

Commonwealth of Australia

Industry Research and Development Act 1986
Biotechnology Innovation Fund Directions No 1 of 2002

I, Ian Elgin Macfarlane, Minister for Industry, Tourism and Resources, acting under subsections 19 (1) and 20 (1) of the *Industry Research and Development Act 1986*, give the following directions to the Industry Research and Development Board.

Dated 21 February 2002

Signed Ian Macfarlane

Minister for Industry, Tourism and Resources

PART 1 — PRELIMINARY

Name of directions

1. These directions are the *Biotechnology Innovation Fund Directions No 1 of 2002*.

Commencement

2. These directions commence on the day on which the directions are published in the Gazette.

Object of these directions

3. The object of this instrument is to give directions to the Board in relation to:
- (a) an additional function of the Board to administer the Biotechnology Innovation Fund, a program to:
 - (i) encourage Australian industry to commercialise promising biotechnology developed in Australia; and
 - (ii) assist in attracting private sector investment in biotechnology.
 - (b) the policies and practices to be followed by the Board in the performance of the function.

Interpretation

4. (1) In these directions, unless the contrary intention applies:

accept means admit for assessment in accordance with these directions and acceptance has a corresponding meaning.

agreement means an agreement mentioned in clause 16;

applicant means a company that makes an application or a proposed company on whose behalf an application is made;

application means an application for financial assistance and includes an application for financial assistance made before these directions commence;

biotechnology means biotechnology of a kind set out in a guideline or determination of the Board;

Biotechnology Innovation Fund means the merit-based program designed to encourage Australian industry to commercialise promising biotechnology developed in Australia and to assist in attracting private sector investment in biotechnology;

company means a company incorporated in Australia;

determination means a determination of the Board under Part 7;

eligible expenditure means expenditure that is eligible expenditure under a guideline or determination but does not include any amount for which an applicant is entitled to receive an input tax credit (whether or not the input tax credit is claimed);

financial assistance means a payment under the Biotechnology Innovation Fund;

funding round means a period of time in which all applications received by the Board will be assessed by comparing the merit of each application under the merit criteria in clause 13 with the merit of all other applications under those merit criteria;

GST has the same meaning as in the *A New Tax System (Goods and Services Tax) Act 1999*;

guideline means:

- (a) a guideline made by the Board under Part 7; or
- (b) if the Board has not yet made a guideline under Part 7, the guidelines for applicants approved by the Minister;

Innovation Investment Fund means the Innovation Investment Fund program administered by the Board under directions given under sections 19 and 20 of the *Industry Research and Development Act 1986*;

input tax credit has the same meaning as in the *A New Tax System (Goods and Services Tax) Act 1999*;

Pooled Development Funds means the scheme established under the *Pooled Development Funds Act 1992*;

proof of concept means work or activities, necessary to establish the commercial and technical viability of a process or product, of a kind set out in a guideline or determination;

revoked directions means the directions revoked by clause 24; and

start-up company means a company formed or acquired for the purpose of commercialising Australian biotechnology and that, at the time the company's application was made, had not been incorporated for more than 24 months.

- (2) These directions apply to a proposed company on whose behalf an application is made as if the company has been incorporated as proposed, unless a contrary intention appears.
- (3) In these directions, ***may*** is permissive and not mandatory.

PART 2 — ADDITIONAL FUNCTION AND POLICIES AND PRACTICES

Additional function of the Board

- 5. (1) The Board must administer the Biotechnology Innovation Fund.
- (2) This is an additional function of the Board being a function relating to the object of the *Industry Research and Development Act 1986*.
- (3) This direction is given under section 19(1) of that Act.

Policies and practices to be followed by the Board

- 6. (1) The policies and practices to be followed by the Board in the performance of its additional function in clause 5, and the exercise of the Board's powers in relation to that additional function, are the policies and practices set out in these directions.
- (2) These directions are made under section 20(1) of the *Industry Research and Development Act 1986*.

Board to follow certain policies

7. The policies to be followed by the Board in administering the Biotechnology Innovation Fund are:
- (a) to increase the rate of commercialisation of Australian biotechnology innovation;
 - (b) to reduce the cost to companies of demonstrating proof of concept for biotechnology innovation;
 - (c) to encourage commercialisation of promising biotechnology developed in Australia;
 - (d) to assist in the development of biotechnology innovation to attract private sector investment; and
 - (e) to increase the level of commercialisation of biotechnology in Australia to provide national benefit.

PART 3 — PROCEDURE FOR CONSIDERING APPLICATIONS

Procedure

8. (1) The Board will grant financial assistance, subject to clause 15, to applicants whose applications are accepted by the Board and assessed on a merit basis under Part 5.
- (2) The Board must consider applications made in relation to a particular funding round as soon as practicable after the closing date for applications determined by the Board for that funding round.
- (3) Funding rounds must be held quarterly unless the Board otherwise determines.

PART 4 — ELIGIBILITY FOR FINANCIAL ASSISTANCE

Eligible applications

9. (1) Subject to subclauses (2) to (4), the Board must accept an application if the Board is satisfied that:
- (a) the applicant meets the requirements of clause 10; and
 - (b) the project to which the application relates meets the requirements of clause 11.
- (2) The Board may refuse an application that the Board reasonably considers is the same, or substantially the same, as another application:
- (a) that was not accepted by the Board; or

- (b) that was accepted by the Board, but related to a project for which the financial assistance (including financial assistance under the Biotechnology Innovation Fund as conducted under the revoked directions) was not granted.
- (3) The Board may refuse an application if the applicant has already made a number of applications:
 - (a) that exceeds 1; and
 - (b) in relation to which the Board has not decided whether to grant financial assistance.
- (4) The Board may refuse a particular application if the Board considers that:
 - (a) the applicant is registered under section 39P or the Act;
 - (b) the applicant, if it is a body corporate, is related to a company that is registered under section 39P of the Act;
 - (c) the application relates to a product, service or process that involves intellectual property developed under a project in relation to which a company is registered under section 39P of the Act; or
 - (d) the application otherwise relates to or is connected with a project in relation to which a company is registered under section 39P of the Act.

Applicant requirements

- 10.** (1) An applicant must:
- (a) be a company or a proposed company that will be incorporated before financial assistance is granted;
 - (b) have rights to intellectual property to enable the applicant to carry out the project; and
 - (c) disclose to the Board any government funding that the applicant has received or will receive in relation to the project.
- (2) The Board must not approve an application for financial assistance for part of the eligible expenditure on a project unless the Board is satisfied that the applicant is able to fund the rest of the eligible expenditure on the project (**matching funding**).
- (3) For the purposes of subclause 10(2), the Board must not take into account:
- (a) funding obtained by the applicant under a program administered by the Board or the Department of Industry Science and Resources except the Innovation Investment Fund and Pooled Development Funds;

- (b) funding of a kind that a guideline or determination states is not to be regarded as matching funding; or
- (c) non-financial (in kind) assistance obtained by the applicant.

Project requirements

11. (1) A project to which an application relates:
- (a) must be for the commercialisation of biotechnology;
 - (b) must be for the proof of concept stage of development;
 - (c) may involve strategies for intellectual property protection; and
 - (d) may involve related business planning and market development studies.

PART 5 — MERIT CRITERIA

Assessment of applications

12. If the Board accepts an application made in relation to a funding round, it must assess the application by comparing the merit of the application with the merit of other applications accepted by the Board made in relation to that funding round.

Merit criteria

13. (1) The merit of applications must be assessed under the following criteria:
- (a) the extent to which the applicant's company structure and arrangements will facilitate commercialisation, including:
 - (i) the extent to which the applicant has a commercial focus demonstrated, for example, by:
 - (A) the commercial skills and experience of the applicant's board and management;
 - (B) an appropriate business plan;
 - (C) strategic partnerships between the applicant and commercially focussed organisations; or
 - (D) other links that the applicant has to commercial skills and experience;
 - (ii) the extent to which the applicant is owned by persons in the private sector;
 - (iii) the extent to which the applicant has or will have its own funds at risk in relation to the project; and

- (iv) the capacity of the applicant to commercialise the biotechnology to which the application relates demonstrated, for example, by:
 - (A) commitment by the applicant and its management to the project; or
 - (B) the management and planning skills of the applicant's key personnel relating to research, commercial and financial areas or other access the applicant has to those skills;
- (b) the extent to which the project will contribute to the commercialisation of leading edge biotechnology including:
 - (i) the commercialisation potential of the biotechnology to which the application relates including:
 - (A) the extent to which a market exists for the commercialised biotechnology;
 - (B) the prospects for growth of that market; and
 - (C) the applicant's ability to access that market; and
 - (ii) the quality of strategies for proof of concept for the project demonstrated, among other things, by:
 - (A) a project plan outlining the project milestones and timelines of the project; and
 - (B) the applicant's access to facilities, equipment and staff needed to undertake the project;
- (c) the extent to which the project will provide commercial and national benefits including:
 - (i) income streams as a result of commercialisation;
 - (ii) additional employment; and
 - (iii) wider economic and community benefits; and
- (d) the extent to which the project can only proceed satisfactorily with financial assistance, including:
 - (i) whether the applicant is a start-up company; and
 - (ii) the extent to which the applicant is related to any person who could provide funding for the project.

PART 6 — GRANT OF FINANCIAL ASSISTANCE

Grant of financial assistance

- 14.** After assessing an application in accordance with Part 5 the Board may, subject to Parliamentary appropriation, approve the application for a project to which the application relates.

Refusal of financial assistance

- 15.** The Board may decide in relation to a particular funding round:

- (a) not to grant any financial assistance; or
- (b) not to grant financial assistance to a particular applicant,

if the Board considers that the merit criteria are not adequately met by the applicant or applicants concerned, or that granting the financial assistance would not be consistent with the policies set out in clause 7.

Board to enter agreements

- 16.** Before financial assistance is provided to the applicant whose application is approved:

- (a) the Board must enter into an agreement with the applicant; and
- (b) in the case of an applicant that is a proposed company, the applicant must become incorporated.

What agreements must contain

- 17.** An agreement:

- (a) must not be inconsistent with a law of the Commonwealth, a State or Territory or these directions;
- (b) must specify the amount of the financial assistance for the project to which the application relates and the timing of payments of the financial assistance;
- (c) must require the applicant to conduct the project to which the application relates;
- (d) must require the applicant to keep records relating to the conduct and management of the project;
- (e) must provide for inspection by the Board of the premises where the project is undertaken and of the records mentioned in paragraph (d);

- (f) must require the applicant to report to the Board on the conduct and management of the project;
- (g) must provide for variation and termination of the agreement; and
- (h) may include other matters.

PART 7 — GUIDELINES AND DETERMINATIONS

Guidelines

- 18.** The Board may make guidelines for the purposes of these directions setting out:
- (a) what kinds of expenditure are eligible expenditure;
 - (b) what kinds of biotechnology in relation to which an applicant may make an application;
 - (c) what kinds of work and activities for a project are for the proof of concept stage of development;
 - (d) what kinds of funding are not to be regarded as matching funding for the purposes of subclause 10(2).

Determinations

- 19.** The Board may determine in writing in relation to a particular applicant or project for the purposes of these directions;
- (a) that expenditure for a project that is incurred after the application for the project is received by the Board is eligible expenditure;
 - (b) whether the project is in the field of biotechnology,
 - (c) whether the project is for the proof of concept stage of development; and
 - (d) whether funding obtained, or to be obtained, by the applicant is of a kind that is not to be regarded as matching funding for the purposes of subclause 10(2).

PART 8 —PAYMENT OF FINANCIAL ASSISTANCE

Authorisation of payment of financial assistance

- 20.** The Board may authorise payments for eligible expenditure under the Biotechnology Innovation Fund to be made in:
- (a) the financial year commencing on 1 July 2001; and

- (b) each following financial year for which the Biotechnology Innovation Fund receives an appropriation.

Maximum financial assistance based on eligible expenditure

- 21.** (1) The total amount of financial assistance for a project must not exceed:
- (a) \$250,000 or 50% of the eligible expenditure for the project, whichever is the lesser; and
 - (b) any further amount payable to the applicant to reimburse the applicant for GST payable by the applicant on supplies made to the Commonwealth under the grant agreement (such further amount not to exceed the amount of GST paid by the applicant).
- (2) The Board must not grant financial assistance to an applicant for an amount greater than the amount sought in the applicant's application, but the Board may grant a lesser amount.

PART 9 — OTHER REQUIREMENTS IN RELATION TO FINANCIAL ASSISTANCE

Time limits on projects receiving financial assistance

- 22.** (1) The period of a project for which financial assistance may be provided must not be more than 18 months.
- (2) However, the Board may extend the period within which a project which receives financial assistance must be completed to a maximum of 2 years if the Board reasonably considers that the objectives of the project would be advanced significantly by the extension.
- (3) For the purposes of subclauses (1) and (2), the Board may determine that the period of a project excludes any time during which work on the project has been suspended if:
- (a) the total time excluded:
 - (i) would not be longer than the total time during which work on the project has been suspended continuously for at least 30 days; and
 - (ii) would not be longer than 1 year, and
 - (b) the determination would significantly advance the objectives of the project.

PART 10 — MONITORING AND EVALUATING PROJECTS

Monitoring and evaluating

23. The Board must:

- (a) ensure that projects for which financial assistance is granted are monitored to obtain relevant information for evaluation; and
- (b) at the request of the Minister, facilitate and cooperate with independent evaluation of the Biotechnology Innovation Fund.

PART 11 — REVOCATION OF EARLIER DIRECTIONS

Revocation of directions

- 24.** Subject to clause 25 and clause 26, the *Biotechnology Innovation Fund Directions No 1 of 2001* are revoked.

PART 12 — TRANSITIONAL PROVISIONS

Transitional provision — certain grants of financial assistance

- 25.** The *Biotechnology Innovation Fund Directions No 1 of 2001*, as in force immediately before the commencement of these directions, continue to apply in relation to financial assistance provided under the revoked directions.

Transitional provision — certain applications for financial assistance

- 26.** (1) This clause 26 applies to an application, for financial assistance made under the *Biotechnology Innovation Fund Directions No 1 of 2001* but not considered by the Board before those directions were revoked.
- (2) The Board must consider an application referred to in subclause 26(1) as if the *Biotechnology Innovation Fund Directions No 1 of 2001* continued to apply.
- (3) The Board may grant an application referred to in subclause 26(1) as if the *Biotechnology Innovation Fund Directions No 1 of 2001* continued to apply.
- (4) If an application referred to subclause 26(1) is granted, the *Biotechnology Innovation Fund Directions No 1 of 2001* continue to apply in relation to the financial assistance to which the application relates.
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