



ACCESS AND BENEFIT-SHARING (ABS)

ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION

The “fair and equitable sharing of the benefits arising out of the utilization of genetic resources” is one of the three overall objectives of the Convention on Biological Diversity (CBD) along with the conservation of biodiversity and the sustainable use of the components of biodiversity. The CBD, in its article 15, sets out principles and obligations of Parties related to access to genetic resources and the fair and equitable sharing of benefits arising out of the utilization of genetic resources, on the basis of prior informed consent and mutually agreed terms.

The CBD establishes that a person or institution seeking access to genetic resources in a foreign country should seek the prior informed consent of the country in which the resource is located. Moreover, the person or institution must also negotiate and agree on the terms and conditions of access and use of this resource. This includes the sharing of benefits arising from the use of this resource with the provider as a prerequisite for access to the genetic resource and its use.

Conversely, countries, when acting as providers of genetic resources, should create conditions to facilitate access to their genetic resources for environmentally sound uses and not impose restrictions that run counter to the objectives of the CBD.

Genetic resources, whether from plant, animal or micro-organisms, are used for a variety of purposes ranging from basic research to the development of products. Users of genetic resources include research and academic institutions, and private companies operat-

ing in various sectors such as pharmaceuticals, agriculture, horticulture, cosmetics and biotechnology.

In some cases, traditional knowledge associated with genetic resources that comes from indigenous and local communities (ILCs) provides valuable information to researchers regarding the particular properties and value of these resources and their potential use for the development of, for example, new medicines or cosmetics. According to article 8j of the CBD: Parties shall respect, preserve and promote the knowledge, innovations and practices of ILCs relevant to biological diversity, with the approval and involvement of the holders of such knowledge and encourage the equitable sharing of benefits arising from its use.

EXAMPLES OF USES:

- ▶ The development of compounds called Calanolides, derived from the latex of a tree (*Calophyllum* species) found in the Malaysian rainforest, as a potential treatment for HIV (type 1) and certain types of cancer.
- ▶ The use of indigenous plant resources for breeding programmes and cultivation, e.g. the so-called “Mona Lavender”, a hybrid of two *Plectranthus* species indigenous to South Africa, is now commercially available as an ornamental plant throughout Europe, the US and Japan.
- ▶ The use of therapeutic properties of a small perennial herb *Trichopus zeylanikus*, known as *Sathan Kalanja* or *Arogyappa-cha*, locally and traditionally consumed to reduce fatigue.

Benefits derived from the use of genetic resources may include the sharing of the results of research and development carried out on genetic resources, the transfer of technologies which make use of



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those resources, and participation in biotechnological research activities. Benefits may also be monetary when products based on genetic resources are commercialised.

EXAMPLES OF BENEFIT-SHARING:

- ▶ Research exchanges: a researcher from a provider country collaborates with research staff from the user country.
- ▶ Collaborative research: a researcher from a user country employs indigenous and local community research assistants from the provider country.
- ▶ Provision of equipment, improvement of infrastructure and sharing of technologies: the user of genetic resources sets up laboratories or a drug manufacturing facility in the provider country.
- ▶ Payment of royalties: royalties generated from the commercialization of a product based on genetic resources are shared between the provider and the user of genetic resources and associated traditional knowledge.
- ▶ Preferential access for the provider country to any medicine derived from genetic resources and associated traditional knowledge: preferential rates to purchase medicine.
- ▶ Joint ownership of intellectual property rights (IPRs): when the user and provider of genetic resources seek joint ownership of IPRs for patented products based on the genetic resource used.

MAIN ABS ACHIEVEMENTS UNDER THE CBD

THE BONN GUIDELINES

In 2002, the Bonn Guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization were adopted by the Conference of the Parties to the CBD at its sixth meeting in The Hague. These voluntary guidelines guide both providers and users of genetic resources in the implementation of the access and benefit-sharing provisions of the Convention.

They were adopted to assist Parties when establishing administrative, legislative or policy measures on access and benefit-sharing and/or providers and users when negotiating agreements for access to genetic resources and benefit-sharing.

For example, they address the steps of the access and benefit-sharing process, by providing guidance with respect to procedures that can be established in a provider country in order to obtain access to genetic resources. They also provide an indicative list of typical elements for inclusion in access and benefit-sharing agreements



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regarding the conditions of access and use of genetic resources and, in addition, they provide guidance with respect to the roles and responsibilities of providers and users of genetic resources.

The Bonn Guidelines are available in the 6 UN languages at www.cbd.int/abs/bonn.

THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT-SHARING

The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity* was adopted on 29 October 2010 by the Conference of the Parties at its tenth meeting, in Nagoya, Japan. It stems from a call to action by the World Summit on Sustainable Development (Johannesburg 2002), later acted upon by the Conference of the Parties to the CBD in 2004, to negotiate within the framework of the CBD an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources. The Ad Hoc Open-ended Working Group on Access and Benefit-sharing established by the COP met eleven times from 2005 to 2010 to negotiate the text of the Nagoya Protocol.

Further information on the Nagoya Protocol is available on an additional fact sheet entitled "The Nagoya Protocol on Access and Benefit-sharing" posted on the CBD Website at www.cbd.int/abs.



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THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT-SHARING

WHAT IS THE NAGOYA PROTOCOL AND WHAT IS ITS OBJECTIVE?

The Nagoya Protocol on Access and Benefit-Sharing is a new international treaty adopted under the auspices of the Convention on Biological Diversity (CBD) in Nagoya, Japan on 29 October 2010. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity and implementing the three objectives of the CBD. The Nagoya Protocol will enter into force when 50 countries ratify it.

WHY IS THE NAGOYA PROTOCOL IMPORTANT?

The Nagoya Protocol will create greater legal certainty and transparency for both providers and users of genetic resources by:

- ▶ Establishing more predictable conditions for access to genetic resources
- ▶ Helping to ensure benefit-sharing when genetic resources leave the contracting Party providing the genetic resources

By helping to ensure benefit-sharing, the Nagoya Protocol creates incentives to conserve and sustainably use genetic resources, and therefore enhances the contribution of biodiversity to development and human well-being.

WHAT DOES THE NAGOYA PROTOCOL COVER?

The Nagoya Protocol applies to genetic resources that are covered by the CBD, and to the benefits arising from their utilization. The Nagoya Protocol also covers traditional knowledge

(TK) associated with genetic resources that are covered by the CBD and the benefits arising from its utilization.

WHAT ARE THE CORE OBLIGATIONS OF THE NAGOYA PROTOCOL WITH RESPECT TO GENETIC RESOURCES?

The Nagoya Protocol sets out core obligations for its contracting Parties to take measures in relation to access to genetic resources, benefit-sharing and compliance.

ACCESS OBLIGATIONS

Domestic-level access measures are to:

- ▶ Create legal certainty, clarity and transparency
- ▶ Provide fair and non-arbitrary rules and procedures
- ▶ Establish clear rules and procedures for prior informed consent and mutually agreed terms
- ▶ Provide for issuance of a permit or equivalent when access is granted
- ▶ Create conditions to promote and encourage research contributing to biodiversity conservation and sustainable use
- ▶ Pay due regard to cases of present or imminent emergencies that threaten human, animal or plant health
- ▶ Consider the importance of genetic resources for food and agriculture for food security

BENEFIT-SHARING OBLIGATIONS

Domestic-level benefit-sharing measures are to provide for the fair and equitable sharing of benefits arising from the utilization of genetic resources, as well as subsequent applications and



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commercialization, with the contracting Party providing genetic resources. Utilization includes research and development on the genetic or biochemical composition of genetic resources. Sharing is subject to mutually agreed terms. Benefits may be monetary or non-monetary such as royalties and the sharing of research results.

COMPLIANCE OBLIGATIONS

Specific obligations to support compliance with the domestic legislation or regulatory requirements of the contracting Party providing genetic resources, and contractual obligations reflected in mutually agreed terms, are a significant innovation of the Nagoya Protocol. Contracting Parties are to:

- ▶ Take measures providing that genetic resources utilized within their jurisdiction have been accessed in accordance with prior informed consent, and that mutually agreed terms have been established, as required by another contracting Party
- ▶ Cooperate in cases of alleged violation of another contracting Party's requirements
- ▶ Encourage contractual provisions on dispute resolution in mutually agreed terms
- ▶ Ensure an opportunity is available to seek recourse under their legal systems when disputes arise from mutually agreed terms
- ▶ Take measures regarding access to justice

- ▶ Take measures to monitor the utilization of genetic resources including by designating effective checkpoints at any stage of the value-chain: research, development, innovation, pre-commercialization or commercialization

HOW DOES THE NAGOYA PROTOCOL ADDRESS TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES AND GENETIC RESOURCES HELD BY INDIGENOUS AND LOCAL COMMUNITIES?

The Nagoya Protocol addresses traditional knowledge associated with genetic resources with provisions on access, benefit-sharing and compliance. It also addresses genetic resources where indigenous and local communities have the established right to grant access to them. Contracting Parties are to take measures to ensure these communities' prior informed consent, and fair and equitable benefit-sharing, keeping in mind community laws and procedures as well as customary use and exchange.

TOOLS AND MECHANISMS TO ASSIST IMPLEMENTATION

The Nagoya Protocol's success will require effective implementation at the domestic level. A range of tools and mechanisms provided by the Nagoya Protocol will assist contracting Parties including:

- ▶ Establishing national focal points (NFPs) and competent national authorities (CNAs) to serve as contact points for information, grant access or cooperate on issues of compliance
- ▶ An Access and Benefit-sharing Clearing-House to share information, such as domestic regulatory ABS requirements or information on NFPs and CNAs
- ▶ Capacity-building to support key aspects of implementation. Based on a country's self-assessment of national needs and priorities, this can include capacity to:
 - Develop domestic ABS legislation to implement the Nagoya Protocol
 - Negotiate MAT
 - Develop in-country research capability and institutions
- ▶ Awareness-raising
- ▶ Technology Transfer
- ▶ Targeted financial support for capacity-building and development initiatives through the Nagoya Protocol's financial mechanism, the Global Environment Facility (GEF)



THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT-SHARING

Towards Early Ratification

I. BACKGROUND

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization builds on the Convention on Biological Diversity and supports the further implementation of one of its three objectives: the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

Heads of State at the World Summit on Sustainable Development (Johannesburg, September 2002) first recognised the need for an international regime to promote and safeguard the fair and equitable sharing of benefits and called for negotiations to be carried out within the framework of the Convention¹. The Convention's Conference of the Parties responded at its seventh meeting, in 2004, by mandating its Ad Hoc Open-ended Working Group on Access and Benefit-sharing to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing in order to effectively implement Articles 15 (Access to Genetic Resources) and 8(j) (Traditional Knowledge) of the Convention and its three objectives.

After six years of negotiations, the tenth meeting of the Conference of the Parties adopted the Nagoya Protocol on 29 October 2010, in Nagoya, Japan.

The Conference of the Parties and the sixty-fifth session of the United Nations General Assembly called upon the Convention's 193 Parties to sign the Nagoya Protocol at the

earliest opportunity, and to deposit their instruments of ratification, acceptance, approval, or instruments of accession, as appropriate, as soon as possible.

The Nagoya Protocol will enter into force 90 days after the deposit of the fiftieth instrument of ratification, acceptance, approval, or accession.

The eleventh meeting of the Conference of the Parties, taking place in India from 8 to 19 October 2012, is the target for convening the Nagoya Protocol's first meeting of the Parties. To achieve this, the Nagoya Protocol must enter into force no later than 8 October 2012, with the fiftieth instrument of ratification deposited no later than 10 July 2012.

The Nagoya Protocol's early entry into force is strategically important for the Convention's successful implementation. Section II provides a rationale for early ratification. Section III describes how to sign or become a Party to the Nagoya Protocol.

II. RATIONALE FOR EARLY RATIFICATION OF THE NAGOYA PROTOCOL

The Nagoya Protocol significantly advances the Convention's third objective by providing greater legal certainty and transparency for both providers and users of genetic resources. Specific obligations to support compliance with domestic legislation or regulatory requirements of the Party providing genetic resources and contractual obligations reflected in mutually agreed terms are a significant innovation of the

¹ See Par. 44(o) of the Plan of Implementation of the World Summit on Sustainable Development.



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Nagoya Protocol. These compliance provisions as well as provisions establishing more predictable conditions for access to genetic resources will contribute to ensuring the sharing of benefits. In addition, the Protocol's provisions on access to traditional knowledge held by indigenous and local communities when it is associated with genetic resources will strengthen the ability of these communities to benefit from the use of their knowledge, innovations and practices.

By promoting the use of genetic resources and associated traditional knowledge, and by strengthening the opportunities for fair and equitable sharing of benefits from their use, the Protocol will create incentives to conserve biological diversity, sustainably use its components, and further enhance the contribution of biological diversity to sustainable development and human well-being.

III. HOW TO SIGN OR BECOME A PARTY TO THE NAGOYA PROTOCOL

The United Nations Secretary-General acts as Depositary for the Nagoya Protocol through the United Nations Treaty Section in New York. The Nagoya Protocol will be open for signature by Parties to the Convention from 2 February 2011 until 1 February 2012 at United Nations Headquarters in New York.

Certified true copies of the Nagoya Protocol are available from the Depositary at:

<http://treaties.un.org/doc/source/signature/2010/Ch-XXVII-8-b.pdf>

States and regional economic integration organizations that are Parties to the Convention on Biological Diversity are eligible to sign or become a Party to the Nagoya Protocol.

(a) Signature

Parties to the Convention are encouraged to sign the Protocol as soon as possible.

Signature would not result in any positive legal obligations under the Nagoya Protocol. However, it would indicate the signatory's intention to take steps to express its consent to be bound by the Protocol at a later date. Signature also creates an obligation, in the period between signature and ratification, acceptance or approval, to refrain in good faith from acts that would defeat the object and purpose of the Protocol.²

A Head of State, Head of Government or Minister for Foreign Affairs may sign the Nagoya Protocol without an instrument of full powers.

All other representatives must present to the Depositary a valid instrument of full powers authorising them to sign. An instrument of full powers must:

- (i) Be signed by a Head of State, Head of Government or Minister for Foreign Affairs;
- (ii) Indicate the title of the treaty (e.g., Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity); and
- (iii) State the full name and title of the representative authorised to sign.

Some countries have deposited general full powers with the Secretary-General. General full powers do not specify the treaty to be signed, but rather authorise a specified representative to sign all treaties of a certain kind.

(b) Depositing instruments of ratification, acceptance, approval or accession

Parties to the Convention that sign the Nagoya Protocol before the closing date for signature may then proceed to take steps at the domestic level that would lead to depositing their instruments of ratification, acceptance or approval with the Depositary.

Those Parties to the Convention that may not be able to sign the Nagoya Protocol by 1 February 2012, but still wish to become Parties, may accede to it by depositing an instrument of accession with the Depositary. Ratification, acceptance, approval and accession have the same legal effect.

The relevant instruments represent an expression of explicit consent, at the international level, by a State or regional economic integration organization to be legally bound by the Nagoya Protocol. They are signed either by a Head of State, Head of Government or by a Minister for Foreign Affairs.

Annex I describes how to make arrangements with the UN Treaty Section to sign a treaty and ratify, accept, approve or accede to it. Annex II provides model instruments of: (i) full powers; (ii) ratification, acceptance or approval; and (iii) accession.³

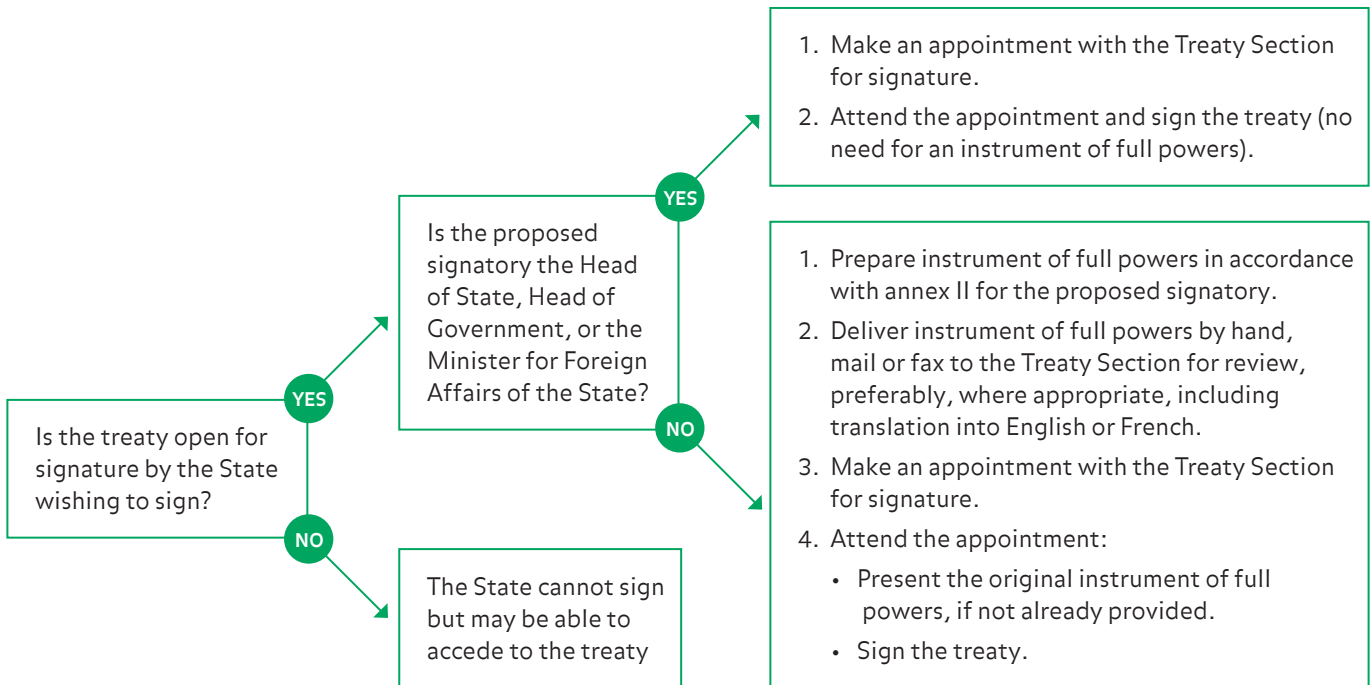
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² Adapted from the UN Treaty Handbook, prepared by the Treaty Section of the Office of Legal Affairs, United Nations, (2006 Reprint).

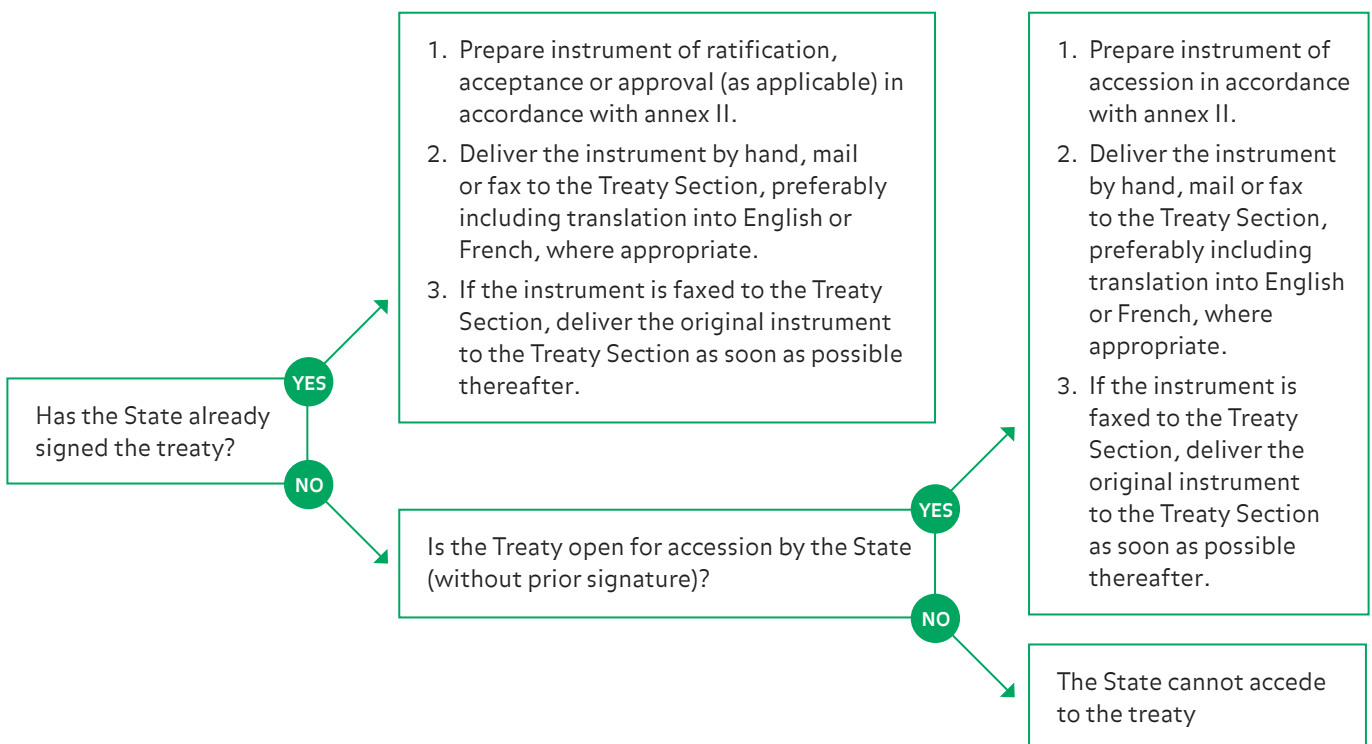
³ Annexes I and II adapted from the UN Treaty Handbook, United Nations, (2006 Reprint).

ANNEX I

Signing a Multilateral Treaty



Ratifying, Accepting, Approving or Acceding to a Multilateral Treaty



ANNEX II

Model Instrument of Full Powers

(To be signed by the Head of State, Head of Government or Minister for Foreign Affairs)

FULL POWERS

I, [name and title of the Head of State, Head of Government or Minister for Foreign Affairs],

HEREBY AUTHORISE [name and title] to [sign*, ratify, denounce, effect the following declaration in respect of, etc.] the [title and date of treaty, convention, agreement, etc.] on behalf of the Government of [name of State].

Done at [place] on [date].

[Signature]

* Subject to the provisions of the treaty, one of the following alternatives is to be chosen: [subject to ratification] or [without reservation as to ratification]. Reservations made upon signature must be authorised by the full powers granted to the signatory.

Model Instrument of Ratification, Acceptance or Approval

(To be signed by the Head of State, Head of Government or Minister for Foreign Affairs)

[RATIFICATION / ACCEPTANCE / APPROVAL]

WHEREAS the [title of treaty, convention, agreement, etc.] was [concluded, adopted, opened for signature, etc.] at [place] on [date],

AND WHEREAS the said [treaty, convention, agreement, etc.] has been signed on behalf of the Government of [name of State] on [date],

NOW THEREFORE I, [name and title of the Head of State, Head of Government or Minister for Foreign Affairs] declare that the Government of [name of State], having considered the above mentioned [treaty, convention, agreement, etc.], [ratifies, accepts, approves] the same and undertakes faithfully to perform and carry out the stipulations therein contained.

IN WITNESS WHEREOF, I have signed this instrument of [ratification, acceptance, approval] at [place] on [date].

[Signature]

Model Instrument of Accession

(To be signed by the Head of State, Head of Government or Minister for Foreign Affairs)

ACCESSION

WHEREAS the [title of treaty, convention, agreement, etc.] was [concluded, adopted, opened for signature, etc.] at [place] on [date],

NOW THEREFORE I, [name and title of the Head of State, Head of Government or Minister for Foreign Affairs] declare that the Government of [name of State], having considered the above mentioned [treaty, convention, agreement, etc.], accedes to the same and undertakes faithfully to perform and carry out the stipulations therein contained.

IN WITNESS WHEREOF, I have signed this instrument of accession at [place] on [date].

[Signature]