In this respect, again, emphasis has to be given to practical, clear and transparent rules and especially a clear interpretation of the above-mentioned - so far ambiguous - notions. In this respect, self-certification and voluntary processes are useful in providing an opportunity for private sector actors to gain a reputational benefit to set against the costs.

If the scientific risks related to research and development related to genetic resources were to be accompanied by further uncertainties arising from unclear and impractical ABS requirements, then commercial R&D of natural products could be severely undermined. Such an outcome would undoubtedly be very damaging for society as a whole, as the aim of promoting biodiversity conservation and using biodiversity to create benefits and useful products for society will not be realized.

Moreover, we envision users could avoid entire markets as sources for new innovation if national implementation of the NP lacks clear, non-discriminatory processes to apply for and obtain PIC, including a clearly designated approval authority or authorities.

In addition, if business confidential information is compromised in the process of seeking access, then companies risk losing their competitive advantage.

3. Would you expect effects on the competitiveness of European users (collections, databases, botanical gardens, research institutions and research based industries) with regard to other countries? If yes, please specify.

YES <input type="checkbox"/>	NO <input type="checkbox"/>
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If the EU implements a user-friendly ABS regime, this will encourage a smooth flow in R&D and innovation involving EU users. If, however, the EU implements in a way that is not friendly to users then there may be a chilling effect on innovation and new product development involving EU users. For example, if the NP is implemented in a way that would create trade barriers, this could have a negative impact on international trade of products using (or suspected of using) genetic resources. As another example, if the EU regime is excessively burdensome or unclear, it will act as a disincentive to investment in research on genetic resources and put companies operating in the EU at a competitive disadvantage. Costs for users and lack of uniformity in the regulations of EU member states are other factors which could put users operating in the EU at a competitive disadvantage with respect to those in other countries.

It should be noted that the loss of potential partners in the EU will also be damaging for bio-diverse countries.

4. What implementing measures would you see in the EU in order to provide greater legal certainty and facilitate relations between users and providers?

The EU should adopt measures that:

- Clarify definitions of yet undefined term;
- Recognize the reality of lengthy supply chains in many sectors and the fact that many participants can be involved in the process of creating value from a genetic resource.
- Ensure that the national focal point is effective and provides legal certainty for both users and providers of genetic resources, including by:
 - Using a single entity to carry out the functions of the national focal point and the Competent National Authority, as envisioned in Nagoya Protocol Article 13.3;
 - Establishing which indigenous groups and local communities have the right to authorize access to particular genetic resources in situ within any member of the CBD/Nagoya Protocol, and acting as an intermediary between the user and such groups for establishing any necessary PIC and MAT.;
 - Providing potential applicants with information on how to apply for prior informed consent;
 - Establishing fair, transparent and effective application procedures for the delivery of access permits within a reasonable period of time.
- Concerning checkpoints specifically, implementation at the EU level should reflect the following points:
 - As stated in NP Article 17(a)(iv), any checkpoint "must be effective"; to be effective any checkpoint should be clearly designated, easily accessible and not unduly burdensome for users. The purpose of a checkpoint is to support compliance by the relevant parties engaging in an ABS agreement through monitoring and enhanced transparency. It should also not create trade barriers nor interfere with other legal/administrative/regulatory processes, such as intellectual property systems, product approvals, or customs clearance. Importantly, any checkpoint should not be seen as a "policing" mechanism;
 - The link between any commercial products and the underlying GRs and permits relating to these should be determined solely through mutually agreed terms agreed at the time of access between the user and provider.

- The lack of a MTA or any other evidence of PIC and MAT, should not be automatically treated as a case of non-compliance with ABS rules; and

- In respect of Article 10 the EU should acknowledge that there is no need for a global multilateral benefit-sharing mechanism. (For this purpose please also see the separate ICC position paper).

If access and benefit sharing is regulated as simply as possible and also easily manageable by small and medium-sized companies, it would be of decisive advantage for the country of origin. The simpler and more reliable the national regulations in force are felt to be, the greater the opportunity will be for the country to attract potential users and profit from subsequent commercialization and sustainable use of the national genetic pool within the framework of benefit sharing. All countries, including EU countries, are both users and providers of GR. Therefore, all countries must contribute equally to the aim of the Nagoya Protocol and recognize that their national access practices are decisive for the potential utilization of their national genetic resources.

5. Do you anticipate administrative burden and costs from an implementation of the NP in the EU in your sector? If yes, what approaches would you suggest to minimise such costs?

YES	NO
X	<input type="checkbox"/>

Many companies will have to deploy more financial, personal and time resources into their activities related to access of GRs (gathering knowledge on national ABS laws and obligations, checkpoints and requirements of compliance; dealing with competent national authorities in many different countries).

In this respect, introduction of practical, clear, transparent and uniform rules within the EU and especially a clear interpretation of the key, but presently ambiguous, notions and obligations would facilitate dealing with the NP. Furthermore, an ABS Clearing-House as foreseen in Article 14 of the NP could be a real facilitating measure in order to reduce administrative burdens. However, this can only work if information provided through the Clearing-House is always up-to-date and legally reliable.

Research-based sectors draw on the whole corpus of existing scientific knowledge in order to innovate. The regime should therefore only oblige public disclosure required by the contractual terms under which genetic resources are acquired.

To minimize administrative burden and costs, we suggest:

- Harmonized EU implementation of the compliance elements of the NP;
- Implementation of Article 15 (Compliance) in a way that recognizes the reality of lengthy supply chains for many sectors, and the fact that several participants may be involved in the process of creating value from a genetic resource;
- Clarity as to what the ABS regime will cover, specific to industries (e.g., specific classes of materials for the cosmetics industry, food industry, etc).

The following questions will elaborate on the current practices and arrangements between users and providers.

6. What are the problems/challenges for users in ensuring conformity with existing legislation in provider countries establishing a procedure and conditions for PIC?

Given the regimes and legislations in place today, users of genetic resources are faced with a series of difficulties when verifying legal conformity to existing norms. Probably the biggest challenge originates from the significant lack of clarity in national legislative frameworks concerning ABS and rules on procedure and conditions for PIC. This situation is frequently worsened by different and diverse bureaucratic systems which are often found to be inefficient.

ABS rules, including rules on procedure and conditions for PIC, are usually absent, or not known. If ABS rules are present, they are generally not transparent and not clear. Moreover, if such rules are present, they often do not work in practical cases, and may not be flexible enough to be usable by all sectors. The practices of national or regional authorities are also often unpredictable, unreliable and cannot be challenged when the users consider them to be inconsistent with the CBD and NP. There may also be reluctance by officials in some countries to enter into MATs.

7. What are the problems for users deriving from the absence of a clear legal framework in provider countries?

It is crucial for users to have a clear understanding of the rights and obligations deriving from the national implementation of the NP. In the absence of these conditions, there is a strong risk that users will not have access to the genetic resources.

An unclear legal framework governing ABS obligations could in fact have the following negative effects on users:

- they will find it time-consuming and burdensome to find out what procedure to follow, what obligations apply and what authorities to address ;
- they may be discouraged from using any material coming from such providers not only because it is burdensome to get information but also because they do not want to take the risk that something is not fully clarified at the time of access and they have to face further requirements or sanctions later on;
- this might jeopardize the expeditious access to genetic resources necessary to address cases of present or imminent emergencies that threaten or damage human, animal or plant health referred to in Article 8(b) of the NP;
- potential users may be discouraged from accessing and developing genetic resources. If GRs are not used, benefits from their development will not accrue and this may have a negative effect on conservation and lead to loss of genetic diversity, contrary to the aims of the CBD.

8. Have certain users/providers developed standard clauses or model contracts for MAT? If yes, please specify.

YES	NO
X	<input type="checkbox"/>

Certain users/providers have developed standard clauses/model contracts for MAT. However, it is always important to include a degree of flexibility which can take into account the specific and unique set of circumstances involved.

Below are examples with respect to model clauses/contracts in a few industries:

- *Biotechnology*: Relevant examples of model agreements are the “Bioprospecting Agreements” which are included in the Guidelines developed in 2005 by the Biotechnology Industry Organization – and are therefore implemented by its members. (see <http://www.bio.org/articles/bio-bioprospecting-guidelines>)

In practice, such agreements – which are concluded between the Transferor and the Transferee of a GR in the case of collection of the resource – include the regulation and grant of prior informed consent and set out the conditions governing the collection and use of regulated genetic resources, including benefit sharing.

In order to provide greater clarity, the above mentioned Guidelines also provide for a “Model Material Transfer Agreement” (which can be incorporated into a Bioprospecting Agreement or even replace one in specific situations) whose primary purpose is that of transferring possession of GR.

- *Plant genetic resources for plant breeding*: The IT PGRFA has, in its Article 10.2, set up a Multilateral System in order to ensure access and benefit-sharing in respect of PGRFA. Facilitated access to PGRs in the Multilateral System is realized through a simplified contractual mechanism.

Because of the different realities of various sectors and situations, flexibility is required in negotiating MATs.

9. Are there practices and arrangements currently being used for access to and sharing of benefits arising from the utilization of the genetic resources and associated TK in transactions between EU-based users and non-EU providers? If yes, please specify:

There are examples of such practices and arrangements which are found in contracts concluded between the transferor and the transferee of genetic resources and that are the basis of mutually agreed terms. However, other bilateral contracts have been difficult to realize due to the unrealistic expectations of providers.

These contractual agreements are governed by national contract law and therefore further measures should not be needed. Moreover, it should be noted that the Bonn Guidelines represent a useful tool in providing guidance to both users and providers on potential contractual terms and elements for the drafting of ABS agreements.

Flexibility with respect to the type of contractual arrangements used for ABS is required to reflect the different realities of various sectors and situations.

Advantages for users and providers in the implementation of such arrangements?

YES	NO
X	<input type="checkbox"/>

Advantages both for users and for providers can be derived from such agreements as they provide the necessary legal certainty for the access and transfer of genetic resources. While expectations in benefit sharing arrangements must be realistic and take into account the potentially high failure rate of projects in the various sectors, benefits that were agreed may become available from such arrangements and may include investment in infrastructure, technology transfer arrangements, capacity building collaboration, free use of the finalized products for further research development and commercialization, royalties and/or, in some cases, up-front payments agreements.

In fact, many of these advantages will be available even in cases where no commercial product is ever developed. For example, the agreement between INBio (Instituto Nacional de Biodiversidad, Costa Rica) and Merck & Co. and the subsequent agreement between INBio and Eli Lilly.

Specific challenges for users and providers?

YES	NO
X	<input type="checkbox"/>

Specific challenges for users arise from the absence of such agreements, especially with regards to the identification of the institution entitled to grant access to GRs.

For example, one company (Eli Lilly and Company) was forced to abandon plans to collaborate with a researcher in Cameroon due to the difficulty in determining the appropriate steps and authorities to ensure proper and correct access to genetic resources. The legal uncertainties the company encountered and the missed opportunity of collaboration are a practical example of the challenges good-faith actors encounter in certain jurisdictions when they attempt to access genetic resources.

Other examples exist in other sectors.

10. Is there existing legislation in EU countries that are both providers and users of genetic resources?

YES <input type="checkbox"/>	NO <input type="checkbox"/>
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All countries, including EU countries, should, in principle, be considered as both users and providers. We have no detailed information on national ABS legislations in EU countries.

It is worth noting that the genetic diversity in industrialized countries – particularly in the microbial context – is rated just as highly in scientific circles as that in the developing and threshold countries. This presents a challenge, particularly for less highly developed nations, to regulate access with a view to securing competitive advantages.

If so, is this expected to disappear once the Protocol will enter into force?

YES <input type="checkbox"/>	NO <input type="checkbox"/>
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How are arrangements being concluded between EU-based providers and the users?

11. What kind of voluntary checkpoints, if any, are currently used to monitor compliance with ABS provisions?

In most sectors, compliance with CBD provisions is today ensured through the conclusion of individual contracts between interested parties.

The following questions will elaborate on the implementation of the NP in the EU.

12. Are you aware of existing EU legislation which might be applicable to the issues covered by the NP within your sector, subject area and affiliation? If yes, please specify whether you feel that there is a need for changes of that legislation.

YES <input type="checkbox"/>	NO <input type="checkbox"/>
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N/A - ICC does not represent a specific sector.

13. Are you aware of national legislation in the EU MS of the respondents' residence and/or legal establishment which might be applicable to the issues covered by the NP, relevant to your sector, subject area and affiliation? If yes, please specify whether you feel that there is a need for changes of that legislation.

YES <input type="checkbox"/>	NO <input type="checkbox"/>
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N/A - ICC does not represent a specific sector.

14. Would national legislation in each individual EU MS be appropriate / sufficient for the purpose of implementing the NP in the EU? If, yes please specify.

YES <input type="checkbox"/>	NO X
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National implementing legislation on individual Member State level might be sufficient for implementing the NP but might not be the appropriate direction to take. As issues of competence may arise – an example of this could be the access to national resources which should be regulated by national norms – ICC believes that those matters of direct national competence should be regulated by Member State laws, whilst common aspects should be regulated by the EU.

ICC is of the view that a harmonized EU-level implementation of at least the compliance elements would be more appropriate for the following reasons:

- It would ensure one common interpretation of and approach to some key elements of the NP such as certificates, checkpoints, compliance, etc., most of which are not clearly defined in the NP;
- It would provide legal certainty regarding applicable rules and obligations in respect of the 27 EU Member States, which would benefit not only intra-EU arrangements but also potential outside recipients desiring to access GRs from EU Member States;

- Since many GRs are not limited to a single EU Member State, bilateral negotiations with individual countries could lead to competition where industry will go for the most favourable offer;
- Given the fact that the EU had an important role and influence in the negotiations of the NP, a harmonized implementation thereof may also serve as a better example to follow for other Contracting Parties than 27 different ones.

15. Is a harmonised approach at EU level necessary to effectively implement the NP and its objectives in the EU? If yes, please specify.

YES	NO
X	<input type="checkbox"/>

See response to the previous question (no. 14.)

16. Do stakeholders feel that a possible ABS legislation at MS level could have consequences for the EU internal market? If yes, please specify.

YES	NO
X	<input type="checkbox"/>

If the NP is implemented on Member State level without any harmonization on compliance at the EU level there may be a risk that different interpretations and implementations of key provisions (such as checkpoints, the internationally recognised certificate of compliance and compliance) will result in obstacles to the internal market.

In order to make sure that the free movement of goods is not hindered in such a way within the EU, harmonized provisions on at least the above-mentioned key notions would be necessary. From a business point of view, it should also be ensured that once a document is accepted as evidence of PIC and MAT by one Member State, the goods are not blocked in another Member State because that Member State does not accept the same document as evidence or requires further documents.

17. With regard to the establishment of access legislation in the EU, can a harmonised approach at EU level better achieve the objectives of the Protocol?

YES X	NO <input type="checkbox"/>
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See response to question no. 14. As mentioned also there, ICC is of the view that the harmonized EU approach should focus on the implementation of the compliance elements of the NP, while in respect of ABS obligations, different rules and approaches may be followed by the different EU Member States.

18. If EU legislation on ABS is called for, what would be the most appropriate legislative instrument?

Regulation? If yes, please specify why and for which areas covered by the NP.

YES X	NO <input type="checkbox"/>
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From the point of view of clarity and legal certainty, ICC would prefer to see an EU level legislation focused on the compliance elements of the NP to be adopted in the form of a Regulation rather than a Directive. A Directive may result in 27 somewhat diverging implementations and interpretations whereas uniform rules in respect of compliance and especially in respect of certain key provisions of the NP would be of importance.

Directive? If yes, please specify why and for which areas covered by the NP.

YES <input type="checkbox"/>	NO <input type="checkbox"/>
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Answer (max. 250 words):

19. Would there be advantages in the EU negotiating agreements, within the framework of Nagoya Protocol, on a bilateral or regional basis with major providers, in order to globally facilitate access to genetic resources and associated TK, especially for non-commercial uses¹?

ICC believes there will be significant problems if the EU creates different rules for non-commercial users. Rather, there would be significant advantages in adopting a common approach which would provide legal certainty and minimize administrative burdens and costs (recognizing that the EU is home to many small and large companies that depend on access to GRs both within and outside the EU.)

We feel strongly that a common approach can be developed to work effectively for both public and private sector users of GR including institutions and organization with large and small operating budgets. In fact, the common approach is necessary to avoid complications that will arise when access to GRs is an integral element of a public-private partnership. Such partnerships can have commercial and non-commercial goals.

Since both sectors are equally important to society, because public-private partnerships occur frequently and are beneficial to the EU, and because efficient access to GR is foundational to the role they play in the EU, a common ABS legislation is needed.

20. How could the implementation of the protocol impact on public health, particularly in relation to sharing of virus samples, to vaccine production and to access to vaccines in the event of a pandemic?

It seems that with the special considerations in Article 8, the NP has taken the necessary steps to require Contracting Parties to give special attention to such issues of public health. It should be noted that plant and animal diseases (e.g. avian flu, West Nile Fever, Soybean rust) may also affect public health not only by endangering directly human health, but also by endangering the food supply which can lead to malnutrition and starvation (e.g historically the potato blight famine in Ireland).

As regards the plant breeding sector, both Article 8(b) and (c) of the NP are very important. As regards pathogens, which play an essential role in plant health improvement, it is key that access is not delayed or blocked by complicated and burdensome ABS rules and procedures. In this respect, implementation in the EU should ensure that expeditious access to pathogens and similar GRs is guaranteed.

¹ Museums, botanical gardens, public and private collections of genetic resources as well as gene-banks, academic research etc

ICC believes that human pathogens, which include viruses, fall outside of the scope of the CBD.

- The overall objectives of the CBD are conservation and sustainable use of genetic resources (preamble and Article 1). The opposite is the case for viruses where the objective is eradication. Human viruses and other human pathogens were not intended to be included within the scope of the CBD and ABS Protocol as CBD members are obliged to control or eradicate alien species which threaten ecosystems, habitats or species (Article 8(c) of the CBD). Any contrary indications would have significant and wide ranging health policy implications.

- Linking CBD principles to human pathogens (e.g. pandemic influenza viruses) would also risk dangerous delays to the start of vaccine production by creating additional burdens. This would clearly undermine national preparedness and must be avoided.

21. Would there be advantages in considering current practices under other international instruments/organisations, such as FAO Commission on genetic resources, for the development of ABS legislation?

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

As ICC has consistently pointed out in past submissions, different sectors have different practices, needs and constraints, so that models appropriate to one sector may not be workable in another sector. A flexible approach which recognizes the realities of different sectors in the implementation of the NP is therefore necessary, especially with respect to MATs.

The following questions will elaborate on monitoring and enforcement.

22. Are there existing checkpoints that could be used for ABS purposes? If yes, please specify which ones and in which area?

YES	NO
<input type="checkbox"/>	X

See response to question no. 11.

As stated in NP Article 17(a)(iv), any checkpoint "must be effective"; to be effective any checkpoint should be clearly designated, easily accessible and not unduly burdensome for users. The purpose of a checkpoint is to support compliance by the relevant parties engaging in an ABS agreement through monitoring and enhanced transparency. It should also not create trade barriers nor interfere with other legal/administrative/regulatory processes, such as intellectual property systems, product approvals, or customs clearance. Importantly, any checkpoint should not be seen as a "policing" mechanism.

23. Should new institutions or procedures be established specifically for ABS purposes? If so, at what level?

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

In the event the Protocol is implemented at EU-level, it might be necessary to establish some new procedures to deal with the obligations related to issuing permits to make sure that the procedures applied in the Member States are the same and foreseeable for users.

As regards institutions, there does not seem to be a particular need to create new institutions to deal with the above issues. There will however have to be a clearly designated National Competent Authority that should also act as focal point. For this, they can of course make use of already existing bodies and structures.

One particular point to mention: Article 15 of the Protocol provides for the obligation that Parties have to check compliance with PIC and MAT as required by the domestic legislation of other parties. This is an obligation that is probably alien to most of the EU Member States which implies that very likely there are no procedures in place for such purpose.

The EU should keep in mind the fact that it is both a user and provider of GR so that it has to both encourage access that will lead to sustainable development and use, and create measures that support legitimate users, rather than measures which focus on sanctioning a small minority of users in bad faith, which could penalise the great majority of legitimate users.

24. What would be the features of any procedures and checkpoints that would ensure that we minimise administrative burdens for users and providers as well as public authorities in MS and at EU level?

In any case procedures should be clear, simple, quick, predictable, reliable, provide for a possibility to appeal and create a level playing field.

As stated in NP Article 17(a)(iv), any checkpoint "must be effective"; to be effective any checkpoint should be clearly designated, easily accessible and not unduly burdensome for users. The purpose of a checkpoint is to support compliance by the relevant parties engaging in an ABS agreement through monitoring and enhanced transparency. It should also not create trade barriers nor interfere with other legal/administrative/regulatory processes, such as intellectual property systems, product approvals, or customs clearance. Importantly, any checkpoint should not be seen as a "policing" mechanism.

Implementation of Article 15 (Compliance) should recognize the reality of lengthy supply chains and the fact that several different participants may be involved in the process of creating value from genetic resources.

There should be clarity about what materials the ABS regime will cover, specific to industries (e.g., the cosmetics industry, food industry).

There should be protection of business confidential information at all times.

THANK YOU!