

L.N. 379 of 2016**ENVIRONMENT PROTECTION ACT
(CAP. 549)****Access to Genetic Resources and the Fair and Equitable Sharing
of Benefits arising from their Utilisation Regulations, 2016**

BY VIRTUE of the powers conferred by article 54 of the Environment Protection Act, the Minister for Sustainable Development, the Environment and Climate Change, after consultation with the Environment and Resources Authority, has made the following regulations:-

Citation.

1. The title of these regulations is the Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations, 2016.

Scope.

2. (1) The aim of these regulations is to ensure the fair and equitable sharing of the benefits arising from the utilisation of genetic resources for which Malta has sovereign rights, as well as the fair and equitable sharing of benefits arising from local traditional knowledge associated with genetic resources.

(2) These regulations shall not apply to:

- (a) human genetic resources;
- (b) genetic resources used as bulk commodities;
- (c) genetic resources acquired prior to the entry into force of the United Nations Convention on Biological Diversity;
- (d) the genetic resources for which access and benefit-sharing are governed by specialised international instruments that are consistent with, and do not run counter to, the objectives of the Convention and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union;
- (e) genetic resources that Malta determines do not require prior informed consent;
- (f) marine resources found in areas beyond national jurisdiction (ABNJ); and

(g) derivatives accessed independently of genetic resources.

(3) The provisions of these regulations shall not prejudice specialised international access and benefit-sharing instruments which are consistent with the Nagoya Protocol, such as the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the 'PIP' Framework) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

(4) These regulations shall place the national legal regime of the access to genetic resources and the fair and equitable sharing of benefits resulting from their utilisation and lay down provisions required for the implementation of:

(a) Regulation (EU) No. 511/2014 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 and related implementing Regulations;

(b) the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity; and

(c) Article 15 of the Convention on Biological Diversity;

and shall be read and construed as one with such legal instruments.

3. For the purpose of these regulations, the definitions laid down in the Convention on Biological Diversity (Incorporation) Regulations, the Nagoya Protocol, and in the Principal Regulations, as well as the following definitions shall apply:

Definitions.
S.L. 549.27

"assistant authorities" means those authorities designated in regulation 4 whose function is to assist the competent authority to implement these regulations;

"certificate of compliance" means a permit or its equivalent issued at the time of access as evidence that the genetic resource it covers has been accessed in accordance with the decision to grant prior informed consent, and that mutually agreed terms have been established for the use and the utilisation specified therein by the competent authority in accordance with Article 6(3)(e) and Article 13(2) of the Nagoya Protocol, that is made available to the Access

and Benefit-Sharing Clearing House established under Article 14(1) of the Protocol;

"Committee" means the Access to Benefit Sharing Advisory Committee;

"Commission Implementing Regulation" means Commission Implementing Regulation (EU) 2015/1866 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices;

"competent authority" means the Director responsible for Plant Health Services;

"Council Regulation" 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;

"due diligence" means the measures taken by a user to ascertain that the genetic resources and traditional knowledge associated with genetic resources concerned have been accessed in accordance with applicable access and benefit sharing legislation or regulatory requirements such that benefits are fairly and equitably shared upon mutually agreed terms;

"genetic resources for which Malta has sovereign rights" means the genetic resources which originate in Malta or which have been acquired in accordance with the Convention after the entry into force of the Nagoya Protocol for the Union;

"inspector" means a person carrying out an inspection in terms of these regulations;

"the Minister" means the Minister responsible for the environment;

"Nagoya Protocol" means the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing Arising from their Utilisation to the Convention on Biological Diversity;

"Principal Regulations" means Regulation (EU) No. 511/2014 of the European Parliament and of the Council of 16 April 2014 and Commission Implementing Regulation (EU) 2015/1866;

"prior informed consent" means a prior permission or

authorisation issued in terms of regulations 5 and 6 to access genetic resources or traditional knowledge associated with genetic resources;

"the register" means the register of collections of genetic resources within the Union, as established through the Principal Regulations;

"traditional knowledge associated with genetic resources" means traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources.

4. (1) The competent authority shall be the Director Authorities. responsible for Plant Health Services.

(2) The competent authority shall be responsible for the implementation of these regulations, the Council Regulation and the Nagoya Protocol.

(3) The responsibility of the competent authority shall include the granting of access to genetic resources through prior informed consent, issuing internationally recognised certificates of compliance, carry out the functions of the Member State under Article 5 of the Council Regulation and advise on applicable procedures and measures relating to these regulations, and the Council Regulation:

Provided that the granting of access to genetic resources through prior informed consent shall be the responsibility for the assistant authorities for the following:

- (a) the Environment and Resources Authority for wildlife, as laid down under the Environment Protection Act, Cap. 549. with the exception of birds protected through the provisions of the Conservation of Wild Birds Regulations; S.L. 549.42
- (b) the Wild Birds Regulation Unit for birds, as laid down under the Conservation of Wild Birds Regulations; S.L. 549.42
- (c) the Department of Fisheries and Aquaculture, as laid down in the Fisheries Conservation and Management Act. Cap. 425.

Provided, further that the competent authority shall be assisted by assistant authorities and an Access to Benefit-Sharing Advisory Committee, as necessary.

(4) The assistant authorities shall assist the competent authority in ensuring that the implementation of these regulations, the

Council Regulation and the Nagoya Protocol is in line with the other relevant sectorial legislations.

(5) Assistant authorities shall establish and maintain an inventory of the prior informed consents granted and which fall under their remit, in terms of these regulations.

(6) The competent authority shall each year compile a report on the implementation of these regulations. The assistant authorities shall submit the necessary information to the competent authority in order to be able to compile the report:

Provided that the competent authority may request any additional document and information from the assistant authorities as reasonably and objectively justified:

Provided further that the information shall not be submitted later than the end of January of the following year.

(7) The report compiled by the competent authority shall include relevant information relating to the utilisation of genetic resources, the granting of prior informed consents and the monitoring of user compliance.

Access to
genetic
resources under
Malta's
sovereignty.

5. (1) The access to genetic resources for which Malta has sovereign rights to other countries shall require prior informed consent from the competent authority or the assistant authorities, in accordance with regulation 4(3).

(2) Access, where granted, shall be on mutually agreed terms between the concerned user of genetic resources and Malta. The drafting and the negotiation process of such mutually agreed terms shall be undertaken by the competent authority. The competent authority shall consult the relevant assistant authorities at any time during the negotiation process.

(3) Such access to genetic resources should guarantee that the benefits arising from the utilisation of genetic resources, as well as any subsequent application and commercialisation shall be shared in a fair and equitable way with Malta.

(4) Upon the establishment of mutually agreed terms, the competent authority shall issue the user of the genetic resources a certificate of compliance as evidence of the decision to grant prior informed consent and the establishment of mutually agreed terms.

(5) In accordance with Article 17 of the Nagoya Protocol, a certificate of compliance issued in terms of sub-regulation (4) shall

constitute an internationally recognised certificate of compliance.

6. (1) The utilisation of traditional knowledge associated with genetic resources held by local communities shall require a joint prior informed consent or approval from the competent authority following consultation with the relevant assistant authority and the community or communities concerned where applicable. Traditional knowledge.

(2) No person shall utilise traditional knowledge associated with genetic resources held by the local communities unless mutually agreed terms have been established. The drafting and the negotiation process of such mutually agreed terms shall be undertaken by the competent authority. The competent authority may consult the assistant authority at any time during the negotiation process.

(3) Mutually agreed terms shall guarantee that the benefits arising from the utilisation of traditional knowledge are shared in a fair and equitable way with the community or communities concerned.

7. (1) The user requesting prior informed consent for the utilisation of genetic resources, hereinafter referred to as "the applicant", shall submit in writing an application to the competent authority or the concerned assistant authority at least six months prior to utilisation. Application for prior informed consent and confidential information.

(2) The application shall be accompanied by the relevant documents and any other requisite information as specified by the competent authority or the concerned assistant authority:

Provided that the competent authority or the concerned assistant authority may request any additional document and information as reasonably and objectively justified.

(3) Unless the applicant indicates that parts of the application should be treated as confidential by the competent authority, the competent authority shall forward the information contained in the application to the relevant assistant authorities as it deems necessary.

(4) In no case may the following information be kept confidential:

- (a) the name and address of the applicant;
- (b) the institution, if any, requiring the authorisation;
- (c) the species involved;

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- (d) the aim and purpose of the application;
- (e) the benefits arising from the permit;
- (f) the possible impacts on local biodiversity, including the species, biotype, natural habitat, or area involved;
- (g) the evaluation of foreseeable effects, in particular any harmful effects on the environment.

(5) The competent authority or the relevant assistant authority shall not divulge to third parties any information provided in the application.

Register of collections.

8. The competent authority shall facilitate the registration of collections in the register to be established and maintained by the European Commission under Article 5 of the Council Regulation.

Checks on collections and users.

9. (1) The relevant assistant authority shall have the right to review the records and any specimens held in a collection which is registered in terms of Article 5 of the Council Regulation, or a collection covered by a request in accordance with regulation 8. The outcome of every review should be communicated to the competent authority within thirty days from the date of inspection.

(2) The competent authority and the assistant authorities under the supervision of the competent authority shall have the right to carry out checks on the users of genetic resources, in accordance with the Council Regulation and the Commission Implementing Regulation.

Monitoring of user compliance.

10. The competent authority shall request all recipients of research funding involving the utilisation of genetic resources and traditional knowledge associated with genetic resources to declare that they exercise due diligence in accordance with Article 4 of the Council Regulation.

Access to Benefit Sharing Advisory Committee.

11. (1) There shall be an advisory committee called the Access to Benefit Sharing Advisory Committee, hereinafter referred to as "the Committee". This Committee shall be composed of eleven (11) members. The Committee shall advise the competent authority in the implementation of the provisions of due diligence as laid down in the Council Regulation, as well as providing advice to the competent authorities on scientific, technical and other relevant matters upon request.

(2) The Committee shall be composed of the following:

- (a) a Chairperson to be appointed by the Permanent Secretary of the Ministry responsible for the environment;
- (b) one representative from the competent authority;
- (c) a representative from each of the assistant authorities listed in regulation 4;
- (d) a representative from the Directorate of Environment and Climate Change;
- (e) a representative from the Ministry responsible for the economy;
- (f) a representative from the Medicines Authority;
- (g) a representative from the Continental Shelf Department;
- (h) a representative from the Veterinary Services Directorate; and
- (i) a representative from the Ministry responsible for research and development:

Provided that the Minister responsible for the environment may, in consultation with the competent authority, appoint experts in the field of genetic resources or property rights, as may be required.

(3) The competent authority shall appoint a person to act as secretary for the Committee.

(4) Without prejudice to any of these regulations, the Committee may regulate its own procedures and meetings.

12. The competent authority shall carry out the functions of the Member State under Article 13 of the Council Regulation. Complementary functions.

13. The competent authority may impose a requirement upon a person to comply with a remedial notice, as set out in these regulations and may also impose an administrative penalty. Power to impose administrative sanctions.

14. (1) Subject to sub-regulations (2) and (3), administrative fines may be imposed in relation to a failure to comply with any of the following provisions: Due diligence obligations of the Council Regulation which are subject to administrative fines.

- (a) Article 4(1) of the Council Regulation (obligation to exercise due diligence);

(b) Article 4(3) of the Council Regulation (obligation to seek, keep and transfer information and documentation to subsequent users);

(c) Article 7(1) and (2) of the Council Regulation (obligation to make a declaration of due diligence).

(2) There is no failure to comply with Article 4(3) of the Council Regulation if the competent authority is satisfied that -

(a) the user is considered to have exercised due diligence under Article 4(4) of the Council Regulation (use of the Plant Treaty's Standard Material Transfer Agreement for material not listed in Annex 1 to that Treaty);

(b) the user is considered to have exercised due diligence under Article 4(7) of the Council Regulation (users obtaining material from a registered collection); or

(c) the user is in accordance with Article 4(8) of the Council Regulation (use of pathogen for the purpose of public health emergency preparedness).

Inspections.

15. The competent authority, or any such officer or any other person as may be authorised by the competent authority for this purpose, shall have the right to inspect any premises or other place for the purposes of:

(a) the making of inspections;

(b) ascertaining that nothing contrary to the provisions of these regulations or of the Council Regulation or to any term, condition, limitation or specification attached to any authorisation issued under these regulations or under the Council Regulation is taking or has taken place, and taking action accordingly;

(c) ascertaining or reproducing such data or information as the competent authority may require;

(d) doing anything that is ancillary or consequential thereto.

Powers of entry.

16. (1) The person carrying out the inspection, after serving a notice on the user, and if so required, with the assistance of the Police Force, may enter premises or other places, except premises used wholly or mainly as a private dwelling house in order to perform inspections.

- (2) The requirement to serve a notice does not apply -
- (a) where reasonable efforts to agree on an appointment have failed;
 - (b) where an inspector reasonably believes that serving a notice would defeat the object of the entry;
 - (c) where an inspector has a reasonable suspicion that an offence has been committed under regulation 23;
 - (d) in an emergency situation; or
 - (e) the premises are unoccupied or the occupier is temporarily absent.
- (3) An inspector shall, if requested, produce a duly authenticated authorisation document.
- (4) An inspector entering premises under this regulation may -
- (a) be accompanied by such other persons as the inspector considers necessary;
 - (b) bring onto the premises such equipment as the inspector considers necessary.
- (5) Where an inspector enters premises which are unoccupied or from which the occupier is temporarily absent, the inspector must leave them as effectively secured against unauthorised entry as they were before the inspector's entry.
- (6) An inspector may require a vehicle, vessel, aircraft or hovercraft, that the inspector has reasonable grounds to believe is transporting evidence, to stop to allow the inspector to exercise the powers conferred by these regulations.

17. (1) An inspector who has entered premises in exercise of a power under regulation 16 may: Powers of inspection.

- (a) inspect the premises and any products, goods or biological material found on the premises;
- (b) search the premises;
- (c) have access to inspect and copy documents, records or other information, in whatever form they are held, and remove them to enable them to be copied;

(d) require the production of, and inspect and check the data on, and operation of, any computer and any associated apparatus used in connection with such documents, records or other information, and require computer records to be produced in a form in which they may be easily accessed and taken away by the inspector;

(e) take samples of products, goods or biological material;

(f) carry out any examination, investigation or test; and

(g) take photographs, measurements or recordings.

(2) An inspector may require any person to provide as may be necessary for the purpose of enforcing these regulations and the Council Regulation any -

(a) assistance;

(b) documents, records or other information.

Restrictions on enforcement powers.

18. Nothing in these regulations must be taken as -

(a) requiring a person to produce any document which that person would be entitled to refuse to produce in any proceedings in any court on the grounds that it is the subject of legal professional privilege; or

(b) authorising a person to take possession of any document which is in the possession of a person who would be so entitled.

Obstruction of an inspector.

19. Where an inspector exercises a power under these regulations, it shall be an offence against these regulations for any person to -

(a) intentionally obstruct the inspector;

(b) without reasonable excuse, fail to give the inspector any information or assistance that the inspector may reasonably require;

(c) knowingly give false or misleading information to the inspector;

(d) without reasonable excuse, fail to produce a record or document when reasonably required to do so by the inspector.

20. (1) Where the competent authority believes that a person has contravened any of these regulations or of the Council Regulation or following checks referred to in regulation 9 the competent authority detects shortcomings, the Director of the said competent authority may serve a remedial notice on such person in accordance with sub-regulation (2).

(2) A remedial notice served upon the person in terms of sub-regulation (1) shall:

(a) require the person upon whom it is served to take such measures as the competent authority may determine in order to remedy, or to prevent the continuation or repetition of, any offence to which the remedial notice relates;

(b) state the period within which any such requirement is to be complied with.

(3) The period stated in the remedial notice for compliance with any such requirement shall be such period as is reasonable in the circumstances.

(4) The competent authority may at any time:

(a) withdraw the remedial notice;

(b) extend the period for compliance with any requirement of the remedial notice; or

(c) modify the requirements of the remedial notice.

21. (1) Where the competent authority has reasonable cause to believe that - Administrative fines.

(a) an offence against these regulations has been committed by any person; and

(b) having regard to the previous conduct of the person concerned, it would be appropriate to impose a penalty under this regulation,

the competent authority may serve a notice in writing, in accordance with sub-regulation (2), in the appropriate form to be served on that person.

(2) Without prejudice to the provisions of the Prevention and Remedying of Environmental Damage Regulations, a notice under sub-regulation (1) shall specify: S.L. 549.97

(a) the date and nature of the offence;

(b) a summary of the facts upon which the allegation that an offence has been committed is based, being a sufficient summary to inform the person of the allegation against him;

(c) any other matter that the competent authority considers relevant to the imposition of a penalty;

(d) the amount of penalty due.

(3) Any person on whom a notice under sub-regulation (1) is served may, within thirty days after such service, by notice in writing in the appropriate form served on the competent authority, require that proceedings in respect of the alleged offence shall be dealt with by the Court, in which case the following provisions shall apply:

(a) no further proceedings shall be taken under this regulation by the competent authority; and

(b) nothing in this regulation shall be construed as preventing the institution of any proceedings in respect of the alleged offence or the conviction of the person for the offence by the Court or the imposition of any penalty or forfeiture under this regulation upon such conviction.

(4) Any person on whom a notice under sub-regulation (1) is served who does not wish that proceedings in respect of the alleged offence be dealt with by the Court may by notice in writing served on the competent authority -

(a) admit the offence; and

(b) pay the amount of the penalty to the competent authority within thirty days after the notice of the penalty is served or after such subsequent period as the Director may determine.

(5) Where under this regulation a person admits an offence, the competent authority shall impose a monetary penalty on that person in respect of the offence amounting to one-third of the maximum penalty to which the person would be liable if he were convicted of the offence by the Court under these regulations.

(6) Any person upon whom a penalty is imposed under sub-regulation (5) shall also be liable to pay for the expenses incurred for the keeping and transport of the concerned specimen, and for any other expense incurred or mitigation measures undertaken to remedy

such doings, damage and infringement.

(7) The penalty imposed under sub-regulation (5) shall be due as a civil debt enforceable by the competent Court of civil jurisdiction in favour of the Government of Malta and the declaration by the person on whom the penalty is imposed that he admits the charge shall constitute an executive title for the purposes of article 253 of the Code of Organisation and Civil Procedure, in the same manner as if it were a judgment of the competent Court of civil jurisdiction. Cap. 12.

(8) Notwithstanding any other provision of these regulations or any other enactment, where an offence has been admitted under this regulation, no charge may be laid in respect of the offence against any person by whom it has been admitted.

(9) Where a person on whom a notice under sub-regulation (1) is served does not, within thirty days after the notice is served upon him, admit the offence, the Director shall institute proceedings or cause proceedings to be instituted before the Court in respect of the alleged offence.

22. (1) Any person -

Offences and
penalties

(a) who fails to observe the provisions of these regulations, or those of the Council Regulation, or fails to obey a lawful order given by virtue of such regulations; or

(b) who infringes any restriction, prohibition or need imposed by these regulations or the Council Regulation or by virtue thereof; or

(c) who fails to observe any condition of mutually agreed terms, prior informed consent or permit granted under any provision of these regulations or under the Principal Regulations; or

(d) who acts in contravention of any provision of these regulations or the Council Regulation; or

(e) who makes a statement or presents information or documentation, which such person knows to be false, for the purpose of obtaining mutually agreed terms, prior informed consent or a permit in terms of these regulations and, or the Council Regulation, or

(f) who conspires or attempts to conspire, aids or attempts to aid, abets or attempts to abet, counsels or attempts to counsel, procures or attempts to procure, any other person to

contravene the provisions of these regulations or the Council Regulation, including any lawful order given by virtue of such regulations, or to infringe any restriction, prohibition or need imposed by such regulations or by virtue thereof;

(g) who fails to comply with the provisions of Articles 4 and 7 of the Council Regulation (obligation to keep information for twenty years after utilisation),

shall be guilty of an offence against these regulations.

(2) Any person who commits or attempts to commit an offence against these regulations shall, on conviction, be liable:

(a) in the case of a first offence, to a fine (*multa*) of not less than eight hundred euro (€800), but not exceeding four thousand and six hundred and fifty-eight euro and seventy-five cents (€4,658.75);

(b) in the case of a second or subsequent offences, to a fine (*multa*) of not less than six thousand euro (€6,000), but not exceeding ten thousand euro (€10,000), or to imprisonment for a period not exceeding two years, or to both such fine and imprisonment:

Provided that such fine shall in all cases be due to the Government as a civil debt, and that where the person guilty of the offence is a director, secretary or manager of a body corporate for the economic benefit of which the offence was committed, such body corporate shall be liable *in solidum* with the offender for the payment of the said civil debt.

(3) Any person who has been found guilty of committing an offence against these regulations or the Council Regulation shall also be liable to pay for the expenses incurred for the keeping and transport of the concerned specimen, and for any other expense incurred or mitigation measures undertaken to remedy such doings, damage and infringement.

Cap. 9.

(4) The provisions of articles 23 and 30(1) of the Criminal Code shall, *mutatis mutandis*, apply to proceedings in respect of offences against these regulations or the Council Regulation, so however that the disqualification of obtaining prior informed consent or of a permit under these regulations shall in no case be for less than one year.

Cap. 9.

(5) Notwithstanding the provisions of article 370 of the Criminal Code, proceedings for an offence against these regulations

or the Council Regulation shall be taken before the Court of Magistrates (Malta) or the Court of Magistrates (Gozo), as the case may be, and shall be in accordance with the provisions of the Criminal Code regulating the procedure before the said courts as courts of criminal judicature.

(6) Notwithstanding the provisions of the Criminal Code, the Attorney General shall always have a right of appeal to the Court of Criminal Appeal from any judgement given by the Court of Magistrates (Malta) or the Court of Magistrates (Gozo) in respect of proceedings for any offence against these regulations. Cap. 9.

23. Without prejudice to the provisions of the Council Regulation, the competent authority and the assistant authorities may for reasons of imminent threats to human, animal or plant health adopt interim measures, as they deem fit in the circumstances. Interim measures in case of emergencies.

24. The competent authority and the relevant assistant authorities may, as appropriate, promote additional measures and provisions which: Special considerations.

(a) consider the importance of genetic resources for food and agriculture and their special role for food security;

(b) encourage research which contributes to the conservation and sustainable use of biological diversity; and

(c) protect human and plant health.

25. Part VIII (Access to Genetic Resources) of the Flora, Fauna and Natural Habitats Protection Regulations shall be substituted by the following: Substitutes Part VIII of the Flora, Fauna and Natural Habitats Protection Regulations. S.L. 549.44

"PART VIII

ACCESS TO GENETIC RESOURCES

Access to genetic resources. S.L. 549.38

36. (1) Without prejudice to the Trade in Species of Fauna and Flora Regulations, and the Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations, 2016 and the related regulations, access to wild fauna and flora to countries other than Malta shall be subject to prior informed consent of the competent authority, provided that wild birds and pathogens are excluded from this provision.

(2) Access, where granted, shall be on mutually agreed terms and subject to the provisions of the Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilisation Regulations, 2016.

Nature of
genetic
resources.

37. For the purpose of these regulations, the genetic resources being provided by Malta are only those genetic resources for which Malta is the country of origin or that Malta is a country providing genetic resources, having acquired such genetic resources in accordance with the provisions of the United Nations Convention on Biological Diversity, done at Rio de Janeiro on the fifth day of June 1992."

