

ACCESS REGULATIONS 200X

FRED GOODWIN

QUEEN'S
REPRESENTATIVE

At Avarua, Rarotonga, this day of 200X

Present:

HIS EXCELLENCY THE QUEEN'S REPRESENTATIVE
IN COUNCIL

1.
PURSUANT to section 65(...) of the Environment Act 200X, His Excellency the Queen's Representative, acting by and with the advice and consent of the Council hereby makes the following Regulations.

ANALYSIS

<p style="text-align: center;">PART I PRELIMINARY</p> <p>1. Title and commencement 2. Interpretation</p>	<p>12. Variation of licence 13. Renewal of licence 14. Minister's decision final</p>
<p style="text-align: center;">PART II BIOPROSPECTING LICENCE</p> <p>3. Bioprospecting prohibited without licence 4. Application for Bioprospecting Licence 5. Exemptions [Expedited procedure] 6. Consultation and public notice 7. Consideration of application 8. Matters to be taken into consideration when granting licence 9. Disposal of application 10. Licence to contain information 11. Duration of licence</p>	<p style="text-align: center;">PART III BIOPROSPECTING EXPORT LICENCE</p> <p>15. Application to export specimen 16. Verification 17. Compliance with any other licence or consent</p>
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ACCESS REGULATIONS

PART I PRELIMINARY

1. Title and commencement

- (1) These regulations may be cited as the Access Regulations 200X.
- (2) These regulations are to come into force on the day on which they are made.

2. Interpretation

In these Regulations, unless the context otherwise requires -

“bioprospecting” means the obtaining of samples of biological or other material containing genetic material, biomolecules or biochemicals from areas within national jurisdiction for purposes of research on, conservation, commercial or industrial utilisation of the genetic material, biomolecules or biochemicals:

- “Council” means the Environment Council established under section 8 of the Environment Act 200X;
- “genetic material” means any material of plant, animal, microbial or other origin containing functional units of heredity, and includes biomolecules and biochemicals;
- “genetic resource” means genetic material of actual or potential value.

PART II BIOPROSPECTING LICENCE

3. Bioprospecting prohibited without licence

Bioprospecting in the Cook Islands is prohibited otherwise than pursuant to the authority of a licence.

4. Application for Bioprospecting Licence

Any person desiring to undertake bioprospecting in the Cook Islands must complete Form 1 in Schedule 1 to these Regulations and return it to the Environment Service together with the prescribed fee.

5. Exemptions

These Regulations do not apply to:

- (1) human genetic resources;
- (2) bona fide research carried out by a local person or body;
- (3) agricultural or aquacultural genetic resources.

[Expedited procedure]

[For domestic research, eg, universities; or MAFF research; or germplasm exchange programmes with other countries.]

6. Consultation and public notice

Upon receiving an application under regulation 4, the Environment Service must:

- (a) consult with [name the bodies] and may establish a consultative process with other governmental or non-governmental bodies;
- (b) at the applicant's expense, publicise the application in such manner as the Environment Service thinks fit in the English and the Cook Islands languages, stating:
 - i) the reason for the application;
 - ii) activities that are to be undertaken including locations, dates, species sought and their number and methods to be used for collection, sampling or evaluation;
 - iii) any potential impacts on ecological or human health that may result from the activities;
 - iv) any environmental monitoring or management plans that may need to be established;
 - v) that submissions on the application may be made in writing by any person;
 - vi) the closing date for submissions, which must not be earlier than thirty calendar days after public notification; and
 - vii) the address where submissions are to be sent.

7. Consideration of application

- (1) The results of consultations with relevant bodies and any submissions received in accordance with regulation 6 shall be conveyed to the Council for consideration after which the Council may require that the applicant conducts an Environmental Impact Assessment or meets any other condition before the Council proceeds further.
- (2) Upon being satisfied as to the matters in clause (1), the Council must then require that the applicant:
- (a) identifies the owners or the persons exercising legitimate control over the genetic resource and ensures that they have been fully informed as to the proposed activity and have freely consented to it; and
 - (b) concludes a legally binding agreement with the owners or the persons exercising legitimate control over the genetic resource, or with any agency representing such people, concerning, *inter alia*:
 - i) rights of access to the resource;
 - ii) collection of samples, including limits on the collection and on the removal of samples;
 - iii) negotiation of rights to traditional knowledge related to the genetic resource, and the payment of appropriate fees, royalties, licence payments and like compensation for such use;
 - iv) such other matters as may from time to time be specified in writing by the Environment Service; and
 - (c) completes a plan, which will outline the intended programme, a suitable monitoring mechanism, the system to be used for recording information and resources gathered, and the process to be used for undertaking an inventory of organisms collected.
 - (d) agrees in writing:
 - i) to regularly report on the nature of any scientific research that results from the bioprospecting that has been undertaken; and
 - ii) to notify the Environment Service prior to any patents or other forms of intellectual property rights being sought;
 and for this purpose the Environment Service may require the lodging of a bond or a guarantee to ensure compliance.
- (3) The Council must be satisfied that the matters in clause (2) have been achieved and in particular that an agreement made pursuant to clause (2)(b) does not disadvantage the owners of genetic resources, after which it may then proceed to forward the application with its recommendation to the Minister for his decision.

8. Matters to be taken into consideration when granting licence

In considering an application for the grant of a licence, the Minister must take into account the recommendation of the Council as well as:

- (a) the level of awareness of owners, or those exercising legitimate control over the genetic resource, of the activity and its implications for them;
- (b) the possible ecological, social or economic harm research into or utilisation of the genetic resource may cause;
- (c) the extent to which the taking of the genetic resource will cause an undesirable impact on the Cook Island's biological diversity;
- (d) the extent to which property rights and customary rights over the genetic resource and traditional knowledge are safeguarded;
- (e) the return to be obtained from the utilisation of the genetic resource and traditional knowledge related to the resource;
- (f) the extent to which the agreement pursuant to regulation 7(2)(b) has been concluded on mutually agreed terms;
- (g) such other matters as the Minister thinks fit.

9. Disposal of application

- (1) The Minister, in considering any application for the grant of a licence, may refuse it, or grant it wholly or partly, and subject to such conditions as he thinks fit.
- (2) Any refusal of an application for a licence must be accompanied by reasons.

10. Licence to contain information

Every licence must contain the following information:

- (a) a full and accurate description of activities that are to be undertaken including locations, dates, species sought and their number and methods to be used for collection, sampling or evaluation;
- (b) any potential impacts on ecological or human health that may result from the activities;
- (c) any environmental monitoring or management plans that may need to be established;
- (d) the methods that shall be used for the storage and transportation of any biological samples;
- (e) conditions and requirements concerning any environmental monitoring or management plans that are to be established.

11. Duration of licence

- (1) Every licence shall take effect on the date stated on the licence and shall, unless sooner revoked or unless expressed to expire on an earlier date, expire on the completion of one year after the date on which it took effect.
- (2) Where an application for renewal is made the licence shall, where the application is not disposed of before the date of its expiry, continue in force until the application is disposed of, unless the Minister otherwise directs.

12. Variation of licence

During the currency of a licence, the Minister, acting on the advice of the Environment Council, may amend or revoke any of the conditions of the licence or add any conditions which he considers necessary.

13. Renewal of licence

- (1) Every application for the renewal of a licence shall be lodged with the Environment Service not less than three months before the date on which the licence expires.
- (2) Regulations 6(b) and 9 to 12 shall apply to every application for renewal as if it were an application for a new licence.
- (3) In considering whether or not to renew the licence, the Minister shall consider
 - (a) submissions received under regulation 6(b);
 - (b) the matters listed in regulation 8;
 - (c) a recommendation by the Council, although the recommendation need not have been made in accordance with regulation 7.
- (4) The renewal of a licence shall be effective, unless expressed to expire on an earlier date, for a period of one year from the expiry date of the licence to be renewed.

14. Minister's decision final

No appeal shall lie from any decision made by the Minister under or for the purposes of this Regulation, and, except on the ground of lack of jurisdiction, no such decision shall be liable to be challenged, reviewed, quashed, or called in question in any Court.

15. Application to export specimen

- (1) Prior to the export of any specimen collected pursuant to a licence issued under regulation 9 the applicant must, in addition to any other requirement required by any other entity, apply to the Environment Service for a licence to export such specimen.
- (2) An application for a licence to export must be accompanied by the prescribed fee and contain the following information:
 - (a) the number and description, including weight and size, of the specimen to be exported;
 - (b) the location where the specimen was collected;
 - (c) the proposed manner of export.

16. Verification

In considering any application to export any specimen, the Environment Service must verify compliance with the requirements of any bioprospecting licence that has been issued, and shall either:

- (a) refuse permission to export any specimen; or
- (b) issue a licence which may specify conditions.

17. Compliance with any other licence or consent

Prior to the export of any specimen pursuant to a licence issued under regulation 9, the Environment Service must inspect the specimen to verify compliance with the conditions of any other licence or consent granted.

PART IV ENFORCEMENT

18. Powers of environment officers to enter and to require information

It is a condition of every licence issued under these Regulations that the licence holder must allow environment officers to carry out inspections authorised pursuant to the Environment Act 200X, of any activity, place or thing to which the licence relates.

19. Compliance with licence

If any requirement or condition contained in a licence is not complied with, the Environment Service may do any one or more of the following:

- (a) direct that bioprospecting cease immediately;
- (b) initiate proceedings against the offender;
- (c) attempt to recover any biological samples that may have been removed or exported; or
- (d) proceed to recover any financial security lodged pursuant to the requirements of regulation 7.

20. Offences

- (1) Any person who:
 - (a) provides false or misleading information pursuant to a requirement under these Regulations to provide information;
 - (b) submits any false or misleading report in respect of any tests or inspections required pursuant to a licence or these Regulations;

- (c) hinders or obstructs an environment officer who is exercising powers or carrying out duties, or attempting to do so, pursuant to the requirements of these Regulations or the Environment Act 200X;
 - (d) knowingly contravenes a term or condition of a licence;
 - (e) does not submit any report or provide information as required pursuant to a licence or these Regulations;
 - (f) fails to give all reasonable assistance to an environment officer who is exercising powers or carrying out duties, or attempting to do so, pursuant to the requirements of a licence or these Regulations;
 - (g) fails to comply with any requirement, licence or condition imposed under these Regulations;
- is guilty of an offence and liable to a fine not exceeding \$5,000.00 or to a term of imprisonment not exceeding 3 months, or to both such fine and imprisonment.
- (2) Where an offence under these Regulations is committed or continued on more than one day, the offender is liable to be convicted for a separate offence for each day on which the offence is committed or continued.
 - (3) If any body corporate commits an offence, every director and every other person concerned in the management of the body corporate also commits the offence, if it is proved that the offence occurred with his authority, permission or consent.

21. Forms and Fees

- (1) The forms set out in Schedule 1, with such modifications as the circumstances require, are prescribed for the purposes of these Regulations.
- (2) The fees set out in Schedule 2 are prescribed for the purposes of these Regulations.

Queen's Representative

Schedule 1
Form 1

Application Form for a Bioprospecting Licence
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TITLE OF PROJECT

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APPLICANT

1. Name
2. Institution
3. Nationality
4. Country of domicile
5. Passport No.
6. Current address
7. Phone no.
8. Fax no.
9. e-mail

PURPOSE OF COLLECTION

1. Name the organisation for which the collection is to be made.
2. What is the purpose of the collection?
3. What tests will be carried out on the material to be collected and what is the purpose of each test?
4. Describe the nature of any expected research and development plans.

DETAILS OF WHAT IS TO BE COLLECTED

1. List the species and name the parts of the organism to be collected
2. List any other material to be collected (soil symbionts, etc.)

COLLECTION

1. Persons to be involved in the collection:

Name	Address	Qualifications

2. Area(s) and date(s) of collection
3. Specify expected number or quantity of material to be collected.
4. Describe how collecting will be physically performed.
5. How will information be collected (eg, by reference to books, note taking, photographs, recordings, etc)?
6. Has contact been made with owners or those in legitimate control of the resources?
If so, describe the result of this contact.

FUNDING

1. How will the collecting be supported and by whom?
2. Provide details of budget.

POTENTIAL IMPACTS

Describe potential impacts of the activity. Include:

- . biological impacts on species
- . ecological impacts on habitats
- . impact on human health
- . any environmental monitoring or management plans that may need to be established.

DISTRIBUTION OF BENEFITS

1. What benefits will (a) the Cook Islands receive (b) those who own or control the resource?
2. What is the extent of local involvement in the collection?
3. Prepare a list of the in-country entities likely to benefit from the activity.
4. To what degree will reliance be made on traditional knowledge.
5. Describe in detail the immediate compensation anticipated, whether in monetary, services, barter or data to be made to the resource owner.
6. Describe in detail the long-term compensation anticipated whether in monetary sharing in future production, royalties, services, equipment, data or goods to be given to the resource owner.

FOR OFFICIAL USE ONLY

For comment:

Director of ...

Director of ...

Schedule 2
Fees

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|---|--------|
| 1. Application for a Bioprospecting Licence: r4 | \$x.00 |
| 2. Application for Bioprospecting Export Licence: r15 | \$x.00 |