Dutch House of Representatives **2**

Session Year 2014-2015

34 142 **Rules for implementation of the Nagoya Protocol (Nagoya Protocol Implementation Act)**

No. 3

The advice of the Advisory Department of the Council of State (of the Kingdom) has not been made public because it is in any case consenting (Article 26(5) of the Council of State Act [*Wet op de Raad van State*]).

EXPLANATORY MEMORANDUM

1. Introduction

This legislative proposal provides a basis for implementing the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (ABS), a protocol to the Convention on Biological Diversity (Treaty Series [*Tractatenblad*] 2012, 16 and Treaty Series 2012, 244, hereinafter: "Nagoya Protocol"), and relevant regulations of the European Union (hereinafter: "EU"). Currently, this means Regulation (EU) No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (OJEU 2014 L 150) (hereinafter: "Access and Benefit-Sharing (ABS) Regulation").

The Nagoya Protocol is a protocol to the Convention on Biological Diversity drawn up in Rio de Janeiro on 5 June 1992 (Treaty Series 1992, 164) (hereinafter: "Biodiversity Convention"), which has been adopted pursuant to Article 28 of the above-mentioned Convention. The Protocol is based on Article 1 and, in particular, Article 15 of the Biodiversity Convention, which provides that the contracting parties shall endeavour to create conditions to facilitate access to genetic resources (also referred to as "genetic material") by not imposing unnecessary restrictions on such access and to ensure the fair and equitable sharing of the benefits.

The present legislative proposal provides for the designation of a number of competent authorities on the basis of the Nagoya Protocol and the ABS Regulation. Furthermore, it provides for the penalisation of contraventions of the provisions of the applicable EU regulations and for the possibility to take administrative law and criminal law measures in the case of non-compliance with these regulations. Simultaneously with the submission of this legislative proposal, a

separate legislative proposal is being submitted for approval of the Nagoya Protocol for the whole Kingdom.[1]

I shall deal below with the creation and background of the Nagoya Protocol (Section 2), the obligations that arise under it (Section 3), and its relationship to other conventions (Section 4). This will be followed by an explanation of the European ABS Regulation (Section 5), after which I will deal with its implementation in the Netherlands (Section 6). I will then discuss the relationship to other legislation (Section 7), followed by an analysis of the burden that implementation of the ABS Regulation entails for citizens, businesses, and government (Section 8). I shall close with the explanation of each article (Section 9).

2. Background to the Nagoya Protocol

2.1 Creation

Pursuant to Article 1, the Biodiversity Convention has the following objectives:
- the conservation of biological diversity;
- the sustainable utilisation of its components; and
- the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, including by appropriate access to those genetic resources and by appropriate funding.

The Parties to the Convention implement the final objective – which is elaborated in Article 15 – in various ways, meaning that unnecessary restrictions remain as regards access. At the tenth Conference of Parties to the Biodiversity Convention in 2010, the text of the Nagoya Protocol was adopted, clarifying and making more specific the obligations regarding this point. The Nagoya Protocol was signed on behalf of the Kingdom of the Netherlands on 23 June 2011. It was also signed on behalf of the European Union.

The Nagoya Protocol took effect on 12 October 2014. That was 90 days after the 50th instrument of ratification was submitted to the Secretariat. Fifty countries and the European Union have now ratified the Nagoya Protocol.[2]

2.2 Background

Mankind uses genetic resources as the basis for all sorts of applications: for new plant varieties in agriculture and horticulture – essential for global food security – and in food, cosmetics and pharmaceuticals, and other chemical products. Genetic resources are available from nature (*in situ*) or from collections (*ex situ*), and consist of material of vegetable, animal, microbial, or other origin that contains functional units of heredity, with actual or potential value for mankind.[3]

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[1] Approval of the Nagoya Protocol drawn up in Nagoya on 29 October 2010 on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (ABS) to the Convention on Biological Diversity, to the Convention on Biological Diversity, with annex (Treaty Series 2012, 16 and Treaty Series 2012, 244).
[2] For a current list of ratifications, see http://www.verdragenbank.overheid.nl.
[3] Article 2, Biodiversity Convention.

Genetic resources can be obtained in the form of organisms, the reproductive parts of organisms – such as seeds, cuttings, and egg or sperm cells, but also in the form of hereditary building blocks, such as separate genes or DNA fragments.

It was confirmed by a decision of the Conference of Parties to the Biodiversity Convention at the second Conference that human genetic resources do not fall within the scope of the Biodiversity Convention.[4] The Nagoya Protocol was adopted at the tenth Conference of Parties and it was concluded in accordance with the resolution at the second Conference that human genetic resources lie outside the scope of the Nagoya Protocol.[5]

In 2002, the then State Secretary for Agriculture, Nature Management and Fisheries and the then Ministers of Housing, Spatial Planning and the Environment and of Development Cooperation submitted the policy memorandum "Sources of Existence: Conservation and the Sustainable Utilisation of Genetic Diversity" [*Bronnen van ons bestaan - behoud en duurzaam gebruik van genetische diversiteit*][6] to the Dutch House of Representatives. In that memorandum, they emphasise that the effective exchange of genetic resources is of great importance, *inter alia* because of the interdependence of countries. The countries of origin of many of the genetic resources that are utilised wish to share in the benefits that are obtained in countries where genetic resources are utilised. Countries of origin are often developing countries that are directly dependent for their existence and food security on genetic resources within their natural environment. These countries attach a great deal of importance to rules on sharing of the benefits of the utilisation of genetic resources. The Netherlands is a country where genetic resources from other countries are utilised, for example to breed new plant varieties. For the Netherlands, it is crucial that the international exchange of genetic resources can take place without unnecessary restrictions, given our economic position as the world's second-largest exporter of basic materials for food, agriculture and floriculture, and because of the importance of food security. Lack of clarity regarding the applicable legislation in the country that provides the resources must be done away with as far as possible. The Netherlands also wishes to be a reliable partner, so that countries from which the resources are supplied continue to provide access to their genetic resources for Dutch users. In that connection, the policy memorandum calls on Dutch researchers and the Dutch business community to ensure maximum openness about the genetic resources that they utilise and manage.

At the tenth Conference of Parties, the Netherlands contributed actively to the creation of the Protocol. The present Dutch Government, like its predecessor, attaches great importance to an international system that offers legal certainty and transparency.[7] The Nagoya Protocol offers a clear framework for access to genetic

[4] CoP 2, decision II/11, 5-7 November 1995, http://www.cbd.int/decisions/.
[5] CoP 10, decision X/1, 18-29 October 2010, http://www.cbd.int/decisions/.
[6] Sources of Existence (2002; lnv0200360), http://www.rijksoverheid.nl/documenten-en-publicaties/rapporten/2002/04/18/bronnen-van-ons-bestaan.html.
[7] Parliamentary Documents II 2010/2011, 26 407, No. 46 and No. 49.

resources and the fair and equitable sharing of the benefits arising from their utilisation.

3. Contents of the Nagoya Protocol

3.1 Objective and scope

The objective of the Nagoya Protocol, as stated in Article 1 of the Protocol, is the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, *inter alia* through appropriate access to genetic resources and by means of appropriate funding, so as to contribute to the conservation of biological diversity and the sustainable use of its components. In order to achieve that objective the Protocol comprises various tools, for example raising awareness of the importance of genetic resources, encouraging the development of codes of conduct, guidelines and best practices, and the exchange of information between Parties to the Convention. The core of the Protocol consists of the provisions regarding facilitated access, sharing of the benefits, and compliance with rules established for all this by the Parties to the Convention.

The Nagoya Protocol applies to genetic resources over which states exercise sovereign rights.[8] Genetic resources located in marine areas outside national jurisdiction are therefore not subject to the Protocol.

The provisions of the Protocol relate to the "utilisation" of genetic resources. Article 2(c) defines what is meant by "utilisation". It means conducting research on and developing the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.[9] Trading in genetic resources does not fall within the scope of the Nagoya Protocol.

3.2 Access to genetic resources and associated traditional knowledge

In Article 3, and more specifically in Article 15(1), the Biodiversity Convention emphasises that countries have sovereign rights regarding their genetic resources, and that countries are therefore empowered to decide on access to genetic resources within their territory. The second paragraph of Article 15 provides that Parties to the Convention shall endeavour to create conditions to facilitate access to genetic resources. Article 6 of the Nagoya Protocol makes this more specific, providing in the first paragraph that access to genetic resources for their utilization shall be subject to the prior informed consent of the party providing such resources that is the country of origin of such resources or a party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that party. Both parties are referred to below as the country from where the resources are supplied.

[8] Article 3, Nagoya Protocol.
[9] Article 2(c), Nagoya Protocol.

Countries that require prior informed consent for access to their genetic resources are required by Article 6(3) of the Nagoya Protocol to:

(a) provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;
(b) provide for fair and non-arbitrary rules and procedures on accessing genetic resources;
(c) provide information on how to apply for prior informed consent;
(d) provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;
(e) provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and to notify the Access and Benefit-sharing Clearing-House accordingly;
(f) where applicable to set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and
(g) establish clear rules and procedures for requiring and establishing mutually agreed terms.

Pursuant to Article 7 of the Nagoya Protocol, parties must also take measures with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of those indigenous and local communities. In order to implement that article, the country from where the genetic resources are supplied must put in place a system that ensures that indigenous and local communities are involved and can issue their consent for access. The country where the resources or associated traditional knowledge are utilised will need to ensure a system to check whether a user has obtained the genetic material in accordance with the regulatory requirements of the country from which the resources have been supplied.

3.3 Sharing of benefits arising from the utilisation of genetic resources and associated traditional knowledge

The Nagoya Protocol does not comprise any rules regarding what constitutes fair and equitable sharing of benefits. It is up to the party that provides the material and the user of the genetic material to agree on terms regarding the sharing of the benefits that arise from the use, as well as subsequent applications and commercialisation (Article 5(1) of the Nagoya Protocol). This applies not only to the utilisation of genetic resources, but also to the use of traditional knowledge associated with genetic resources (Article 5(5) of the Nagoya Protocol). In the provisions concerned, the Nagoya Protocol speaks of mutually agreed terms between the party providing the material and the party that will utilise that material.

The third and fifth paragraphs of Article 5 require Parties to the Convention to take measures to ensure that the benefits are shared in a fair and equitable way. This may mean, for example, encouraging

private parties to agree on terms for sharing the benefits and promoting the use of model contractual provisions. Checks can also be carried out in the country where the material is utilised to determine whether the user has obtained the material in accordance with the regulatory requirements of the country from which the material has been supplied. It should be noted that, pursuant to the fourth section of Article 5, “benefits” must be interpreted broadly: they may be of a monetary or non-monetary nature. The annex to the Protocol gives a non-exhaustive list of possible benefits.

If a party, pursuant to Article 6(1) of the Nagoya Protocol requires prior informed consent, Parties to the Convention must, pursuant to the third section of Article 6, establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms must be set out in writing and may include, *inter alia*:

(i) a dispute settlement clause;
(ii) terms on benefit-sharing, including in relation to intellectual property rights;
(iii) terms on subsequent third-party use, if any; and
(iv) terms on changes of intent, where applicable.

3.4 Compliance

It follows from Articles 15 and 16 that parties to the Nagoya Protocol must take measures to ensure that the genetic resources that are utilised within their jurisdiction have been obtained in accordance with the regulatory requirements of the country from which the resources are supplied, and that parties must address situations of non-compliance. The measures must be appropriate, effective and proportionate. To support compliance, Parties to the Convention are required by Article 17 to take measures, as appropriate, to monitor and to enhance transparency about the utilisation of genetic resources. Such measures include designating one or more “checkpoints”, encouraging the inclusion in the mutually agreed terms of provisions regarding the sharing of information on the implementation of such terms, including through reporting requirements, and encouraging the use of cost-effective communication tools and systems.

3.5 The Nagoya Protocol in actual practice

In practice, access to genetic resources and the fair and equitable sharing of benefits may involve, for example, a Dutch plant breeding company that wishes to obtain a wild variety of a certain plant in a third country so as to then develop a new variety of the plant in the Netherlands. The country from which the material is supplied can set an access requirement pursuant to Article 6 of the Nagoya Protocol. The Dutch company will then need to obtain consent from that country to obtain and utilise the plant. Pursuant to Article 5 of the Nagoya Protocol, the party providing the material and the Dutch enterprise that is going to use it can agree in mutually agreed terms that the user will make a payment for access or will pay royalties. Another example would be a Dutch pharmaceutical company that wishes to obtain a herb in a third country that supposedly has medicinal properties, so as to carry out research in the Netherlands on whether it can be used to

develop medication. Agreements on sharing the benefits can, for example, include the pharmaceutical company sharing the results of the research with the party that has supplied the herb.

4. Relationship to other conventions

The Nagoya Protocol does not affect the rights and obligations arising from existing international conventions, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity (Article 4(1) of the Nagoya Protocol). The third paragraph of Article 4 of the Nagoya Protocol emphasises that the Protocol will be implemented in a mutually supportive manner with other international instruments relevant to it. Pursuant to Article 4(4), the Nagoya Protocol does not apply to genetic resources for which a specific system for access or sharing of benefits applies (the "ABS instrument"), if that instrument does not run counter to the objectives of the Biodiversity Convention and the Nagoya Protocol. The international conventions that are relevant in this connection are dealt with below.

4.1 International Convention for the Protection of New Varieties of Plants

The International Convention for the Protection of New Varieties of Plants was adopted in Paris on 2 December 1961 (Treaty Series 1962, 21). This convention obliges parties to implement, nationally, plant breeder's rights and the plant breeder's exemption. The holder of a plant breeder's right has the exclusive right to produce, propagate, and market propagating material of the variety protected by that plant breeder's right. Other parties may only carry out those actions with the consent of the holder of the plant breeder's right. Under the plant breeder's exemption, however, the protected material may be freely utilised for actions performed to breed or discover and develop other plant varieties. New plant varieties that are developed in this way fall outside the scope of the plant breeder's right and can be freely exploited commercially without payment being made to the holders of the plant breeder's rights in respect of the original plant varieties. The plant breeder's exemption acts as an incentive for the development of new plant varieties and thus contributes to increasing biodiversity. The Nagoya Protocol does not affect the plant breeders' exemption.

4.2 Specific ABS regimes

The Nagoya Protocol stands alongside the International Treaty on Plant Genetic Resources for Food and Agriculture that was adopted in Rome on 3 November 2001 (Treaty Series 2002, 134) (hereinafter: ITPGRFA). The ITPGRFA has a multilateral "ABS" system, whereby the Parties to the Treaty have agreed for certain crops which are of great importance for food and agriculture – including for the Netherlands – on uniform arrangements for facilitating access and sharing benefits so as to offer legal certainty and transparency. The Treaty applies to 64 crops, which are specified in Annex 1 to the ITPGRFA. The multilateral system specified in the Treaty is in fact restricted to those genetic resources that are under

the management and control of the authorities and in the public domain.[10] In the Netherlands, that means the collection of the Centre for Genetic Resources, The Netherlands (hereinafter: “CGN”). Private collections, such as those belonging to companies and private individuals, are not included, but the contracting parties have agreed to request other owners of plantgenetic resources for food and agriculture to participate voluntarily in the multilateral system (Article 11 of the ITPGRFA). Based on Article 11, three other Dutch collections besides the CGN have been registered with the Secretariat of the ITPGRFA, namely the *Solanaceae* collections of Radboud University Nijmegen, the apple collection of the North Holland Pomological Association, and the apple collection of the Frederiksoord Fruit Farm Foundation.[11]

In the exchange under the ITPGRFA of plantgenetic resources for research, breeding and education, use is made of the standard agreement provided for in the Treaty, the “standard material transfer agreement” (hereinafter: “SMTA”).[12] It should be noted that countries can decide to also apply the SMTA to plantgenetic resources for food and agriculture that are not listed in Annex 1, so as to simplify the international exchange of those resources. In the Netherlands, this also takes place in actual practice: all plantgenetic resources for food and agriculture that the CGN provides for research, breeding, and education are given to users subject to a SMTA. That ensures that the genetic resource has been obtained with due diligence. The ABS Regulation has a specific provision regarding this point.[13]

The World Health Organisation (WHO) has also adopted a specific ABS regime regarding certain pathogens, i.e. disease-causing agents of biological origin. In 2011, agreement was reached within the WHO on the “Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits”.[14] This is a non-legally-binding instrument that applies to H5N1 and other influenza viruses with the potential for causing a human pandemic. The aim is to simplify the sharing of influenza viruses with the WHO and to increase access to vaccines, so as to be able to take more effective action if an epidemic breaks out. When genetic material is exchanged on the grounds of this regime, Article 4(4) of the Nagoya Protocol provides that the Protocol does not apply.

5. European ABS Regulation

5.1 Entry into force

The ABS Regulation implements the Nagoya Protocol within the European Union. It was published in the Official Journal of the European Union on 20 May 2014 and came into force on 9 June 2014. The ABS Regulation applies as soon as the Nagoya Protocol comes into force for the European Union, namely op 12 October 2014.

[10] Article 11.2 of the ITPGRFA.
[11] Notification letter, reference TRCDL/2008/1099, April 24, 2008. <http://www.planttreaty.org/sites/ default/files/inclu_Netherlands.pdf>
[12] Article 12.3(a) of the ITPGRFA.
[13] See Section 5.4.
[14] World Health Assembly Resolution 64.5, 24 May 2011.

An exception applies to Articles 4, 7, and 9. These will apply from one year after the Nagoya Protocol comes into force for the European Union, i.e. on 12 October 2015, because they impose obligations on users and regulate supervision and monitoring of compliance by users, for the implementation of which national legislation is necessary.

5.2 Relationship to the Nagoya Protocol

The European Union and the Member States have shared competence in the field of the environment, which contributes to the pursuit of the following objectives:

- preserving, protecting and improving the quality of the environment;
- protecting human health;
- prudent and rational utilisation of natural resources; and
- promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change.[15]

In the case of shared competence, the Member States may only exercise their competence to the extent that the European Union has not yet exercised its competence by adopting internal measures (Article 2(2) of the Treaty on the Functioning of the European Union). Shared competence applies to the great majority of matters to which the Nagoya Protocol relates. The European ABS Regulation provides rules for all matters dealt with in the Nagoya Protocol, with the exception of Articles 6 and 13 of the Protocol.

Article 6 of the Nagoya Protocol regulates access to genetic resources and – like Article 15 of the Biodiversity Convention – acknowledges the sovereign rights of parties to their genetic resources. Access to genetic resources in the separate Member States is not a matter provided for in the ABS Regulation. Although the Netherlands therefore retains the scope for imposing rules in this regard, it is not the Dutch Government's intention to impose an access requirement. I shall deal with this further in Section 6.2.

Article 13 of the Nagoya Protocol obliges Parties to the Convention to designate a national "focal point" on access and benefit-sharing, whose task shall be to make information available to users of genetic resources, and to designate one or more competent national authorities on access and benefit-sharing, which will be responsible, as applicable, for granting access. The Member States of the European Union must provide for this themselves. Pursuant to Article 6(3) of the ABS Regulation, the European Union in fact also designates a focal point on access and benefit-sharing, which is responsible at European level for maintaining contact with the Secretariat of the Biodiversity Convention.

5.3 Scope of the ABS Regulation

Pursuant to Article 2(1), the ABS Regulation, like the Nagoya Protocol, applies to genetic resources over which states exercise

[15] Article 191(1), VWEU

sovereign rights and to traditional knowledge associated with genetic resources. The regulation does not apply to genetic resources to which access and benefit-sharing are regulated in specific international instruments which are in accordance with the objectives of the Biodiversity Convention and the Nagoya Protocol (Article 2(2) of the regulation).

With a view to legal certainty, the first paragraph of Article 2 of the ABS Regulation provides that the regulation only applies to genetic resources to which access is acquired after the Nagoya Protocol has come into force for the European Union. The regulation therefore has no consequences for genetic material to which users have already acquired access prior to the Nagoya Protocol coming into force for the Union and which holders already have in their possession. Finally, pursuant to Article 2(4), the regulation only applies to genetic resources and traditional knowledge associated with genetic resources to which the legislation or regulations regarding access and benefit-sharing of a party to the Nagoya Protocol applies. The regulation does not therefore apply when genetic resources are utilised that have been supplied by a country that is not a party to the Nagoya Protocol. That does not affect the fact, however, that the country concerned can have legislation or regulatory requirements regarding access to genetic resources and the equitable sharing of benefits. Enforcement of such legislation or regulation is then solely a matter for the country concerned.

Within the European Union, it is still a matter of debate to what extent the regulation also applies to material that is used subject to the plant breeder's exemption referred to in Section 4.1 of this Explanatory Memorandum. The Dutch Government considers that the ABS Regulation must be implemented in a way that it does not cause any disproportionate burdens and that does not affect the plant breeder's exemption. The question of the extent to which the regulation applies to material that is used subject to the plant breeder's exemption does not affect the present legislative proposal, because that proposal provides solely for the designation of public bodies, the penalisation of contravention of the provisions of the applicable regulations, and the possibility of taking measures under administrative and criminal law.

5.4 Obligations of users

The European Union implements the obligations set out in the Nagoya Protocol by means of a system of due diligence obligations. The responsibility for collecting, preserving, and passing on information demonstrating that access to genetic resources and associated traditional knowledge has been acquired in accordance with the rules of the country from which the resources have been supplied lies primarily with users. Experience has been gained with the European Timber Regulation[16] with a system of due diligence obligations, with which the ABS Regulation links up.

[16] Regulation (EU) No. 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market (OJEU L 2010, 295).

Users must observe appropriate due diligence – specified in Article 4 of the ABS Regulation – by ascertaining that access to genetic resources and traditional knowledge associated with genetic resources has been acquired in accordance with the legislation of the country from which the resources are supplied, and that, where relevant, the benefits are fairly and equitably shared in accordance with mutually agreed terms. In order to comply with the system of due diligence obligations, users, pursuant to Article 4, must collect, preserve, and pass on information to subsequent users. Pursuant to the third paragraph of that article, that information must consist of:

a) the internationally-recognised certificate of compliance, as well as information on the content of the mutually agreed terms relevant for subsequent users; or
b) where no internationally-recognised certificate of compliance is available, information and relevant documents on:
    i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;
    ii) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised;
    iii) the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;
    iv) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation;
    v) access permits, where applicable;
    vi) mutually agreed terms, including benefit-sharing arrangements, where applicable.

Pursuant to Article 4(5) of the ABS Regulation, when the information in their possession is insufficient or uncertainties about the legality of access and utilisation persist, users must obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation. It follows from the sixth paragraph of Article 4 that users must keep the information relevant to access and benefit-sharing for twenty years after the end of the period of utilisation.

Users within the EU obtaining genetic material from a collection included in the register of collections within the EU (dealt with in greater detail in Section 5.6) will be considered to have exercised due diligence as regards the seeking of the above information (Article 4(7) of the regulation). This also applies to a user that obtains plantgenetic resources in a country that is a party to the Nagoya Protocol and that provides plantgenetic resources for food and agriculture that are not listed in Annex 1 to the ITPGRFA under the standard contract with the ITPGRFA, the SMTA (Article 4(4) of the regulation).

5.5 Monitoring of compliance by users

Pursuant to Articles 15 and 16 of the Nagoya Protocol, parties must take measures to ensure compliance with the legislation or regulatory requirements that apply in the country from which the resources are supplied regarding access and benefit-sharing of genetic resources

and associated traditional knowledge. Article 17 of the Nagoya Protocol obliges parties, as appropriate, to monitor the utilisation of genetic resources, including by designating “checkpoints”. In the ABS Regulation, this is implemented in Article 7 and Article 9. Article 7 regulates the provision of information by users to the competent authorities. Article 9 comprises obligations for the Member States to implement checks and if necessary to implement enforcement measures.

Article 7 of the ABS Regulation comprises provisions regarding the issuing of a declaration that the system of due diligence obligations has been complied with and the provision of information in that regard. Pursuant to the first paragraph, the Member States and the European Commission shall request users that receive research funding involving genetic resources and associated traditional knowledge to declare that they exercise due diligence in accordance with Article 4 of the regulation. Users will be required to provide that declaration, to the competent authority at an appropriate point in the research process. Additionally, at the stage of final development of a product developed via the utilisation of genetic resources or traditional knowledge associated with such resources, Article 7(2) of the ABS Regulation requires users to declare to the competent authority that they have fulfilled the obligations under Article 4 and submit the relevant information. Users must further provide evidence to the competent authority upon request.

Article 7(3) of the regulation requires the competent authority to transmit the information received on the basis of paragraphs 1 and 2 of that article to the Access and Benefit-Sharing Clearing House established under the Nagoya Protocol, to the European Commission, and, where appropriate, to the competent national authorities on access and benefit-sharing. The competent authorities must take due account of the respecting of confidentiality of commercial or industrial information where such confidentiality is provided for in legislation (Article 7(5)). Article 7(4) 4 requires that the competent authority shall cooperate with the Access and Benefit-Sharing Clearing House.

Pursuant to Article 9 of the ABS Regulation, the competent authority must carry out checks to verify whether users comply with the obligations specified in Articles 4 and 7 of the regulation. Pursuant to the first paragraph of Article 9, they must, in doing so, take into account that the implementation by a user of a best practice may reduce that user’s risk of non-compliance. Article 9(3) requires that the checks must be carried out in accordance with a periodically reviewed plan developed using a risk-based approach. Checks also take place when the competent authority is in possession of relevant, substantiated, information regarding a user’s non-compliance with the regulation. Article 9(3) of the regulation requires that special consideration be given to such concerns raised by supplier countries of the genetic resources.

Users of genetic resources must offer all assistance necessary to the competent authority to facilitate the performance of the checks (Article 9(5)).

If shortcomings have been detected during the checks, the competent authority must issue a notice of remedial action or measures to be taken by the user. Depending on the nature of the shortcomings, Member States may also take immediate interim measures (Article 9(6)). Finally, Article 11 of the regulation requires Member States to lay down the rules on penalties applicable to infringements of Articles 4 and 7 of the regulation. The penalties provided for shall be effective, proportionate and dissuasive.

5.6 Supporting measures

To help users comply with their obligations, the regulation provides for a register of collections within the Union (Article 5) and the recognition of best practices (Article 8).

As pointed out in Recital 28 to the ABS Regulation, collections are major suppliers of genetic resources and can play an important role in helping other users to comply with their obligations. In order for this to be done, a system of registered collections within the European Union has been put in place through the establishment of a voluntary register of collections, to be maintained by the European Commission. A collection holder can request the Member State where it is established to include a collection, or part of it, in the register of collections. Article 5(3) of the regulation sets out the conditions with which a collection must comply. The competent authorities of the Member States must verify whether a collection complies with the requirements for recognition as a collection that can be registered, and must notify the European Commission. Pursuant to Article 5(4), the Member States must regularly verify that the collections still meet the criteria, and, where that is no longer the case, can identify remedial actions or measures. Article 5(4) requires a Member State which determines that a collection or a part of a collection within its jurisdiction no longer complies with the criteria to inform the European Commission thereof without undue delay; the collection concerned will then be removed from the register.

A best practice is a combination of procedures, tools or mechanisms, developed and overseen by an association of users or other interested parties (Article 8(1)). An association of users or another interested party can submit an application to the European Commission for a best practice to be recognised. The European Commission will then decide on such recognition and, pursuant to Article 8(5), can withdraw the recognition when repeated or significant cases of non-compliance by users relate to deficiencies in the best practice.

5.7 Implementing acts

Pursuant to the ABS Regulation, the European Commission will adopt implementing acts with respect to the register of collections (Article 5), the monitoring of compliance by users (Article 7), and the best practices (Article 8). The European Commission will be assisted in this by a committee consisting of representatives of the Member States,

which will provide advice regarding the European Commission's proposal.[17]

The implementing acts that relate to Article 5 concern the procedures for implementing the first to fourth paragraphs. These specify how and subject to what conditions a collection holder can request to have its collection, or part of it, included in the register of collections, and how a collection can be removed from the collection.

The implementing acts that are adopted for implementing the first to the third paragraphs of Article 7 of the regulation concern the monitoring by the competent authority of compliance with the regulation by users. In those implementing acts, the Commission will determine, *inter alia*, an appropriate point in the research process when a declaration must be provided in connection with the acquisition of funds and the stage of final development of a product, in order to determine the final stage of utilisation in various sectors. This is the point at which users must provide a declaration to the competent authority that they have complied with the obligation to exercise due diligence within the meaning of Article 4 of the regulation.

The implementing acts that are adopted for the first to fifth paragraphs of Article 8 of the regulation concern the procedures regarding the application for recognition of a best practice and the possible withdrawal of that recognition.

6. Implementation in the Netherlands

6.1 General

The legislative proposal provides for the designation of competent authorities, and provides a basis for establishing rules regarding delegated regulation for implementation of the Nagoya Protocol and the implementation of EU regulations regarding genetic resources, in this case the ABS Regulation.

It is generally preferable in the case of the delegation of regulation to make use of the general administrative order [*algemene maatregel van bestuur*]. That is different when rules of an administrative nature are concerned and when one is dealing with the implementation of components of binding EU regulations, with the Dutch legislature having no discretion as regards taking substantive policy decisions. In that case, delegation can also take place to the level of the ministerial regulation [*ministeriële regeling*].

Against that background, this legislative proposal provides a basis for establishing rules by means of a ministerial regulation to implement components of EU regulations regarding genetic resources which do not allow any room for discretion and to implement obligations relating to the manner in which applications and documents can be submitted

[17] Regulation (EU) No. 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJEU 2012, L 55).

(proposed Article 2(2)). The legislative proposal also provides a basis for establishing rules by means of a general administrative order where the Nagoya Protocol and EU regulations allow discretion regarding the precise manner in which the international and European obligations will be implemented (proposed Article 2(3)), and for creating exemption or dispensation from those rules in accordance with the conditions and restrictions arising from the Nagoya Protocol or EU regulations (proposed Article 3). National rules may turn out to be necessary, *inter alia* for proper implementation and effective enforcement.

6.2 Implementation of Nagoya Protocol obligations not covered by EU rules

6.2.1 Access requirement Nagoya Protocol

Article 6(1) of the Nagoya Protocol provides that access to genetic resources for their utilisation shall be subject to the prior informed approval of the country of origin of such resources, unless otherwise determined. It follows from this that the Nagoya Protocol also gives countries scope for not requiring approval for access to genetic resources that are within the jurisdiction of that country.

In the policy memorandum “Sources of Existence: Conservation and the sustainable utilisation of genetic diversity (2002)”, the then Government considered that it is not necessary to embed the national sovereignty of the Netherlands regarding access to and utilisation of genetic resources in legislation because the Netherlands is the country of origin for only a few species. The current Government shares that view. The present legislative proposal does not therefore further regulate access to Dutch genetic resources. Access to genetic resources is restricted, however, by means of legislation and regulatory requirements in the area of species protection, territorial protection, and animal and plant diseases.

6.2.2 Competent authority for access and benefit-sharing

Pursuant to Article 13 of the Nagoya Protocol, parties must designate a national authority for access and benefit-sharing. The obligation to designate a competent authority also applies if a country decides not to impose access requirements itself. The national authority is responsible for advising users about the applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms. In relevant cases, the national authority is also responsible for granting access. Article 4(2) of the present legislative proposal designates the Minister of Economic Affairs as the competent national authority for access and benefit-sharing within the meaning of Article 13(2) of the Nagoya Protocol. Because the Netherlands does not impose any access requirement, the task of the competent national authority is restricted to providing information for users who submit a request to acquire access.

6.2.3 National focal point on access and benefit-sharing

Article 13 of the Nagoya Protocol also obliges parties to designate a national focal point on access and benefit-sharing. The task of the national focal point is to inform users about access to and the sharing of benefits from the utilisation of genetic resources. The focal point also provides information about the competent national authority and relevant stakeholders, and is responsible in this area for liaison with the Secretariat of the Biodiversity Convention. Article 4(1) of the legislative proposal provides for designation by the Minister of Economic Affairs of a national focal point on access and benefit-sharing.

As the National Information Centre, the CGN plays a key role in communication about genetic resources in the Netherlands. Given that the CGN already carries out that task and has experience in this area, it is my intention to designate the CGN as the national focal point.

6.3 Implementation of EU regulations

6.3.1 Prohibition on contravening EU provisions

Article 2(1) of the legislative proposal prohibits the contravention of provisions of EU regulations regarding genetic resources that have been designated by means of a ministerial regulation. It is my intention, pursuant to that article, to so designate the requirements set out in Articles 4 and 7 of the ABS Regulation. Article 4 comprises the due diligence obligations with which users of genetic resources must comply. Article 7 of the ABS Regulation comprises provisions for users regarding the submission of information to the competent authority on the basis of which it can be determined whether the requirements of Article 4 of the regulation have been observed. Reference is made to Sections 5.4 and 5.5 of this Explanatory Memorandum, where those provisions are dealt with.

6.3.2. Competent authority

Pursuant to Article 4(3) of the present legislative proposal, the Minister of Economic Affairs is the competent authority for the implementation of EU regulations regarding genetic resources. Pursuant to the ABS Regulation, the competent authority is charged with various tasks, for example receiving declarations by users stating that they have complied with their due diligence obligations, monitoring compliance by users in accordance with Article 9 of the regulation, registering checks, and cooperating with the competent authorities of other Member States and the European Commission to promote compliance by users. Article 6(1) of the regulation provides that each Member State shall designate one or more competent authorities to be responsible for the application of the regulation.

It is my intention to have the tasks of the competent authority exercised by the Netherlands Food and Consumer Product Safety Authority [*Nederlandse Voedsel- en Warenautoriteit*] (hereinafter: “NVWA”). The NVWA already inspects the main target groups of the present legislative proposal, for example plant breeders, the food industry, pharmaceutical companies, animal breeders, and holders of

collections, for example zoos and botanical gardens. Furthermore, the NVWA has experience of inspection of compliance with the European Timber Regulation, which also provides for a system of due diligence obligations. The tasks which the competent authority must carry out in the context of the ABS Regulation link up well with this work. The legislative proposal also provides for the possibility of designating another competent authority.

6.4 Enforcement

6.4.1 Monitoring authorities

The proposed Article 4(4) concerns the designation of public officials responsible for monitoring. In accordance with my intention to have the tasks of the competent authority carried out by the NVWA, the officials of the NVWA will monitor compliance with what is provided by or pursuant to the present legislative proposal. The officials of the NVWA have been designated as special investigating officers within the meaning of the Economic Offences Act [*Wet op de economische delicten, WED*] and in that capacity have the relevant powers to investigate contraventions of the prohibition in Article 2(1). Given that the officials of the NVWA are also the monitoring authority pursuant to the proposed Article 4(4)(b), they also have the powers specified in Title 5.2 of the General Administrative Law Act [*Algemene wet bestuursrecht, Awb*].

6.4.2 Sanctions and other measures

Criminal law enforcement
Article 8 of the present legislative proposal amends Article 1a(1°) of the Economic Offences Act. This designates actions in contravention of the rules set by or pursuant to this legislative proposal as an economic offence. In the case of a serious offence [*misdrijf*], a prison sentence of a maximum of six years, a community service order, or a fine of the fifth category can be imposed. This is EUR 81,000 for persons and EUR 810,000 for legal entities. In the case of a lesser offence [*overtreding*], a prison sentence of a maximum of one year, a community service order, or a fine of the fourth category can be imposed. This is then EUR 20,250 for persons and EUR 81,000 for legal entities. This links up with the sanctions foreseen in the legislative proposal on Nature Conservation in respect of the contravention of provisions of the European CITES Regulation[18] and the Timber Regulation.[19] These regulations also set rules with the objective of preserving biodiversity. The difference, however, is that in the CITES Regulation and the Timber Regulation, rules are set that relate to trade, whereas the ABS Regulation regulates access to genetic resources and the fair and equitable sharing of the benefits arising from their utilisation.

Administrative penalty

[18] Council Regulation (EC) No. 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJEU L 61).
[19] Regulation (EU) No. 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market (OJEU L 2010, 295).

Pursuant to the proposed Article 7(2), the Minister of Economic Affairs is empowered to impose an administrative penalty for administrative offences regarding access to genetic resources and the fair and equitable sharing of the benefits arising from their utilisation. It is desirable for it to be possible to pursue an on-the-spot penalty policy, and for contraventions to be penalised rapidly. Effective monitoring of compliance with the rules will, after all, be made difficult if administrative records are not kept or are only kept insufficiently, or if information is not provided, or not provided on time. It is also desirable that the Public Prosecution Service not be made responsible for prosecuting or settling frequent and relatively minor offences. This concerns offences that can be ascertained in a simple manner and for which it is not necessary to deploy powers of investigation.

By means of a general administrative order, the specific contraventions will be designated for which an administrative penalty can be imposed, and what maximum will apply for this (proposed Article 7(3)). As a general maximum amount, this legislative proposal foresees a fine of EUR 405 per contravention, with this being increased to EUR 4050 when the offender is a legal entity or a company. This links up with criminal law fines of the first category which generally apply to this kind of economic offences of an administrative nature. The contraventions that can be dealt with pursuant to this legislative proposal by the imposition of an administrative penalty have also been designated as economic offences. Situations may always occur, after all, in which the nature of the contravention is so serious that adjudication via the criminal law is appropriate, rather than their being dealt with administratively. With that in mind, Article 7(5) of the legislative proposal provides that in such cases the contravention will be submitted to the Public Prosecution Service. To make clear that the powers to impose an administrative penalty and an administrative punishment issued by a special investigating officer [*strafbeschikking*] within the meaning of Article 257ba of the Code of Criminal Procedure [*Wetboek van Strafvordering*] cannot apply simultaneously to the same offence, the proposed Article 7(6) provides that no administrative punishment issued by a special investigating officer can be imposed for offences that are designated pursuant to the first paragraph of the article.

Remedial sanctions

Article 5 of the legislative proposal empowers the Minister of Economic Affairs to impose an order subject to administrative enforcement [*last onder bestuursdwang*] or an incremental penalty [*dwangsom*]. Article 9(6) of the ABS Regulation provides that Member States, besides issuing a notice of remedial action or measures to be taken by the user, may also take immediate interim measures, depending on the nature of the shortcomings. Article 6 empowers the Minister of Economic Affairs to take these measures in respect of users who act in contravention of what is provided pursuant to this legislative proposal. For the measures to be taken, an attempt has been made to link up with the measures that can be imposed pursuant to the legislative proposal on Nature Conservation in respect of timber and timber products that have been imported or placed on the market

in contravention of the European Timber Regulation. The costs of the measures will be at the expense of the owner, transporter, importer, or its agent. The NVWA will be mandated to impose these measures on behalf of the Minister.

7. Relationship to other legislation

The Netherlands has flanking legislation in various fields that is relevant to the utilisation of genetic resources. This concerns regulation in the area of nature conservation, animal and plant health, agriculture, and intellectual property rights. The present legislative proposal does not affect the applicability of existing legislation and regulations.

7.1 Legislative proposal on nature conservation

The legislative proposal on nature conservation is intended to replace the present Nature Conservation Act 1998 [*Natuurbeschermingswet 1998*], the Flora and Fauna Act [*Flora- en faunawet*], and the Forestry Act [*Boswet*] with an integrated and simplified legal framework that provides rules for the protection of nature conservation areas, species, and stands of timber. On the basis of this, access to and utilisation of genetic resources can be prohibited or restricted, for example by prohibitions on their possession or trading. The legislative proposal on nature conservation implements various international and European obligations, including the abovementioned European CITES Regulation and the European Timber Regulation.

The European CITES Regulation sets rules on trade in dead and living animals and plants of species that are or may be threatened with extinction. The regulation implements the CITES Convention, the purpose of which is to prevent animal and plant species being threatened with extinction as a result of their being taken and exploited excessively for international trade.

The European Union has adopted two regulations comprising obligations for companies that trade in timber or timber products. These regulations form part of the European policy to combat illegal logging and to reduce demand for illegally harvested timber on the internal market. These are the “FLEGT Regulation” and the European Timber Regulation. The European Timber Regulation obliges the Member States to prohibit the marketing of illegally harvested timber or timber products. It also comprises provisions regarding the traceability of timber and timber products throughout the whole distribution chain and regarding a system of due diligence obligations with which market participants must comply.

7.2 Legislation regarding plants and animals

The Nagoya Protocol and the ABS Regulation concern access to and utilisation of genetic resources. These resources may be of both vegetable and animal origin. A number of pieces of legislation set requirements regarding plants and animals and products of vegetable and animal origin. These laws continue to apply in full when genetic resources are imported and utilised. The Plant Diseases Act

[*Plantenziektenwet*], for example, sets rules to prevent the spread of harmful organisms. These rules also apply to genetic resources of vegetable origin originating in third countries. The Animal Health and Welfare Act [*Gezondheids- en welzijnswet voor dieren*] and the Animals Act [*Wet dieren*] set rules, *inter alia*, to prevent animal diseases and regarding the manner in which animals are transported or kept. These also apply to genetic resources of animal origin. If genetic resources are placed on the market in applied form, as a product, they must comply with the requirements set by or pursuant to the Agriculture Act [*Landbouwwet*] and the Commodities Act [*Warenwet*].

7.3 Intellectual property rights

Intellectual property rights are not covered by the Nagoya Protocol and the ABS Regulation. The relationship between genetic resources and intellectual property is, however, the subject of discussion by the World Trade Organisation (WTO) and the World Intellectual Property Organisation (WIPO).

7.3.1 Patent law

Inventions that relate to biological material can be protected by a patent. A patent is granted for an invention that is new, inventive and industrially applicable, including applicable in agriculture. As long as the biological material, and material derived from it, has the property determined by the patented invention, the material falls within the scope of protection of the patent, and the approval of the patent holder is necessary in order to use the material for commercial purposes. An amendment to the Patents Act 1995 [*Rijksoctrooiwet 1995*] came into force on 1 July 2014 which introduced the “restricted breeding exemption” into patent law. This exemption is a facility which allows plant breeders to use patented biological material to breed, discover, and develop new plant varieties without a licence from the holder of the patent for an invention relating to that biological material. The breeding exemption is restricted. It applies only to the use of patented biological material for breeding purposes, but not to the commercial exploitation of biological material obtained by means of such breeding.

7.3.2 Plant breeder’s right

Inventions that relate to plant material can be protected with a patent. Plant varieties as such do not qualify for being patented. The plant breeder’s right forms the intellectual property right for plant varieties. Pursuant to the Seeds and Planting Materials Act 2005 [*Zaaizaad- en plantgoedwet 2005*], the holder of the plant breeder’s right to a variety has the exclusive right to create propagating material of that variety, increase it, process it for the purpose of increasing it, market it, export or import it, or hold a stock of it with a view to one of the above actions. Others may only carry out these actions if the holder of the plant breeder’s right has granted approval. The plant breeder’s right does not extend to actions carried out with a view to breeding, discovering, or developing other varieties. This is also referred to as

the plant breeder's exemption. Section 4.1 explains the plant breeder's exemption in greater detail.

8. Burden

8.1 Regulatory burden effects for companies, institutions, and citizens

The present legislative proposal implements the Nagoya Protocol and the ABS Regulation. The regulatory burden effects for companies, institutions, and citizens that/who work with genetic resources arise directly from the provisions of the ABS Regulation.

8.1.1 Number and type of users

The extent of the regulatory burden and the compliance and monitoring burdens for individual companies, institutions, and citizens is partly dependent on the way in which a number of matters have been worked out in implementing acts within the European Union.

The ABS Regulation applies to all users of genetic resources. The consequences that the ABS Regulation has for users are partly dependent on the origin and quantities of the genetic resources that they utilise. The groups of users within the business community are varied, involving plant and animal breeders, tree nurseries, the food industry, the pharmaceutical industry (medical and veterinary), the other biotechnological sectors, the natural cosmetics and medicines sector, and the biological pesticides/herbicides sector.

Besides for users within the business community, this regulation also has an impact on non-commercial users of genetic resources, for example researchers at universities and other knowledge institutions, zoos, holders of collections of genetic resources, including botanical gardens, and private individuals.

This involves a total of some 1500 users in the Netherlands, of which about one third are private individuals and 60% are the business community, with collections and educational and research institutions also being affected. The effects will largely be felt by small and medium-sized businesses with fewer than 250 employees and microbusinesses with 1 to 9 employees.

Various meetings have been held with stakeholders regarding the consequences of the present legislative proposal in actual practice. In consultation with the sector organisations, an effective system is being sought for complying with the due diligence obligations that will be imposed, for the smaller businesses in particular. The estimates below of the extra costs and regulatory burden have been drawn up partly on the basis of consultations with businesses.

8.1.2 Regulatory burden resulting from the system of due diligence obligations

Users of genetic resources must comply with the system of due diligence obligations, which is explained in greater detail in Section 5.4 of this Explanatory Memorandum. The regulatory burden

arises *inter alia* because the appropriate due diligence that users of genetic resources must observe means that they must first investigate the origin of all genetic resources that they obtain, so as to determine whether these do or do not fall within the scope of the ABS Regulation. The scope of application of the regulation has been explained in Section 5.3. It is estimated that some 5% of all the genetic material utilised is subject to the ABS Regulation. Users obtain most of their resources from elsewhere, for example from gene banks or company collections in their own country or from third countries that are not parties to the Nagoya Protocol.

When users utilise material that is subject to the ABS Regulation, they must provide a declaration to the competent authority that they comply with the system of due diligence obligations and must make information about this available. The estimate is that this will take a maximum of one hour. Assuming an hourly rate of EUR 45, this will costs a business EUR 45 per declaration. The frequency with which businesses will need to carry out this action will vary greatly, depending on the quantity of resources that individual businesses utilise. Assuming that only 5% of the material that is utilised is material that is subject to the ABS Regulation, that means that a large plant breeding company that utilises 1000 accessions annually will need to issue a declaration 50 times per year. However, the number of large companies using genetic resources in the Netherlands is relatively limited. There will also be users that only utilise 60 accessions per year, which means that they will have to issue three declarations per year. The costs for issuing declarations will therefore be between EUR 135 and EUR 2250 per year.

In order to comply with the system of due diligence obligations, users may perhaps need to incur once-only burdens consisting of setting up or adapting an information system for recording the origin of the genetic resources and information about them. However, many businesses already have a database in which they record the genetic resources that they obtain.

It is expected that some 20% of the 1500 users will need to set up a new system. These will mainly be small businesses which do not currently use such systems. Setting up a simple system is expected to cost EUR 1000 per user. 80% of users will already have a system but may need to adapt it so as to be able to register all the information required pursuant to the regulation. 50% of all users will need to make a minor change to their present system, with the cost amounting to EUR 500. The other users will have a more advanced system which will cost more to adapt. The costs involved for this are estimated at EUR 2000. For the whole sector, the burdens for setting up or adapting the system will come to EUR 1,575,000 (once only).

Various businesses in the Dutch plant breeding sector have expressed concern regarding the erosion of the plant breeder’s right and the plant breeder’s exemption, and the burdens that the regulation involves for material that is used subject to the plant breeder’s exemption. It has already been explained in Section 5.3 that the Dutch Government considers that the ABS Regulation must be implemented in such a way that it does not involve any

disproportionate burdens in this regard, and with the plant breeder's exemption remaining unaffected.

8.1.3 Burdens regarding undergoing monitoring

The ABS Regulation allows the Member States to determine the specific intensity of monitoring. In the Netherlands, it has been decided that the inspection frequency should be a maximum of 4% on the basis of the risk approach; additionally, ad hoc monitoring will need to take place on the basis of signs of non-compliance. Assuming the average time taken for undergoing monitoring to be four hours per user at an hourly rate of EUR 37, based on the Standard Costs Model, the collective structural monitoring burden will come to EUR 8880 per year. The individual monitoring burden will differ from one business to another, mainly dependent on the risk assessment.

Pursuant to the ABS Regulation, users are offered a number of instruments that enable them to comply with their obligations at affordable cost and with a high degree of legal certainty. This involves, in particular, linking up with and observing a best practice in their sector and obtaining material from registered collections. Both instruments have been explained in Section 5.6 and can result for users in a reduction in their risk profile and therefore to a reduction in their being monitored.

8.2 Burdens for the authorities

The competent authority will monitor users on the basis of a risk approach and, where necessary, on the basis of signs of non-compliance by individual users. The extent of monitoring will therefore vary according to the risk profile of users; when the risk profile is higher, monitoring will be more frequent than when it is low. Given the known information about users and use in the Netherlands, it is estimated that 2 to 4.5 full-time equivalents ("FTEs") will be necessary on an annual basis to carry out monitoring. Given that the ABS Regulation offers measures with which users can reduce their risk profile, it is expected that after the ABS Regulation has been applied for a certain time monitoring can be carried out less frequently.

9. Explanation of each individual article

Article 1

The term "EU regulations regarding genetic resources" is restricted to regulations within the meaning of Article 288 of the Treaty on the Functioning of the European Union that relate to access to genetic resources and the fair and equitable sharing of benefits arising from their use. Regulation (EU) No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (OJEU 2014 L 150) is in any case covered by this, as are the implementing acts that are yet to be determined by the European Commission. The definition makes it possible to implement this, if the ABS Regulation is in future amended or when supplementary

regulations in this field are determined, on the basis of the present legislative proposal, once it has become law. This has been decided on because the Government does not exclude the possibility of amendments to the ABS Regulation being implemented in the future, or new regulations being adopted in this field. This is in the light of the experience that must still be acquired by both the users and the competent authorities with the system of due diligence obligations and given the fact that the ABS Regulation is the first regulation in the area of access and benefit-sharing.

Articles 2 and 3

The proposed Article 2(1) is explained in Section 6.3 of this Explanatory Memorandum and Article 2(2) and (3) and Article 3 in Section 6.1.

Article 4

It is provided in the first paragraph of Article 4 that the Minister of Economic Affairs will designate a national focal point on access and benefit-sharing. It is my intention to designate the CGN as such. In the second paragraph, the Minister of Economic Affairs is designated as the national authority for access and benefit-sharing. Designation of these two authorities serves to implement Article 13 of the Nagoya Protocol.

Pursuant to the third paragraph of that article, the Minister of Economic Affairs is designated as the competent authority with responsibility for the implementation of EU regulations regarding genetic resources. The intention is to mandate performance of the tasks of the competent authority to the NVWA. The Minister can also designate another competent authority.

Article 5

The Minister is empowered to impose an order subject to administrative enforcement so as to enforce the provisions of or pursuant to the present legislative proposal. It follows from Article 5:32 of the General Administrative Law Act that an administrative authority that is empowered to impose an order subject to administrative enforcement can also impose an order subject to an incremental penalty.

Articles 6, 7, and 8

Reference is made to the explanation in Section 6.5.2.

The State Secretary for Economic Affairs,
S.A.M. Dijksma

Annex 1 Concordance tables for Legislative Proposal on Implementation of the Nagoya Protocol

Table 1. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Treaty Series 2012, 244)

Protocol	*ABS Regulation*	*Legislative Proposal*	*Explanation*
Article 1	-	-	Does not require implementation, concerns purpose of Protocol.
Article 2	-	-	Does not require implementation, concerns definitions.
Article 3	-	-	Does not require implementation, concerns scope of Protocol.
Article 4	-	-	Does not require implementation, concerns relationship to international conventions and instruments.
Article 5	Article 4	Article 2(1)	Implementation via European ABS Regulation.
Article 6	-	-	See Section 6.2 of Explanatory Memorandum.
Article 7	-	-	Does not require implementation. The Netherlands has no "indigenous and local communities" within the meaning of the Nagoya Protocol.
Article 8	-	-	Does not require implementation, concerns general policy requirement.
Article 9	-	-	Does not require implementation, concerns general policy requirement.
Article 10	-	-	Does not require implementation, task for Parties to Protocol.
Article 11	-	-	Does not require implementation, task for Parties to Protocol.
Article 12	-	-	Does not require implementation. The Netherlands has no "indigenous and local communities".
Article 13	-	Article 4(1) and (2)	
Article 14	-	-	Does not require implementation, clearing-house mechanism for access and benefit-sharing set up.
Article 15(1)	Article 4	Article 2(1)	Implementation via European ABS Regulation.
Article 15(2)	Article 9 and Article 11	Article 4(3) and Article 8	Implementation via European ABS Regulation.
Article 15(3)	-	-	
Article 16(1)	Article 4	Article 2(1)	Implementation via European ABS Regulation.
Article 16(2)	Article 9 and Article 11	Article 4(3) and Article 8	Implementation via European ABS Regulation.
Article 16(3)	-	-	
Article 17	Article 7	Article 2(1)	Implementation via European ABS Regulation.
Article 18	-	-	Does not require implementation, provision already implemented by existing law.
Article 19	-	-	Does not require implementation, concerns general policy requirement.
Article 20	-	-	Does not require implementation, concerns general policy requirement.
Article 21	-	-	Does not require implementation, concerns general policy requirement.
Article 22	-	-	Does not require implementation, concerns general policy requirement.
Article 23	-	-	Does not require implementation, concerns general policy requirement.
Article 24	-	-	Does not require implementation, concerns general policy requirement.
Article 25	-	-	Does not require implementation, concerns provisions on financial mechanism and means.

Protocol	*ABS Regulation*	*Legislative Proposal*	*Explanation*
Article 26	-	-	Does not require implementation, concerns provisions on Conference of Parties that acts as the meeting of the Parties to this Protocol.
Article 27	-	-	Does not require implementation, concerns provisions on subsidiary bodies.
Article 28	-	-	Does not require implementation, concerns provisions on Secretariat.
Article 29	-	-	Does not require implementation, concerns task of Parties to Protocol.
Article 30	-	-	Does not require implementation, concerns task of Conference of Parties.
Article 31	-	-	Does not require implementation, concerns task of Conference of Parties.
Article 32	-	-	Does not require implementation, concerns signature.
Article 33	-	-	Does not require implementation, concerns entry into force provision.
Article 34	-	-	Does not require implementation, concerns provisions on reservations.
Article 35	-	-	Does not require implementation, concerns provisions on withdrawal.
Article 36	-	-	Does not require implementation, concerns language of authentic texts.

Table 2. Regulation (EU) No. 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (OJEU 2014 L 150).

Regulation	*Place in Legislative Proposal*	*Policy scope*	*Explanation*
Article 1	-	-	Does not require implementation, concerns description of subject of the regulation.
Article 2	-	-	Does not require implementation, concerns description of scope of the regulation.
Article 3	-	-	Does not require implementation, concerns definitions.
Article 4	Article 2(1) (prohibition provision) -	-	
Article 5(1)	-	-	Does not require implementation, concerns task of European Commission.
Article 5(2)	Article 2(2) (implementation components of binding EU legal acts)	-	
Article 5(3)	-	-	Does not require implementation, concerns conditions for inclusion in register of collections.
Article 5(4)	Article 2(2) (implementation components of binding EU legal acts)	-	
Article 5(5)	-	-	Does not require implementation, concerns power of European Commission to establish implementing acts.
Article 6(1)	Article 4(3) (designation of competent authority)	-	
Article 6(2) to (4)	-	-	Does not require implementation, concerns task of European Commission.
Article 7(1) and (2)	Article 2(1) (prohibition provision)	-	
Article 7(3) to (5)	-	-	Does not require implementation, concerns detail frameworks for monitoring.
Article 7(6)	-	-	Does not require implementation, concerns power of European Commission to establish implementing acts.

Regulation	*Place in Legislative Proposal*	*Policy scope*	*Explanation*
Article 8	-	-	Does not require implementation, concerns task of European Commission.
Article 9(1)	Article 4(3) (designation of competent authority)	-	
Article 9(2) to (4)	-	-	Does not require implementation, concerns detailed frameworks for checks.
Article 9(5)	-	-	Does not require penalisation, a similar obligation applies on the basis of Article 5:20 of General Administrative Law Act.
Article 9(6)	Article 6 (designation of Minister of Economic Affairs and prohibition provision)	Power to take immediate interim measures.	See Section 6.5 Explanatory Memorandum.
Article 10	Article 4(3) (designation of competent authority)	-	
Article 11	Article 2(1) (prohibition provision) and Article 8 (amendment WED)	-	
Article 12	Article 4(3) (designation of competent authority)	-	
Article 13	-	-	Does not require implementation, concerns tasks of European Commission and Member States.
Article 14	-	-	Does not require implementation, concerns committee procedure.
Article 15	-	-	Does not require implementation, concerns task of European Commission.
Article 16(1)	-	-	Does not require implementation, concerns task of Member States.
Article 16(2) to (4)	-	-	Does not require implementation, concerns tasks of European Commission.
Article 17		-	Does not require implementation, concerns entry into force and application.