



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 20 March 2013**

**7680/13**

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**Interinstitutional File:  
2012/0278 (COD)**

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<b>SAN</b>	<b>105</b>
<b>CODEC</b>	<b>625</b>

**NOTE**

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from: General Secretariat

to: Council

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No. Cion prop.: 14641/12 ENV 750 AGRI 650 WTO 321 PI 116 DEVGEN 272 MI 604 SAN 221  
- COM(2012) 576 final + COR 1

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Subject: Proposal for a Regulation of the European Parliament and of the Council on  
Access to Genetic Resources and the Fair and Equitable Sharing of Benefits  
Arising from their Utilization in the Union  
- Orientation debate  
= Contributions from Member States

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Delegations will find in Annex contributions from DE, CY, NL, PL, FI and UK to the orientation  
debate on the above-mentioned proposed Regulation (ABS) at the Environment Council of  
21 March 2013.

GERMANY

Deutscher Kommentar zum Tagesordnungspunkt 6:

***Vorschlag für eine Verordnung des Europäischen Parlaments und des Rates über den "Zugang zu genetischen Ressourcen und die ausgewogene und gerechte Aufteilung der sich aus ihrer Nutzung ergebenden Vorteile in der Europäischen Union" (Erste Lesung)***

*1. Sind Sie der Auffassung, dass die im Rechtsetzungsvorschlag vorgesehenen Verpflichtungen der Nutzer den Anforderungen des Nagoya-Protokolls in geeigneter Weise entsprechen, was die Einhaltung der Regeln durch die Nutzer in der Union betrifft? Werden sie zu dem Ziel beitragen, die wirksame Umsetzung der Regelungen zur Aufteilung der Vorteile zu gewährleisten?*

- Wir danken der Kommission für ihren Vorschlag und begrüßen ausdrücklich eine EU-weit einheitliche Umsetzung des Nagoya-Protokolls. Aus unserer Sicht sind drei Punkte wichtig:
  - Erstens, dass wir unsere internationalen Verpflichtungen aus dem Nagoya-Protokoll einhalten und damit einen Vorteilsausgleich unterstützen, der den Zielen des Nagoya-Protokolls entspricht, um so eine vertrauensvolle Zusammenarbeit mit den Herkunftsländern zu erreichen.
  - Zweitens, dass die betroffenen Nutzer Rechtssicherheit haben und das Nagoya-Protokoll wirksam umgesetzt wird. Darum sollten die Rechte und Pflichten der Nutzer möglichst präzise definiert werden.
  - Und drittens, dass die Umsetzung des Nagoya-Protokolls die Nutzung von genetischen Ressourcen nicht unverhältnismäßig erschwert. Der Aufwand für Nutzer und Mitgliedstaaten sollte verhältnismäßig sein.
- Um dies zu erreichen, sollte die Umsetzung des Nagoya-Protokolls so „schlank“ und effizient erfolgen, wie dies völkerrechtlich möglich ist. In Bezug auf den Kommissionsvorschlag sehen wir noch Nachbesserungsbedarf.
- Den ursprünglichen Bestimmungen zu den Sorgfaltspflichten der Nutzer stehen wir sehr kritisch gegenüber. Aus unserer Sicht sollte das international anerkannte Konformitätszertifikat des Nagoya-Protokolls in jeder Hinsicht ausreichen, um die Einhaltung aller Regeln durch die Nutzer nachzuweisen.
- In Notfällen, die die öffentliche Gesundheit bedrohen, ist der zügige internationale Austausch von Pathogenen notwendig. Die derzeit vorgesehenen Nutzerverpflichtungen (Art. 4) könnten dies behindern und sollten so angepasst werden, dass ein zeitnaher Erregeraustausch ermöglicht wird.

- Den Besonderheiten der genetischen Ressourcen für Ernährung und Landwirtschaft muss in der Umsetzung Rechnung getragen werden. Offene Fragen bestehen beispielsweise noch hinsichtlich der Definition der Nutzung oder hinsichtlich der Ursprungsdefinition bei gezüchteten genetischen Ressourcen. Dazu gehören die Anerkennung bestehender ABS-Instrumente wie dem Internationalen Saatgutvertrag und die angemessene Berücksichtigung weiterer völkerrechtlicher Übereinkommen wie dem Internationalen Übereinkommen zum Schutz von Pflanzenzüchtungen (UPOV-Konvention).

2. *Ist das vorgeschlagene Gleichgewicht zwischen den Verpflichtungen der Nutzer und der Überwachung dieser Verpflichtungen durch die Mitgliedstaaten Ihrer Auffassung nach und im Lichte des Nagoya-Protokolls angemessen, um die Nutzung genetischer Ressourcen in der Union zu gewährleisten, zu denen der Zugang gemäß den einschlägigen Anforderungen erfolgt?*

- Was die Überwachung der Verpflichtungen der Nutzer angeht, sind wir der Auffassung, dass der Kommissionsvorschlag über das hinausgeht, was zur Umsetzung des Nagoya-Protokolls erforderlich wäre. Im Hinblick auf den Verwaltungsaufwand und die damit verbundenen Kosten für die Mitgliedstaaten wünschen wir uns eine effizientere Lösung.
- Die Kommission schlägt ein enges System von regelmäßigen und anlassunabhängigen Kontrollen vor. Der zuständigen Kontrollbehörde sollen erhebliche Eingriffbefugnisse – zum Beispiel für Vor-Ort-Kontrollen – gewährt werden. Wir haben Zweifel, ob dies ein effektiver, kosteneffizienter und verhältnismäßiger Weg zur Umsetzung des Nagoya-Protokolls ist. Vielmehr sollten die Kontrollen gezielt an zwei Stellen ansetzen:
  - Erstens sollten sich die Kontrollen auf die Erklärungen konzentrieren, die die Nutzer bei Vermarktung und Marktzulassung von Produkten oder beim Empfang von öffentlichen Fördergeldern abgeben müssen.
  - Zweitens sollten Kontrollen dann durchgeführt werden, wenn geeignete Informationen wie z.B. Anzeigen durch Dritte vorliegen.
- Besondere Bedenken bestehen gegen die Ermächtigung zum Erlass von Durchführungsrechtsakten beim Vollzug der Verordnung. Wir denken nicht, dass zur Gestaltung des Vollzugs Durchführungsrechtsakte erforderlich sind. Der Vollzug von Verordnungen ist grundsätzlich allein den Mitgliedstaaten überlassen, und jeder einzelne Mitgliedstaat wird den Vollzug im Einklang mit seinem nationalen Verwaltungssystem und seinen verfassungsrechtlichen Erfordernissen organisieren. Die Mitgliedstaaten verfügen über große Erfahrungen bei der behördlichen Kontrolle der Einhaltung von Umwelt- und Naturschutzgesetzen.

## GERMANY

(Courtesy translation)

German comments on agenda item 6 (courtesy translation):

***Proposal for a Regulation of the European Parliament and of the Council on "Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union" (First reading)***

*1. Do you consider that the obligations of users contained in the legislative proposal adequately reflect the requirements of the Nagoya Protocol with regard to user compliance in the Union? Will they contribute to the aim of effective implementation of benefit sharing arrangements?*

- We would like to thank the Commission for the proposal, and we fully welcome the fact that the Nagoya Protocol will be implemented in a uniform way throughout the EU. In our opinion, three aspects are particularly important:
  - Firstly, we must fulfil our international obligations under the Nagoya Protocol and support a benefit sharing scheme that corresponds to the goals of the Protocol to ensure that cooperation with the countries of origin is based on mutual trust.
  - Secondly, the users concerned need legal certainty, and implementation of the Nagoya Protocol must be effective. The rights and obligations of users should be defined as precisely as possible.
  - And thirdly, implementation of the Nagoya Protocol should not make the use of genetic resources excessively difficult. The effort required from users and member states should be proportionate.
- To achieve this, implementation of the Nagoya Protocol should be as “lean” and efficient as possible in line with international law. We believe the Commission proposal requires some improvements in this regard.
- We are very critical of the original provisions laying down due diligence requirements for users. In our opinion, the internationally recognised certificate of compliance should be sufficient in every regard to allow the user to prove compliance with all the rules.
- In emergency situations which pose a threat to public health, a quick international exchange of pathogens is necessary. The obligations for users as specified in the current version (Art. 4) could impede this process and should be amended so as to allow for a speedy exchange of pathogens.

- When implementing the Protocol, it is important to take into account the particular characteristics of genetic resources for food and agriculture. Some open questions remain, such as the definition of use and the definition of origin for bred genetic resources. This includes recognising existing ABS instruments such as the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) and paying proper regard to other international conventions such as the International Convention for the Protection of New Varieties of Plants (UPOV Convention).

2. *In your view and in the light of the Nagoya Protocol, is the proposed balance between the obligations of users and the monitoring of these obligations by Member States appropriate in order to ensure the use within the Union of genetic resources accessed in accordance with relevant requirements?*

- As regards monitoring of user compliance, in our opinion the Commission proposal goes beyond what is necessary to implement the Nagoya Protocol. We would prefer a more efficient solution in terms of the administrative effort and associated costs for member states.
- The Commission proposes a tight system of regular, non-incident related checks. The competent authorities are to be given considerable powers of intervention, for example the right to carry out on-the-spot checks. We doubt that this is an effective, cost-efficient and proportionate way of implementing the Nagoya Protocol. Instead of pursuing the proposed approach, checks should target two areas:
  - Firstly, checks should be focused on the declarations that users must provide on the occasion of requesting market approval for products, at the time of commercialisation or if they are recipients of public research funding.
  - Secondly, checks should be carried out if appropriate information is available, e.g. notifications by third parties.
- We are particularly concerned about the empowerment to adopt implementing acts for the enforcement of the regulation. We do not consider implementing acts to be necessary to establish procedures for enforcement. In principle, the enforcement of regulations is the sole responsibility of the member states, and each individual member state will organise enforcement in accordance with its national administrative system and constitutional requirements. The authorities in the member states have ample experience in monitoring compliance with environmental and nature conservation legislation.

## CYPRUS

### **QUESTION 1**

Regarding the issue of user's obligations, we consider that legal clarity is essential taking into consideration the importance and complexity of the issue of access and benefit sharing. We specifically suggest the following:

- a) We consider that it is important for the users to exercise due diligence not only for genetic resources which they already utilize, but also for those they intend to utilize. Therefore we agree with the inclusion of the relevant provision in the text of paragraph (1) of article 4, since the precautionary principle is taken into consideration and compliance with the provisions of the Protocol is more effectively ensured.
- b) Reference to the additional information necessary to be submitted by the users in case they cannot comply with paragraph 2 of Article 4, should be more specific in order to make sure that the obligations of users are clear and concise.
- c) We agree with the timeline of 20 years for keeping records after utilization of genetic resources.

### **QUESTION 2**

We agree in general with the proposal as it has been formulated, however some points for further consideration are mentioned below:

- a) Concerning the reference on recipients of research funding and the relevant obligation of due diligence as mentioned in paragraph 1, we consider that it is important to include the obligation of due diligence to be exercised before the last payment of funding in order to ensure that the provisions of the Protocol will be met.

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## THE NETHERLANDS

*The Netherlands thanks the Irish Presidency for the opportunity to send in a written contribution to the orientation debate on the regulation implementing the Nagoya Protocol on Access and Benefit Sharing. Please find our comments below.*

### Introduction

The Netherlands values proper implementation of the Nagoya Protocol at both the national and EU level. The exchange of genetic resources is international, and for that reason EU-implementation regarding the utilization of these resources and the sharing of the benefits from their use is of great importance.

### Compliance measures

The feasibility and affordability of legislative measures must be guaranteed. If we take on new obligations, these must be as cost-effective as possible, without losing sight of the objectives of the Nagoya Protocol. With that in mind, the Netherlands is of the opinion that the relation between due diligence by users and monitoring of these obligations by member state authorities needs to be more balanced in the proposal.

It is very important that users apply due diligence when using genetic resources and that they are able to demonstrate this on request. The competent authority then acts as a checkpoint, and this is in our opinion a proper way of implementing the Nagoya Protocol. However, the proposal for an EU Regulation takes this a step further. Member State authorities would actively have to carry out detailed checks regarding user compliance. This, in our understanding, goes beyond the obligations set out in the Protocol and could lead to a significant additional burden for authorities. However, Member State authorities must of course take action if there are indications that the obligations of the Protocol are not being met. However, there are many different ways in which these signals might reach the authorities, and national authorities are in our view best equipped to handle these signals and to determine how these could best be followed up. To sum up: the feasibility and costs of implementing measures should be in proportion to the goals of the Nagoya Protocol.

### Genetic resources for food and agriculture

In implementing the Nagoya Protocol, the EU and its Member States should make good use of existing practices, especially in the exchange of genetic resources for food and agriculture. These are critical for food security and adaptation to climate change, and exchange needs to be quick yet well regulated.

On the basis of the agreement within the European Crop Genebank Network (ECPGRN) it is EU-practice to apply the standard material transfer agreement (SMTA) from the International Treaty on Plant Genetic Resources for Food and Agriculture broadly. The EU implementation of the Nagoya Protocol should acknowledge this. Issuing material under the SMTA entails a Prior Informed Consent from a providing Party, also when used for crops that are not included in the Treaty's Annex.

In our opinion, the SMTA could constitute an internationally recognised certificate of compliance in the context of article 17 of the Nagoya Protocol. This would facilitate both compliance and inspection with the many users of the SMTA. The regulation should clearly acknowledge these matters, both for legal clarity and transparency and for facilitating fast exchange of genetic resources critical to food security and adaptation to climate change.

### Other issues

As a final remark, we consider that a continued cooperation with stakeholders both within and outside the EU is essential in order to come to a successful implementation. This also applies with regard to the register of trusted collections and best practices, which can contribute significantly to the compliance of users and providers of genetic resources with the proposed regulation. This idea could be further developed with partners outside of the EU.

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## POLAND

1. *Do you consider that the obligations of users contained in the legislative proposal adequately reflect the requirements of the Nagoya Protocol with regard to user compliance in the Union? Will they contribute to the aim of effective implementation of benefit sharing arrangements?*

We would like to welcome the progress of work on the draft regulation made on the forum of the Working Party on the Environment (WPE). These works result in more detailed elaboration of the draft proposal submitted by the Commission and they aim at better adjustment of the draft both to the Nagoya Protocol, the existing EU and national legislation as well as a possibility of its practical implementation. There are still many issues requiring further in-depth discussion and development of optimal solutions. Thus it is our recommendation to conduct further substantive works on the level of the working party, which will aim at clarification of the regulation's provisions, discussion of the effects of the proposed solutions and agreeing upon a common position of the Council on the issue.

The obligations of the users following from Article 4 of the draft regulation, which consist in exercising due diligence by the users in ensuring the legality of the source of the genetic resources and traditional knowledge associated with genetic resources as well as collection and storage of applicable information on the obtained genetic resources, are basically able to ensure compliance with relevant provisions of the Nagoya Protocol. It will be expedient to further develop some individual provisions, in order to make the text clearer and eliminate all possible interpretative discrepancies.

The draft regulation doesn't deal directly with benefit sharing arrangements, but certain its provisions (among others: on trusted collections and best practices) promote the idea of benefit sharing.

2. *In your view and in the light of the Nagoya Protocol, is the proposed balance between the obligations of users and the monitoring of these obligations by Member States appropriate in order to ensure the use within the Union of genetic resources accessed in accordance with relevant requirements?*

It is necessary to consider the Article 4, 7 and 9 jointly in order to keep the balance between the obligations of the users, and the monitoring and control system for their compliance by the Member States. In our opinion, the recent draft of the Presidency of 8 February reflects the balance well by way of provisions of Articles 4, 7 and 9 and clear definition of the obligations of both the users and competent authorities, which will make it possible to fully implement the Nagoya Protocol by the European Union and its Member States within this scope.

## FINLAND

Finland supports the objective of the regulation to prevent the utilisation of genetic resources or traditional knowledge in the Union that has not been accessed in accordance with the requirements of the Nagoya Protocol. Research and development should be based on legal activities and on the use of legal material.

1. *Do you consider that the obligations of users contained in the legislative proposal adequately reflect the requirements of the Nagoya Protocol with regard to user compliance in the Union? Will they contribute to the aim of effective implementation of benefit sharing arrangements?*

The Nagoya Protocol requires that each Party shall take *appropriate, effective and proportionate* measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent (PIC) and that mutually agreed terms (MAT) have been established as required by the domestic requirements of the other Party.

The requirement of appropriate measures usually implies a duty of due diligence in the international treaty context. The legislative proposal provides, in accordance with the Nagoya Protocol, a comprehensive due diligence obligation for the users in the Union with the aim of ensuring that the requirements of PIC and MAT are met. Finland feels that the obligations of users in the proposal are appropriate in this respect. We also support the view that research alone does not fall in the scope of the user obligations.

The requirement of effective measures can be taken to mean such measures that have the desired effect. The effectiveness of the proposed user obligations is ensured with the article of penalties applicable to infringements of the user obligations. Finland considers that the obligations of users in the proposal are thus sufficiently effective.

However, we feel that it is also important to view the proposed user obligations in the light of the rule of law which requires actions sanctioned by penalties to be defined exactly (legal certainty). In this respect, Finland considers that some of the proposed user obligations are too open to interpretation and should be better defined.

The requirement of *proportionate* measures in the Nagoya Protocol is closely related to user compliance in the Union. Taking into account that most of the users in the Union are per se complying with the requirements, the proposal contains quite extensive user obligations. Finland considers that the user obligations should meet the requirements of the Nagoya Protocol, but they should not be unnecessarily extensive, keeping in mind the actual need to regulate the utilisation in the Union. The obligations should not, more than is factually necessary, weaken the general conditions for research and development activities or endanger the opportunities for using the results of research and development.

Finland considers that the legislative proposal would contribute to the effective implementation of benefit sharing arrangements. We also find it is important to encourage directing the benefits arising from the utilisation of genetic resources towards the conservation of biological diversity and sustainable use of its components.

2. *In your view and in the light of the Nagoya Protocol, is the proposed balance between the obligations of users and the monitoring of these obligations by Member States appropriate in order to ensure the use within the Union of genetic resources accessed in accordance with relevant requirements?*

The Nagoya Protocol requires that in order to support compliance with the protocol, each Party shall implement *necessary* measures to monitor and enhance transparency about the utilization of genetic resources.

Finland considers that the proposed user obligations and the monitoring of these obligations by the Member States together provide means to ensure the appropriate utilisation of genetic resources in the Union.

Finland supports the proposed uniform monitoring system in the Union, but we have concerns about the extensive monitoring obligations in the proposal. We feel that the monitoring obligations should not be more extensive than what is necessary to effectively implement the requirements of the Nagoya Protocol, and what is necessary taking into account the factual need for monitoring the utilisation in the Member States.

Finland also feels that it is important to leave more flexibility in the obligations to ensure the proportionate enforcement of the regulation in the Member States.

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## UNITED KINGDOM

1. *Do you consider that the obligations of users contained in the legislative proposal adequately reflect the requirements of the Nagoya Protocol with regard to user compliance in the Union? Will they contribute to the aim of effective implementation of benefit sharing arrangements?*

We believe that the obligations in the legislative proposal adequately reflect the requirements of the Nagoya Protocol with regards to user compliance. Furthermore we believe that the proposed due diligence approach is a workable solution. A prohibition of use may dissuade the use of genetic resources and the subsequent sharing of benefits. A facilitative approach to addressing cases of non-compliance, rather than a prohibition, is likely to increase benefit-sharing rather than limit it.

2. *In your view and in the light of the Nagoya Protocol, is the proposed balance between the obligations of users and the monitoring of these obligations by Member States appropriate in order to ensure the use within the Union of genetic resources accessed in accordance with relevant requirements?*

An overly burdensome process for monitoring would be costly and impractical for Member States to implement, whilst burdensome obligations for users would create a disincentive for compliance. We believe that the process of making a due diligence declaration should not be burdensome, but should contain sufficient detail for a risk-based monitoring process. Member States should maintain flexibility as to how they fulfil this requirement. We believe that a risk-based approach to monitoring is appropriate and would allow authorities to focus efforts on facilitating benefit-sharing by those who are either ignorant of requirements or on the exceptional few who knowingly do not comply with the regulation.

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