ESA REPLY TO THE 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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Please describe the main activities of your company/organisation/association.

ESA is the voice of the European seed industry, representing the interests of those active in research, breeding, production and marketing of seeds of agricultural, horticultural and ornamental plant species.

Plants from seed are the origin of all food, provide innovative and environmentally friendly industrial products and beautify our landscape.

ESA's mission is to work for:

- effective protection of intellectual property rights relating to plants and seeds;
- fair and proportionate regulation of the European seed industry;

- freedom of choice for customers (farmers, growers, industry, consumers) in supplying seeds as a result of innovative, diverse technologies and production methods;

By continuous development and creation of improved plant varieties the seed industry has always responded to one of the basic needs of society: enough food that is healthy and produced for reasonable prices in an efficient and environment-friendly way. To continue to meet future expectations of society and contribute to the development of sustainable agriculture, plant breeders need access to the genetic variability of plant species as it is the starting point for the crossing and selection work. Facilitated access to these genetic resources is thus one of the key factors in achieving policy goals such as food security and food quality, preservation of the environment and sustainable agricultural production.

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.

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?

First of all, it has to be noted that a part of the plant breeding sector may not really be concerned by the Nagoya Protocol itself. In its Article 4(4), the Protocol explicitly recognizes other, specialized international ABS instruments and excludes the application of the Protocol to the specific genetic resources for the purposes covered in those specific instruments in respect of the Parties member to those specific instruments. The International Treaty on Plant Genetic Resources for Food and Agriculture (IT PGRFA) and more specifically its Multilateral System is such an instrument and therefore plant genetic resources for food and agriculture (PGRFA) included therein fall outside the scope of the Protocol. All EU Member States as well as the Union itself are bound by the IT PGRFA.

However, given that on one hand not all PGRFA as well as ornamentals are covered by the Multilateral System established by the IT; and on the other hand the text of Article 4(4) of the Protocol implies that in case PGRs are used for a purpose different from the ones covered by the IT

the Protocol applies, ESA feels the need to address its concerns regarding the following elements of the Protocol:

1. Lack of legal certainty: For users of PGRs it is of utmost importance that any national rules and obligations (adopted in implementation of the Protocol) concerning ABS be absolutely clear and transparent. This becomes even more important with the provisions of the Protocol on certificate, checkpoints and compliance. If ABS rules are not clear, it will be impossible for users to know if they have complied with all the obligations, which results in a huge lack of legal certainty. Furthermore, implementing new rules, procedures and responsibilities stemming from the Protocol may also take long time. Therefore, using already established tools such as the standard material transfer agreement (sMTA) providing a well-working framework for facilitated access to PGRs under the IT and widely accepted by the international plant breeding sector would avoid legal uncertainties.

2. Lack of clarity regarding use of GRs without permit 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 is in itself a challenge and it will be an important question to see how it can work in practice when it comes to implementation. Furthermore it also has to be clarified that the non-existence of information does not directly imply a case of bio-piracy. In fact, at the moment most of GRs used in commercial products have been legally obtained but do not have a 'permit' in the sense of Article 6(3)(e) of the Nagoya Protocol. It remains a question how the checkpoint will deal with this. In addition, as the IT PGRFA clearly recognizes, GRs are practically never commercialized "in the form received", which means that the checkpoint will have to find a way to link commercial products with the GRs that were accessed.

3. Uncertainty regarding the recognition of the sMTA as international certificate of compliance (Article 6(3)(e) and Article 17(2)): As already mentioned, under the IT PGRFA facilitated access to PGRs in the Multilateral System is ensured via a sMTA which provides perfectly for PIC and MAT and is in conformity with the requirements of Article 6(3)(e) of the Protocol regarding permit or its equivalent. The sMTA can in practice be used for the transfer of any PGRs. The sMTA should therefore be recognized as capable of serving as a 'permit' and/or 'international certificate of compliance' under the Protocol.

4. Accumulation of obligations (for the different groups of stakeholders from all countries due to the interdependency in breeding activities) in breeding products: Breeders use GRs in the development of new products, adding one or more traits to an existing product. Over time the added traits lose their market value and newer traits will be added to develop new products, improving upon the just released product. Thus, with the traces of GRs, also the BS obligations connected to those GRs will accumulate over generations of breeding, lower the progress in innovation and reduce competitiveness. The sMTA deals with this aspect in a transparent and

acceptable way and therefore is a sufficiently efficient tool for the plant breeding sector. However, in ESA's opinion benefit-sharing should only be due when essential components of the PGRs are included in the final product. In other words at least 25% or a valuable trait from the GR should be found in the final product. Moreover, benefit-sharing obligations should be exhausted after the first commercialization.

5. Checkpoints lead to administrative burden (Article 17(1)): As under current EU legislation no such checkpoints exist the setting up of such checkpoints will be a new legislative and administrative burden for users of GRs and may also constitute a *de facto* restriction on the free movement of goods within the EU.

6. A Global Multilateral Benefit-Sharing Mechanism leads to more uncertainty while it is not needed (Article 10): Even though the Protocol only foresees an obligation for Parties to consider the need and modalities of such a mechanism ESA sees concerns with this provision as – from the way it is worded and as it was negotiated – it seems to intend to set up obligations for situations which fall outside the scope of the CBD both temporally and geographically. ESA disagrees with this approach.

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	☐

As stated above, for PGRFA covered by the Multilateral System of the IT PGRFA the Protocol does not apply, i.e. there will be limited economic impacts. However, the compliance elements of the Nagoya Protocol may have a negative economic impact on the PGRFA covered by the IT PGRFA if the tracking of PGRFA and linked commercial products becomes more stringent than it is under the rules of the IT. In connection to checkpoints additional administrative burdens can be foreseen even in cases where the Nagoya Protocol does not apply.

In cases where the Protocol would apply to certain PGRs a negative economic impact is certain. This has to do with the fact that companies will have to deploy more financial, personnel and time resources into their activities related to access to GRs (gathering knowledge on national ABS laws and obligations, checkpoints and requirements of compliance; documentation; lengthy bilateral negotiations etc.). Furthermore, this economic impact will also have an influence on the cost-effectiveness of the food production as such costs will be inevitably included into the prices and passed on to the final 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. The acceptance of the sMTA for the purposes of compliance with PIC and MAT could reduce also the economic impact companies would face.

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	NO
X	☐

It depends on the implementation of the Protocol by the EU and by others. Depending on the implementation by others, the Nagoya Protocol can be used wrongly, to create technical barriers to trade.

Furthermore, if the EU is quicker in implementing the Protocol provisions than anybody else, in particular with regard to compliance, it may have a negative effect on the competitiveness of the European seed and plant breeding sector.

However, in any case effects on competitiveness can be expected with regard to US competitors given that the USA is not a Party to the CBD and to the Nagoya Protocol. Furthermore, European research institutes and organizations might encounter difficulties in getting access to material needed for their research not only because of the legal uncertainties but also because they have limited capacities to deal with the requirements resulting from the Protocols. This could be harmful to the high standards Europe would like to maintain/achieve in research and breeding none the less with the aim of coping with new challenges such as climate change, food security, sustainable food production etc.

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

In any case the EU should adopt the following clear rules:

- Apply the sMTA to all PGR under the management and control of the EU Member States that are used in plant breeding. This is necessary to have a continuous flow of genetic resources, which is needed for an innovative breeding sector which contributes to

conservation and sustainable use of PGRs as well as to sustainable and environment-friendly food production.

- In respect of PGRs and all uses of such PGRs the EU should recognize the sMTA – as set up under the IT PGRFA – as a permit or its equivalent as evidence of PIC and MAT as required by Article 6(3)(e) of the Protocol and provide that it is accepted by checkpoints set up in the EU as an international certificate of compliance containing the information as required under Article 17(1) of the Protocol. (For this purpose please also see separate ESA position paper.)
- Concerning checkpoints, as also mentioned above, the EU should make sure that for PGRs a sMTA is always accepted as covering all information as required by Article 17(1) of the Protocol. Furthermore, the EU should also make sure that the non-existence of a sMTA or any other evidence of PIC and MAT is not automatically treated as a case of non-compliance and should agree on how the link is created between the commercial product and the underlying GRs including their permits.
- As regards Article 15(1) – in consistency with the above – the EU should adopt the approach that as long as the GRs utilized within its jurisdiction have been accessed via an sMTA it will consider PIC and MAT as required by national laws of other Parties to have been complied with and will see no issue of possible non-compliance.
- In respect of Article 10 the EU should acknowledge that at least as concerns PGRs and plant breeding activities there is no need for a global multilateral benefit-sharing mechanism. (For this purpose please also see separate ESA position paper.)

We are of the view that the EU should also promote this same approach to the implementation of the Nagoya Protocol among other Parties to the Protocol.

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	☐

In cases where the Protocol would apply to PGRs it can be anticipated that many companies will have to deploy more financial, personal and time resources into their activities related to access to GRs (gathering knowledge on national ABS laws and obligations, checkpoints and requirements of compliance; dealing with competent national authorities in many different countries; bilateral negotiations for each exchange of PGRs). Furthermore, these extra financial burdens will also have

an influence on the cost-effectiveness of the food production as such costs will be inevitably included into the prices and passed on to the final consumer.

Where the sMTA applies, also some administrative burdens and costs can be anticipated in relation to the practical implementation of compliance elements of the Nagoya Protocol such as the checkpoint. In order to keep administrative burdens and costs low for all breeders, farmers, scientists, researchers, it would therefore be preferable that the EU applies the sMTA to all PGRs.

In this respect, introduction of practical, clear, transparent and uniform rules within the EU and its Member States and especially a clear interpretation of the key, but presently ambiguous, notions and obligations would facilitate dealing with the Protocol. Furthermore, an ABS Clearing-House as foreseen in Article 14 of the Protocol 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.

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?

Probably the biggest challenge under the current regimes is that ABS rules, including rules on procedure and conditions for PIC, are usually absent, or not known, not transparent and not clear. These rules also differ considerably from country to country which entails that every new bilateral negotiation for PIC and MAT is a new journey to the unknown. Moreover, if rules are present, they do not work in practical cases, as officials often seem to be afraid to establish MAT. Since the CBD was created the seed industry has experienced increasing difficulties in access to GRs. In many countries access, compliant with national laws, is very time-consuming or not possible at all. All in all, the situation regarding ABS obligations is often absolutely lacking legal certainty and clarity.

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

In case there is no clear legal framework in place regarding ABS obligations it may have the following effects for users:

- time-consuming and burdensome to find out what procedure to follow, what obligations apply and what authorities to address at all. The time involved in bilateral negotiations is also very long and until present such negotiations have been often unsuccessful;
- users may be discouraged to use any material coming from such providers not only because it is burdensome to get information but also because they don't 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;
- difficulties to enter into contractual arrangements (MAT) because it is not easy to put in place contracts which respect the interests of both parties (provider and user) and which would take into consideration the real commercial value of GRs (and not an unrealistic appreciation) and the costs involved in research and breeding before putting a product on the market;
- in case of some GRs, like pests and pathogens as well as GRs containing resistances to pests and pathogens, quick and effective access for resistance screening may be essential for food/feed production and food safety, which is impossible in an unclear legal environment;
- the consequence of GRs not being used may have a negative effect on the conservation and may lead to losses of genetic diversity;
- unclear legal frameworks may *de facto* limit access to genetic variability creating a standstill or drawback in developing new varieties which may result in a threat for food security in the world.

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

YES	NO
X	☐

As already mentioned above, 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, in harmony with the CBD. Facilitated access to PGRs in the Multilateral System is realized via an sMTA which has to be signed by the recipient (the user) when accessing the material from the Multilateral System. The sMTA sets

out in details the conditions of access, as laid down in Article 12.3 of the IT, and thus provides for mutually agreed terms as well as prior informed consent.

The sMTA creates a level playing field for all users world-wide. ESA is of the view that the sMTA, agreed by 127 parties, is the best and most effective means to provide for mutually agreed terms and prior informed consent in respect of PGRs and plant breeding, and advocates that in order to foster progress in plant breeding for all stakeholders access to PGRs shall be to the highest possible degree standardized, quick, transparent and cost effective.

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:

Please see reply to the previous question (no. 8) detailing the features of the Multilateral System and the sMTA established under the IT PGRFA. For example, under the sMTA there is also a possibility to have additional contractual arrangements for material under development. These parts of the contracts however fall under confidential business information and are not available to us.

Furthermore, we are aware that some bilateral contracts exist as well but the terms of such contracts are also not available to us.

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

YES	NO
X	☐

- given the fact that the system provided by the IT PGRFA is a Multilateral benefit-sharing system it allows to avoid burdensome and long bilateral discussions with several provider countries and with that also the complications related to administrative burdens;
- the Multilateral System also implies that there is only one set of rules regulating the obligations on ABS related to PGRFA providing thus a clear and simple legal framework to comply with for the users;

- it creates a level playing field, which is good for all users: individuals, SMEs or big companies as well as developed and developing countries.

Specific challenges for users and providers?

YES	NO
X	☐

One specific challenge for users of PGRFA under the Multilateral System is to broaden its scope. Currently formally it only applies to those PGRFA which are listed in Annex I to the IT (64 species). Even though some countries use the sMTA also in respect of non-Annex I PGRs a formal extension of the list in Annex I remains one of the major tasks for the future. (The timeliness of such an extension was also confirmed recently at the 10th anniversary event of the IT: http://www.bioversityinternational.org/read_more/marking_10_years_of_the_international_treaty_full_report.html).

Moreover, even though the Multilateral System is ratified by 127 countries, many countries have not implemented the system yet and/or not included all relevant GRs in the Multilateral System. In order to improve the effectiveness of the system better implementation of the IT is necessary.

Any bilateral negotiations will probably create an impossible burden for SMEs to get access to GRs, if at all possible. This is one of the big advantages of the Multilateral System under the IT PGRFA where such negotiations are avoided.

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

ESA would like to recall that regarding PGRs all EU member States should, in principle, be considered as both users and providers of GRs.

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

YES	NO
☐	☐

How are arrangements being concluded between EU-based providers and the users?

Given that the EU is party to the IT for PGRFA covered by the Multilateral System arrangements between providers and users within the EU are normally concluded via a sMTA. In many cases a sMTA is used also in respect of PGRFA not directly covered by the Multilateral System.

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

As stated in Article 17(a)(iv) of the Nagoya Protocol, any checkpoint "must be effective"; and 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, market approvals, or customs clearance. Importantly any checkpoint should not be seen as "policing" mechanisms.

In the plant breeding sector it is the approach of the IT PGRFA and its sMTA that is used, which approach consists in an annual reporting by the provider (Article 5(e) of the sMTA) and reporting requirements on the recipient (user) in case of transfer of the GRs to a third party (Article 6.4(b) of the sMTA) based on the contractual arrangements of the sMTA signed by both parties (provider and recipient). It is therefore a trust-based system because facilitated access to PGRFA benefits all stakeholders everywhere in the world. This is the most appropriate way to simplify exchanges in PGRs and should be continued also in the future also against the background of the need to cope with future challenges related to food security.

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	NO
X	☐

The EU – with Council Decision 2004/869/EC – became party to the IT PGRFA. According to Article 216(2) of the Treaty on the Functioning of the European Union international agreements concluded by the EU bind the institutions of the EU as well as its Member States. It has also been confirmed by the European Court of Justice in its case law that international agreements concluded by the EU become integral part of the EU legal order (see cases C-21-24/72 *International Fruit Company NV*).

The IT PGRFA should therefore be considered as existing EU legislation addressing matters covered by the Protocol within the seed and plant breeding sector. Besides the issue of expanding Annex I of the IT, ESA does not see any need to change the provisions of the IT and supports its full application by the EU and its Member States.

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	NO
X	☐

Several Member States have implemented the IT PGRFA while others are still in the process. See also answer to the previous question (no. 12).

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	NO
☐	X

National implementing legislation on individual Member State level might be sufficient for implementing the Protocol but might not be the appropriate way to act. ESA 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 assure one common interpretation and implementation of and approach to some key elements of the Protocol on the European level such as certificate, checkpoints, compliance, global multilateral benefit-sharing mechanism etc., most of which are not clearly defined in the Protocol;

- it would provide legal certainty regarding applicable rules and obligations in respect of the 27 EU Member States which would not only benefit intra-EU arrangements but would also benefit potential outside recipients willing 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 the user will go for the lowest offer;

- given the fact that the EU had an important role and influence in the negotiations of the Protocol 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	☐

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	☐

If the Protocol is implemented on Member State level without any harmonization on EU level there may be a risk that possible different interpretations and implementations of key provisions (such as checkpoints, the certificate of compliance and compliance) result in some hindrance for the internal market.

In order to make sure that the free movement of GRs and goods is not unduly hindered within the EU harmonized provisions on at least the above-mentioned key notions would be necessary. From a business point of view it is essential to have only a single kind of checkpoint in all Member States and it should also be made sure 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	NO
X	☐

See response to question no. 14. As mentioned also there, ESA is of the view that the harmonized EU approach should focus on the implementation of the compliance elements of the Protocol, 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	NO
X	☐

From the point of view of clarity and legal certainty ESA would prefer to see an EU level legislation focused on the compliance elements of the Protocol 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 related key provisions of the Protocol would be of importance. On the other hand, in respect of ABS obligations more flexibility could be given to the Member States.

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

YES	NO
☐	X

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?

Yes. In particular the EU should try to negotiate on a regional basis with major providers agreements which are as close to the IT/sMTA approach as possible. ESA is prepared to support the EU authorities to achieve such agreements.

In order to globally further facilitate access to GRs the EU should also engage in negotiations aimed at the expansion of the scope of the IT PGRFA and its Annex I.

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

In case one would do something specific for non-commercial use, one should realize that work done may stay on the shelf from there, as additional ABS conditions may be unpredictable or too high to pick it up for further application in commercial use. For agricultural research and plant breeding activities we would like to reiterate that the Multilateral System of the IT PGRFA and the sMTA are a good workable system that is also easy and practical for all uses, including also non-commercial use.

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 Protocol has taken the necessary steps to require Contracting Parties to give special attention to such issues of public health, including plant health.

As regards the plant breeding sector, both Article 8(b) and (c) of the Protocol are very important. As regards pests and pathogens as well as GRs related to pathogens/pathogen resistances, which both play an essential role in plant health diagnostics and improvement, it is key that the access is not delayed or blocked by complicated and burdensome ABS rules and procedures. In this respect the implementation in the EU should assure that expeditious access to pests and pathogens as well as GRs related to pathogens / pathogen resistances and similar GRs is guaranteed and that expeditious access to improved material (resistant to pathogens) will be provided for further research and breeding.

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
X	☐

The FAO commission on genetic resources has decided in July 2011 to set up a working group on ABS for GRFA. This working group will reflect on the most appropriate way to further develop reflexion in this field taking into consideration plant species such as ornamentals or forest material not covered by the ITPGRFA.

As already mentioned above under the IT PGRFA a Multilateral System for ABS has been set up which provides a flexible and workable framework for the plant breeding sector. Facilitated access to PGRs in the Multilateral System is ensured via the sMTA which provides perfectly for PIC and MAT. In practice, the sMTA can be used for the transfer of any PGRs. Therefore, in our view, all plant breeding activities, including ornamental plant breeding should be covered by the ITPGRFA rules.

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
☐	X

As already indicated under question no. 11, in the plant breeding sector currently it is the approach of the IT PGRFA and its sMTA that is used, which is a self-reporting system by the provider and the user based on the contractual arrangements of the sMTA signed by both parties.

ESA suggests having such a trust-based, self-reporting system where breeders could report to the FAO for the sMTA derived products and possibly to an EU office or agency established for this purpose for any other products they intend to market.

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

YES	NO
X	☐

If the IT/sMTA approach is followed for all plant breeding activities most of the provisions of the Protocol do not necessarily require setting-up of new procedures and/or institutions. However, in case an EU level implementation of the Protocol is the chosen direction it might be necessary to establish some new procedures to deal with the obligations related to issuing permits and checking certificates in order to make sure that also the procedures applied in the Member States are the

same and predictable for users. As regards institutions, there does not seem to be a particular need to create new institutions to deal with the above issues but obviously Member States would need to clearly designate the competent national body. For this they can of course make use of already existing bodies and structures. Also, as indicated under the previous question (no. 22) it could be considered to create a new EU agency or office where users of GRs could report on their compliance.

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 which is very likely alien to most of the EU Member States which implies that very likely there are no procedures in place for such purpose. Therefore, implementation of this obligation might in fact require the setting-up of new procedures.

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, transparent, business friendly and provide for a possibility to appeal and create a level playing field. The approach to link the commercial products to the underlying GRs and their permits should also be clear.

Checkpoints should be clearly designated, easily accessible for users.

THANK YOU!