

## **EXPLANATORY STATEMENT**

### **Select Legislative Instrument 2005 No. 251**

Issued by the Authority of the Minister for the Environment and Heritage

*Environment Protection and Biodiversity Conservation Act 1999*

Environment Protection and Biodiversity Conservation Amendment Regulations  
2005 (No. 2)

Section 520 of the *Environment Protection and Biodiversity Conservation Act 1999* (the EPBC Act) provides that in part the Governor-General may make regulations prescribing all matters required or permitted by the Act to be prescribed. In addition, Subsection 520(3) of the Act provides in part that the Governor-General may make regulations for and in relation to giving effect to the Convention on Biological Diversity.

Section 301 of the EPBC Act provides for the making of regulations for the control of access to biological resources in Commonwealth areas, and includes provisions about the equitable sharing of benefits arising from the use of such biological resources; the facilitation of access to such resources; the right to deny access to such resources; the granting of access to such resources and the terms and conditions of such access.

The purpose of the Regulations is to introduce a new Part 8A to the *Environment Protection and Biodiversity Conservation Regulations 2000* (the Principal Regulations) and to make consequential amendments to incorporate the new Part into the existing permitting provisions. Part 8A establishes a legal framework to control access to, and utilisation of, the genetic resources of native species in Commonwealth areas.

Under the amendments, a party seeking access to biological resources in Commonwealth areas must apply for an access permit to be issued by the Minister for the Environment and Heritage (the Minister). The Minister would issue the permit upon being satisfied that:

- the proposed access would be ecologically sustainable and consistent with the conservation of Australia's biodiversity;
- an environmental assessment (if required) was undertaken and the process is complete;
- submissions from interested persons and organisations (if required) had been taken into account; and
- there was a benefit-sharing contract between the parties which addressed the following major issues:
  - mutually agreed terms;

- adequate benefit-sharing arrangements including, that if practicable, some benefits would be used for biodiversity conservation in the area from which the resource was obtained; and
- where applicable prior informed consent of any Indigenous owners of biological resources has been obtained and full disclosure made of any use of Indigenous knowledge and the terms on which that knowledge is to be used.

The access and benefit-sharing agreement would only have effect if the Minister issues an access permit.

The amendments are consistent with the *Native Title Act 1993* and other Acts relevant to indigenous people's land.

The Regulations give effect to:

- the Government's commitment to regulate access to genetic resources in Commonwealth areas, an element of the Government's *National Biotechnology Strategy* released on 3 July 2000;
- the commitment made by the Natural Resource Management Ministerial Council, endorsed by all Australian jurisdictions, known as the '*Nationally consistent approach for access to and the utilisation of Australia's native genetic and biochemical resources*'; and
- the Commonwealth's responsibility under the National Strategy for the Conservation of Australia's Biological Diversity, and under the Convention on Biological Diversity.

Details of the Regulations are set out in Attachment A.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The Regulations commence on 1 December 2005 to allow for the development of joint administrative arrangements with Commonwealth, State and Territory authorities, and the communication of the new requirements to all stakeholders.

Authority: Section 520 of the  
*Environment Protection and  
Biodiversity Conservation Act 1999*

**ATTACHMENT A****Details of the *Environment Protection and Biodiversity Conservation Amendment Regulations 2005 (No. 2)*****Regulation 1 – Name of Regulations**

This regulation provides that the title of the Regulations is the *Environment Protection and Biodiversity Conservation Amendment Regulations 2005 (No. 2)*.

**Regulation 2 – Commencement**

This regulation provides for the Regulations to commence on 1 December 2005 to allow for the development of joint administrative arrangements with Commonwealth, State and Territory authorities, and the communication of the new requirements to all stakeholders.

**Regulation 3 – Amendment of *Environment Protection and Biodiversity Conservation Regulations 2000***

This regulation provides that the *Environment Protection and Biodiversity Conservation Regulations 2000* (the Principal Regulations) are amended as set out in Schedule 1.

**Schedule 1 – Amendments****Item [1] – Part 8A - Access to biological resources in Commonwealth areas****Division 8A.1 Preliminary****8A.01 – Purpose of Part 8A**

This regulation provides a statement of the objectives of the regulations.

**8A.02 – Application of Part 8A to Commonwealth areas**

This regulation determines the extent of application within Commonwealth areas in respect to lands leased by the Commonwealth.

**8A.03 – Meaning of access to biological resources**

Subregulation 8A.03(1) defines the meaning of *access to biological resources* and in doing so establishes that it applies only to native species in Commonwealth areas as defined in the EPBC Act and only to access for certain purposes, namely ‘for research and development on any genetic resources, or chemical compounds, comprised or contained in the biological resources’.

Subregulation 8A.03(02) establishes that a person has accessed biological resources if the person has taken them for the purposes described in 8A.03(1).

Paragraph 8A.03(3)(a) stipulates that the taking of biological resources by Indigenous people for a purpose not specified in subregulation 8A.03(1) is not ‘access to biological resources’. This addresses concerns that allowing access to biological resources might limit Indigenous people’s existing uses of those resources, unless the purpose of that use is for research and development on any genetic resources, or chemical compounds.

Paragraph 8A.03(3)(b) stipulates that access does not include access to any human remains. Inclusion of this explicit provision is made to avoid any doubt on this point and responds to public concerns on this issue.

Paragraphs 8A.03(3)(c) and (d) stipulate that normal commercial and other uses of biological material such as fishing or plant production are not being regulated under these regulations.

Paragraph 8A.03(3)(e) stipulates that genetically modified organisms, and plant varieties granted under the Plant Breeders Rights Act, are not regulated under these regulations.

Paragraph 8A.03(3)(f) establishes that the regulations do not apply to an action involving access to biological resources where the Minister has made a declaration under regulation 8A.05 which exempts specified biological resources from the regulations.

Subregulation 8A.03(4) expands on the exclusion at paragraph 8A.03(2)(d) to avoid any doubt that other activities involving the use of public resources listed are not included in the regulations.

#### **8A.04 - Meaning of *access provider***

Subregulation 8A.04(1) identifies the access provider for each class of Commonwealth area and includes any native title-holder for any area. The access provider is the party with whom an applicant must enter into a benefit-sharing agreement.

Subregulation 8A.04(2) includes airspace over land in the reference to land in Subregulation 8A.04(1).

#### **8A.05 – Exemption for specified biological resources or collections**

Subregulation 8A.05(1) authorises the Minister to declare that the regulations do not apply to biological resources specified in the declaration. Relevant persons will be able to request the Minister to make a declaration.

Paragraph 8A.05(1)(a) enables an exemption to be made for biological resource collections held by a Commonwealth agency. Such an exemption is conditional on the existence of systems which achieve the same purposes as the regulations.

Paragraph 8A.05(1)(b) enables an exemption to be made where access to the resources is controlled by another Commonwealth, Territory or State law, to avoid

duplication of any access arrangements applying in a Commonwealth area and to ensure that all objectives of the Part will be addressed through the making of the declaration.

Paragraph 8A.05(1)(c) enables an exemption to be made where biological resources are managed in accordance with international agreements such as the Food and Agriculture Organisation's *International Treaty on Plant Genetic Resources for Food and Agriculture*.

Subregulation 8A.05(2) provides that holders of biological resources seeking declarations under Regulation 8A.05 make application in writing.

Subregulation 8A.05(3) enables the Minister to ensure that the objectives of the Part are met by restricting the operation of the declaration to certain specified circumstances (for example, requiring evidence of a benefit-sharing agreement to be provided to the Minister).

Subregulation 8A.05(4). In keeping with the importance of transparency, the Minister's declarations must be published in the *Gazette*.

#### **8A.06 – Access to biological resources requires a permit**

This regulation establishes that a permit is required for lawful access to biological resources in a Commonwealth area covered by the regulations and provides a penalty for accessing those biological resources without a permit.

### **Division 8A.2 – Access to biological resources for commercial purposes or potential commercial purposes**

#### **8A.07 –Benefit-sharing agreement required**

This regulation sets out the requirements for benefit-sharing agreements.

Subregulation 8A.07(1) requires that an applicant must enter into a benefit-sharing agreement with each access provider of the resources sought.

Subregulation 8A.07(2) establishes that where the access provider is the Commonwealth, the Secretary of the Department with administrative responsibility for the area may sign the benefit-sharing agreement on behalf of the Commonwealth.

Subregulation 8A.07(3) provides that an agreement may be both a benefit-sharing agreement and an Indigenous land use agreement as defined by the *Native Title Act 1993*.

Subregulation 8A.07(4) enables the Minister to publish a model benefit-sharing agreement. It also establishes that any published model agreement will exist as a non-mandatory guide to parties.

#### **8A.08 – Benefit-sharing agreements**

Agreements must contain reasonable arrangements, including protection, recognition and valuing of, any Indigenous knowledge provided by the access provider or other

group of Indigenous persons. This regulation sets out certain elements that must be included in any benefit-sharing agreement. These elements are mandatory in order to maximise consistency between benefit-sharing agreements, provide a guide to access providers and applicants, and ensure that use of Indigenous people's knowledge is protected, recognised and appropriately valued.

#### **8A.09 – Consultation with owners of leased land**

Where the Commonwealth, or a Commonwealth authority, has leased land, the access provider must consult the owner of the land before entering into a benefit-sharing agreement. A prudent access provider occupying leased land would need to satisfy themselves that they had the necessary authority to provide biological resources to a third party. This provision ensures that communication takes place.

#### **8A.10 - Informed Consent**

Subregulation 8A.10(1) requires that where the access provider is the owner of Indigenous people's land or holds native title, the access provider must have given prior informed consent to the benefit-sharing agreement.

Subregulation 8A.10(2) identifies the factors the Minister must take into account in considering whether informed consent has been given. These include the provision of information, the negotiation process, the amount of time involved (including for consultation), the views of representative bodies and the provision of independent legal advice.

#### **8A.11 - Requirement for a Permit**

This regulation establishes that a benefit-sharing agreement only has effect once a permit is issued. Without a permit, the agreement has no effect.

### **Division 8A.3 – Access to biological resources for non-commercial purposes**

#### **8A.12 – Written permission of access provider required**

Subregulation 8A.12(1) requires that written permission from relevant access providers be obtained prior to entering Commonwealth land, taking samples from the area or removing samples from the area.

Subregulation 8A.12(2) specifies that the Secretary of the Commonwealth Department with administrative responsibility for the area may give written permission as an access provider.

Subregulation 8A.12(3) provides that an Indigenous land use agreement (ILUA) is considered a written agreement, if in accordance with other provisions of this Division.

#### **8A.13 - Statutory declaration**

This regulation requires applicants to provide a statutory declaration to each access provider, declaring that access is for non-commercial purposes, undertaking to provide written reports and offer taxonomic duplicate samples, undertaking not to pass samples on to third parties without permission, and undertaking to enter into a

benefit-sharing agreement should the samples be used for commercial purposes at a later date.

#### **8A.14 - Requirement for permit**

This regulation provides that written permission for access only has effect if a permit for the proposed access has been issued.

### **Division 8A.4 - Assessment of applications**

#### **8A.15 - Assessment by Minister**

Subregulation 8A.15(1) enables the Minister to consult Commonwealth bodies in relation to a permit application or benefit-sharing agreement.

Subregulation 8A.15(2) requires the Minister, when assessing an application for access for commercial purposes, to take into account the extent to which requirements set out in Division 8A.2 have been met. This includes the requirement for a benefit-sharing agreement, and the elements of such agreements as listed at 8A.08 (a)-(1).

Subregulation 8A.15(3) requires the Minister, when assessing an application for access for non-commercial purposes, to take into account the extent to which requirements set out in Division 8A.3 have been met. This includes the requirement for a statutory declaration to be made in respect to the non-commercial purposes and the requirement to negotiate a benefit-sharing agreement should those biological resources be utilised for commercial purposes in the future.

#### **8A.16 - Assessment of environmental impact**

Subregulation 8A.16(1) establishes that the regulation applies to applications for an access permit not involving a controlled action (as defined in the EPBC Act). Controlled actions are subject to assessment and approval in accordance with the Act.

Subregulation 8A.16(2) provides for an objective threshold test that enables the Minister to determine whether an assessment should proceed by public notice.

Subregulation 8A.16(3) establishes the process and timeframes for an assessment by public notice of the likely environmental impacts of the proposed access to biological resources, incorporating the principles of natural justice and transparency in decision making. The assessment process established by the subregulation is as follows:

- The Minister must inform the applicant within 20 days after the Department has received the application that the application will be assessed by public notice;
- The applicant must give the Minister a summary of the likely environmental impacts of the proposed access;
- Within 10 working days of receiving that summary, the Minister must:
  - invite comment on the likely impacts - this invitation must be published on the internet or by other means and comments must be received within 10 working days;

- invite comment from persons on the consultation register for this form of assessment - persons on the register have 10 working days to make their comments; and
- make available copies of documents for comments for inspection and purchase; and
- Within 5 days after the end of the invitation period, the Minister must also give the applicant a copy of any comments received.

Subregulation 8A.16(4) provides the applicant with an opportunity to respond to any comments received in accordance with principles of natural justice.

#### **8A.17 - Register of consultation when assessment by public notice is required**

This regulation establishes a register of persons wishing to be consulted when an application is required to be assessed by public notice. Registration will be renewed annually, and the notice inviting registration shall be posted on the Internet, published in the Gazette, and published in a daily newspaper of national circulation.

#### **Division 8A.5 - Register of permits**

##### **8A.18 - Register of permits**

This regulation requires that the Minister keep a register of information about permits granted under Part 8A. This register must be available for public inspection but information would not be included if the Minister believes that it is culturally sensitive or its release could damage a person's commercial interests, create a risk to the environment or damage the national interest.

#### **Division 8A.6 - Records and samples**

##### **8A.19 - Permit holder to keep records**

This regulation sets out the records that a person granted a permit for access to biological resources must keep in relation to each sample taken. A copy of these records must be provided to the Department and each access provider within a reasonable time period after the sample is taken, and must be retained by the holder of the sample.

##### **8A.20 - Disposal of samples**

This regulation provides that in the case where the holder of a sample does not intend to keep the samples obtained under a permit for access to biological resources, they must first be offered to each access provider. If then disposed of, the details of that disposal must be forwarded to the Department.

#### **Item [2] – After paragraph 17.01(aa)**

Item [2] establishes that the permit regulations in Part 17 apply to permits issued by the Minister authorising access to biological resources.

#### **Item [3] – After paragraph 17.02(2)(g)**

Item [3] sets out the information to be included in an application for an access permit. The applicant would be expected to provide this information to the best of



their ability. The degree of specificity maintains transparency and assists certainty in decision-making.

**Item [4] – Subregulation 17.03(1)**

Item [4] brings the permitting arrangements for access to biological resources into the existing permitting regime under the EPBC Act.

**Item [5] – Before paragraph 17.03(2)(a)**

Item [5] provides that the circumstances that must apply before a permit may be issued are those set out in the new subregulation 17.03A(6).

**Item [6] – After regulation 17.03**

**17.03A – Permits for access to biological resources**

Regulation 17.03A sets out the criteria that must be met to issue a permit for access to biological resources.

Subregulation 17.03A(1) links the permit criteria that follow to permits for access to biological resources.

Subregulation 17.03A(2) allows the Minister 10 working days to decide whether to approve an application where the proposed access to biological resources is a controlled action.

Subregulation 17.03A(3) requires the Minister to decide on an application only when all information has been received, where an assessment by public notice is required.

Subregulation 17.03A(4) sets out matters that must be taken into account by the Minister in making a decision on proposed access to biological resources that is a controlled action or assessed by public notice.

Subregulation 17.03A(5) enables the Minister to request more information from any person who may have information relevant to the application, where there is insufficient information to decide whether to issue the permit.

Subregulation 17.03A(6) sets out the criteria that must be met in order for the Minister to issue an access permit.

For both commercial and non-commercial purposes, the criteria include that:

- the Minister believes that some of the benefits arising from access, if any and if practical, will be used for biodiversity conservation in the area from where the resources were taken;
- the agreement is consistent with any Commonwealth management plan or lease in operation in that area; and
- the access would be ecologically sustainable and consistent with the conservation of Australia's biodiversity.

For commercial purposes, the criteria also include that:

- the applicant has entered into a benefit-sharing agreement with each access provider and provided a copy of that agreement to the Minister; and
- the Minister is satisfied that Indigenous land owners, if any, have given their prior informed consent.

For non-commercial purposes, the criteria require that:

- written permission has been obtained from all access providers; and
- a copy of the required statutory declaration has been provided to the Minister.

Subregulation 17.03A(7) requires the Minister, in determining whether access would be ecologically sustainable and consistent with the conservation of Australia's biodiversity, to consider adverse affects on the conservation status of any species or population, or adverse affects on any ecosystem or ecological community.

### **17.03B – Access to biological resources – effect of native title**

This regulation provides a further criterion for issuing a permit or varying conditions of a permit for access in areas which are not Aboriginal/Torres Strait Islander land or waters, as defined under the *Native Title Act 1993*. This means that the regulation does not apply to the Indigenous people's land in Kakadu National Park, Uluru-Kata Tjuta National Park or Booderee National Park.

The Minister must be satisfied that the action would not be an invalid future act under the *Native Title Act 1993*. One way in which the Minister may be satisfied of this is if an Indigenous land use agreement authorises the action and sets out the native title-holders consent to the permit.

### **Item [7] – Regulation 17.08**

Item [7] extends the existing penalty provision for permit condition breaches to access permits.

### **Item [8] – Paragraph 17.09(5)(b)**

Item [8] extends the provisions dealing with applications by a permit holder to vary or revoke a permit condition to access permits.

### **Item [9] – Subregulation 17.10(1)**

Item [9] extends the provisions enabling a permit holder to authorise another person to take action under the permit to access permits.

### **Item [10] – Subregulation 18.02(2)**

Item [10] corrects a previous drafting error.

### **Item [11] – Subregulation 18.02(4)**

Item [11] corrects a previous drafting error.

### **Item [12] – Regulation 18.03**

Item [12] deletes a provision that relates only to permits issued within one year of the commencement of the EPBC Act, and is therefore no longer required.

**Item [13] – Schedule 11, after Part 1A**

Schedule 11 of the Principal Regulations provides for a permit application fee of \$50 for commercial purposes, and nil for non-commercial purposes. The low fee recognises that the potential value of biological resources is realised and established only through research and development, and that this value is captured in benefit-sharing agreements. As the biodiscovery process may yield only one or two promising leads from many thousands of samples tested, it is important to minimise upfront costs in order to maximise significant research into Australia's biodiversity.

**Item [14] – Dictionary, after definition of *artificially propagated***

Item [14] provides a definition of *assessment by public notice*.

**Item [15] – Dictionary, before definition of *biodiversity***

Item [15] provides a definition of *benefit-sharing agreement*.

**Item [16] – Dictionary, after definition of *burial***

Item [16] provides a definition of *business day*.

**Item [17] – Dictionary, after definition of *Commonwealth area***

Item [17] provides a definition of *Commonwealth Department*.

**Item [18] – Dictionary, after definition of *contact details***

Item [18] provides a definition of *controlled action*.

**Item [19] – Dictionary, after definition of *ecological community***

Item [19] provides a definition of *ecosystem*.

**Item [20] – Dictionary, after definition of *Indigenous person***

Item [20] provides a definition of *indigenous people's land*.

**Item [21] – Dictionary, after definition of *native species***

Item [21] provides a definition of *native title*, *native title holder*, and *native title rights and interests*.

**Item [22] – Dictionary, after definition of *porpoise***

Item [22] provides a definition of *precautionary principle*.