



MALAYSIAN BIOTECHNOLOGY CORPORATION SDN BHD
(Company No. 691431-D)

GUIDELINES ON THE PROCESS & PROCEDURES FOR BIONEXUS STATUS APPLICATION

<GP/BDD/EVALUATION/BNX001>

DECEMBER 2011

Please note that the information contained herein is intended to be used for guidance and knowledge only. Whilst every effort has been taken to ensure the accuracy and completeness of the contents at the time this Guidance Paper is issued, inaccuracies may exist due to several reasons including changes in circumstances and/or amendments brought about due to a change in the policy (s) or prevailing rules or regulations.

BiotechCorp does not hold out, warrant or guarantee that reliance on the information contained herein will result in the granting or approval of the matters applied for. BiotechCorp welcomes feedback and comments on this document. Feedback and comments can be sent to info@biotechcorp.com.my and by stating clearly in the subject line the document title and document Reference No.

CONTENTS

1	OBJECTIVES AND INTRODUCTION	1
1.1	Objectives	1
1.2	Introduction	1
2	INTRODUCTION TO BIONEXUS STATUS	1
2.1	BioNexus Status	1
2.2	Bill of Guarantees	1
2.3	Tax Incentives	2
3	BIONEXUS STATUS APPLICATION PROCESS	3
3.1	Eligibility Criteria	3
3.2	BioNexus Status Pre-Application Process	4
3.3	BioNexus Status Application Process	7
3.4	Documents Required	12
3.5	Application Fee	12
	APPENDIX	14
	BioNexus Application Process Flow	14

1 OBJECTIVES AND INTRODUCTION

1.1 Objectives

The objective of this paper is to provide interested applicants with a guide on the information required and criteria used in evaluating a BioNexus Status submission.

This paper also outlines the underlying framework and processes involved in a BioNexus Status application.

1.2 Introduction

Biotechnology has been identified as the next engine of economic growth for Malaysia. It is envisioned that biotechnology will be able to improve the quality of life, generate new wealth creation and income for both rural and urban population and improve the socio-economic status of people as a whole.

To spur biotechnology growth, the Government launched the National Biotechnology Policy (NBP) in 2005 and introduced the designation of 'BioNexus Status' to qualified biotechnology companies, making them eligible for privileges and incentives offered by the Government.

The BioNexus Status was launched by the YAB Prime Minister of Malaysia on 7 September 2006 during the inaugural meeting of the Biotechnology Implementation Council.

2 INTRODUCTION TO BIONEXUS STATUS

2.1 BioNexus Status

BioNexus Status is a recognition awarded by the Malaysian Government, through Malaysian Biotechnology Corporation Sdn Bhd ("BiotechCorp"), to qualified companies that participate in and undertake value-added biotechnology and/ or life science activities.

BioNexus Status companies enjoy a set of incentives and privileges contained within the BioNexus Bill of Guarantees.

2.2 Bill of Guarantees

The Bill of Guarantees refers to the commitment of the Government of Malaysia towards the creation of a conducive environment to encourage the development of the biotechnology industry. They include:

- i. Freedom of ownership;
- ii. Freedom to source funds globally;
- iii. Freedom to bring in knowledge workers;
- iv. Eligibility for competitive incentives and other assistance;
- v. Eligibility to receive assistance for international accreditations and standards;
- vi. Strong intellectual property (IP) regime;
- vii. Access to supportive information network linking research centres of excellence;
- viii. Access to shared laboratories and other related facilities; and
- ix. BiotechCorp as the one-stop agency.

2.3 Tax Incentives

A BioNexus Status company is eligible for the following incentives:

- i. An exemption from tax on 100% statutory income :
 - For a period of ten (10) consecutive years of assessment from the first year the company derived statutory income from the new business; or
 - For a period of five (5) consecutive years of assessment from the first year the company derived statutory income from the existing business and expansion project; or
 - An exemption of 100% statutory income derived from a new business or an expansion project that is equivalent to an allowance of 100% of qualifying capital expenditure incurred for a period of five (5) years;
- ii. A BioNexus Status company is entitled to a concessionary tax rate of 20% on statutory income from qualifying activities for ten (10) years upon the expiry of the tax exemption period;
- iii. Tax exemption on dividends distributed by a BioNexus Status company;
- iv. Exemption of import duty and sales tax on raw materials/components and machinery and equipment;
- v. Double deduction on expenditure incurred for R&D;

- vi. Double deduction on expenditure incurred for the promotion of exports;
- vii. With effect from 2 September 2006, buildings used solely for the purpose of biotechnology activities will be eligible for Industrial Building Allowance to be claimed over a period of ten (10) years;
- viii. A company or an individual (that carry on business) investing in a BioNexus Status company is eligible for a tax deduction equivalent to the total investment made in seed capital and early stage financing; and

Please refer to the *Guidelines on Incentives Accorded to BioNexus Status Companies* and *Tax Incentives for BioNexus Status Companies – Process and Procedures* (Paper Ref. No. GP/CSSD/A&P/TAX001) for details.

3 BIONEXUS STATUS APPLICATION PROCESS

3.1 Eligibility Criteria

- i. The applicant is a provider of a product or service based on life sciences, or substantially utilise biotechnology processes;
- ii. The applicant must undertake continuous developmental research work with access or capability to carry out said activity.
- iii. The applicant employs a significant percentage of knowledge workers as part of its total workforce;
- iv. There must be a separate legal entity for the BioNexus-qualifying business and activities; and
- v. The applicant complies with applicable and related laws, regulations, and guidelines.
- vi. The applicant must have a minimum paid-up capital of RM250,000. (This requirement must be complied at the Application Processing Stage)

In addition to the above said criteria, the applicant is required to declare if it is currently enjoying and /or has enjoyed any status and/or incentive approved by other relevant authorities. Please refer to the *Guidelines on BioNexus Qualifying Criteria* (Paper Ref No. GP/CSSD/A&P/BNX002), Paragraph 7 “Other Considerations”.

The BioNexus Status application process involves two (2) stages :

Stage 1 – Pre-Application Process

Stage 2 – Application Process

3.2 BioNexus Status Pre-Application Process

3.2.1 Initiating a BioNexus Status Application

- a) An applicant who wishes to apply for BioNexus Status is advised to go through and understand the requirements contained within the following Guidance Papers:
 - i. **Guidance Paper 1** : Guidelines on the Process and Procedures for BioNexus Status Application;
 - ii. **Guidance Paper 2** : Guidelines on BioNexus Qualifying Criteria;
- b) An applicant must initiate the BioNexus Status Application process via an on-line Pre-application Form;
- c) The on-line Pre-application Form can be accessed by logging into BiotechCorp's website at www.biotechcorp.com.my;

MALAYSIAN BIOTECHNOLOGY CORPORATION SDN BHD
BioNexus Pre-Application Form

1. Applicant Background

Name of Applicant

Has any company been incorporated? Yes No

If "Yes", please provide Company Name

Date of Incorporation Day Month Year

Equity Participation % Malaysian % Foreign

2. Proposed Activities / Product

Industry (please tick all that apply) Agriculture Healthcare Industrial

BioNexus Proposed Activities (please describe in max 2000 words)

Any R&D Undertaken? Yes No

BioNexus Proposed R&D Activities (please describe in max 2000 words)

- d) An Account Manager from BiotechCorp will be assigned to the applicant;
- e) The responsibilities of the Account Manager, amongst others, are:
 - i. to evaluate the eligibility of the applicant according to the BioNexus Criteria established; and
 - ii. to act as the liaison officer between the applicant and BiotechCorp's on all matters pertaining to BioNexus status application

3.2.2 Information Required in the BioNexus Status Pre-Application Form

An applicant is required to fill in **ALL** the information within the Pre-Application form which is outlined below:

- a) Particulars of the applicant, which should include the following:

The name of the applicant company, date of incorporation, shareholding structure of the company, correspondence address, contact telephone number, facsimile number, e-mail address, website, mobile number and name and designation of a contact person within the applicant's organisation;
- b) Proposed activities for the BioNexus Status application which should include the following:
 - i. The applicant should identify the range of biotechnology and/or life sciences activity(ies) to be provided and components of the same.

Example A

Company A is involved in the production of biofertilizer from Empty Fruit Bunch (EFB) using specific microbial strains via fermentation process.

Example B

Company B is involved in the production of *in-vitro* diagnostic kits for the detection of cervical cancer using specific molecular (DNA/ Protein) markers.

Example C

Company C is involved in the extraction of standardised extracts from herbal X which contains identified active constituents which has proven health benefits and has potential to be developed into phytopharmaceutical products.

- ii. The applicant should indicate whether the products and/or services offered are ready for commercialisation (i.e proof of concept or pilot scale completed, certification obtained and etc);
 - iii. Description of the technology used. Detailed information on the technology, its application and as to whether it is in-house developed or licensed from a third party should be provided.
- c) Proposed Research and Development Programme
- The applicant should provide a description of its proposed R&D projects for the next three (3) years.
- d) To indicate any other incentives awarded by the Government of Malaysia (i.e MIDA, MOA, MDEC, HDC, Iskandar Malaysia, NCER, ECER etc.) to the applicant or any other companies within the Group.

3.2.3 Pre-Application Evaluation Criteria

- a) BiotechCorp will consider the pre-application together with the accompanying information against a set of criteria which may include, but is not limited to the following:
- i. Biotechnology and/or life sciences element within the activity;
 - ii. Level of readiness for commercialisation;
 - iii. Ownership of the technology;
 - iv. Relevance of R & D to be undertaken in relation to the current project; and
 - v. Regulatory requirements
 - vi. Level of capitalisation
- In addition to the above criteria, due consideration shall also be given to any existing status and/ or incentive approved by other relevant authorities that the applicant has received.
- b) Applicant who fulfils the pre-evaluation criteria will be required to submit documents as indicated in Section 3.4 of this paper for further assessment.
- c) Unsuccessful pre-applications will be declined. However, applicants can reapply once they fulfil the required pre-application criteria.

3.3 BioNexus Status Application Process

3.3.1 Information Required in the BioNexus Business Plan

Successful pre-applicants will be provided with BiotechCorp's BioNexus Application Form and Business Plan template. The Business Plan template only serves as a guide. Information that should be included is as follows:

a) Particulars of the Company, which should include the following:

- i. Name of the company, date and number of incorporation, business and registered address, e-mail address, website, contact telephone and facsimile numbers;
- ii. Detailed information on corporate and shareholding structure including relationship with holding, subsidiary and associated companies. If the holding company is a public entity, details of the public listing should be provided; and
- iii. Details of the composition of the Board of Directors;

b) Details of the applicant's BioNexus Activity

- i. The proposed biotechnology and/or life sciences activities which include in detail the range of products/services to be offered;
- ii. Industry / market overview;
- iii. The target market analysis;
- iv. Competitor overview
- v. Threat of substitutes
- vi. Consumer behaviour; and
- vii. Project milestones.

c) Technology

Details of the technology to be utilised. This section should include the following information:

- i. Technology Licensing Agreement, Technology Acquisition Agreement, Deed of Assignment or any

- relevant legally binding agreement (to be attached, if any);
- ii. Description of the processes involved, including process flow diagram;
- iii. Waste stream generated and treatment technology (if any);
- iv. Details on intellectual property;
- v. Application of technology (utilization and benefits); and
- vi. Comparative assessment with current/existing technology in a similar capacity.

d) Expansion Plan (Applicable for companies that has existing business)

Company to provide details on:

- i. Reason for expansion;
- ii. Description of expansion plan;
- iii. Detailed list of capital expenditure incurred for expansion plan, cost involved and expected period of occurrence.

e) Research & Development (R & D) Plan

The applicant is required to provide a detailed and extensive R&D programme for the next three (3) years. The R&D programme described should include the following:

- i. Title of the project(s);
- ii. Name, address and email/ website of the Project Investigator(s) and Institution;
- iii. A clear description of the issue to be addressed;
- iv. Objectives of the project ;
- v. Project benefits / how the proposed research will contribute towards improving the products/services of the company;
- vi. R&D work in the proposed area already accomplished by the proposer(s)/others with published references (if any);
- vii. Specific work plan including:
 - Description of research methodology;

- Key milestones;
 - Specific activities;
 - Time schedule; and
 - Deliverables over three (3) years
- viii. Financial requirements for complete project duration and phasing for each year;
- ix. Inter-institutional or industrial links, if any;
- x. Facilities and infrastructure available to the team for implementing the project;
- xi. Specific research facilities required for the project with detailed justification;
- xii. Specific infrastructure required for the project with detailed justification; and
- xiii. R&D collaboration agreement with other research institution/universities (to be attached, if any)

The applicant is also required to complete the R&D Project Summary Template in Section 7.0 of the BiotechCorp's Business Plan template.

- f) Human Resource Requirements and Projections
- i. Detailed resumes of the key management team indicating relevant prior experience, qualifications, other source of expertise and the roles and responsibilities of each member;
 - ii. Applicant is required to indicate clearly its full-time employees and those that are on shared-basis with its holding company or sister companies; and
 - iii. The applicant is also required to complete the Human Resource Projection Template in Section 6.0 of the BiotechCorp's Business Plan template;
- g) Description of the facility which include information on the location, space requirement, layout plan, accreditation, equipments and capability; and
- h) The applicant is required to also provide information on the value proposition of how the applicant's operations and proposed activities will benefit the country and the biotechnology/ life sciences industry.

3.3.2 Information Required in the BioNexus Financial Projection

Successful pre-applicants will be provided with BiotechCorp's Financial Projection template. The applicant is required to complete the said Financial Projection and no other format is accepted. The financial projection for the proposed activity shall include:

- a) Projected Profit & Loss Account, Balance Sheet & Cashflow Statement on an annual basis for the next three (3) years;
- b) Details of revenue including the method of calculation should be clearly outlined;
- c) All assumptions used in the preparation of the financial projection must be clearly provided; and
- d) The breakdown of the proposed capital expenditure and working capital requirement for the first three (3) years of operation.

3.3.3 The applicant may submit any other information not specified in Section 3.3.1 and 3.3.2 which may be considered helpful for evaluation of the application.

3.3.4 BiotechCorp reserves the right to request for clarification or any other information from the applicant regarding its application.

3.3.5 The applicant must submit the documents required in Section 3.4 within sixty (60) calendar days from the date of receipt of the Business Plan and Financial Projection templates from the Account Manager.

3.3.6 BiotechCorp reserves the right not to accept applications which are incomplete in this respect.

3.3.7 The evaluation process will only commence once complete information is received from the applicant. A Letter of Acceptance for Complete Submission will be sent by BiotechCorp to the applicant once complete information has been received. BiotechCorp will take twenty-eight (28) working days to evaluate the application upon issuance of the letter.

3.3.8 Evaluation Process and Criteria

- a) BiotechCorp will consider the application together with the accompanying information based on its merits. The merits of each application will be evaluated against a set of criteria which may include, but is not limited to the following:
 - i. The applicant's background including the directorship and shareholding structure and the business segment in which the applicant is involved in. New company with no track record will also be considered based on the

- proposed activities and relevant expertise of its promoter;
- ii. The feasibility of the applicant's proposed activities against the current market environment. The roll out plan of the proposed activities and the timeframe will also be evaluated;
 - iii. The feasibility and benefit of the technology to be utilized in the provision of the service or carrying out the proposed activities;
 - iv. Relevance of research and development initiatives;
 - v. Relevant managerial and technical expertise to carry out the proposed activities and R&D programs;
 - vi. Target market including potential demand for the activities being proposed and the projected market share that the applicant will be able to acquire;
 - vii. The applicant's competitive advantage against existing and/ or similar business providers;
 - viii. The applicant's financial capability and/ or plan to carry out the proposed activities;
 - ix. The benefits that will be brought by the applicant to the overall biotechnology and life sciences industry in Malaysia; and
 - x. BiotechCorp will also take into account the various regulations, laws, policies and guidelines imposed by the relevant authorities in relation to the applicant's business operations and activities.

3.3.9 Approval Process

- a) BioNexus Status applications are presented to the BioNexus Evaluation Committee (BEC) for deliberation. The BEC comprises of :
 - Secretary General, Ministry of Science, Technology and Innovation (MOSTI);
 - Non-Executive Director, BiotechCorp;
 - Representative from Ministry of Finance (MOF);
 - Representative from Ministry of Agriculture and Agro-based Industry;
 - Representative from Ministry of Health (MOH);
 - Representative from Ministry of International Trade and Industry (MITI) or Malaysian Industrial Development Authority (MIDA);

- Under Secretary, National Biotechnology Division, Ministry of Science, Technology and Innovation (MOSTI); and
 - Chief Executive Officer, BiotechCorp.
- b) The BEC may decide to either approve, reject or request for further information for any given application.
- c) The final conferment of the BioNexus Status and tax incentive is subject to the approval of the Minister of Finance. Approved applications will receive a Letter of Award while unsuccessful applications will receive a Letter of Rejection.
- d) For applications that require further information, the Account Manager will assist with the preparation of the re-submission to the BEC upon obtaining the information requested from the applicant.

3.4 Documents Required

- a) An applicant is required to submit the following documents for BioNexus Status Application Process:
- i. BioNexus Application Form;
 - ii. Business Plan (Refer to Section 3.3.1 for details);
 - iii. Financial Projection (Refer to Section 3.3.2 for details);
 - iv. Company statutory documents which include Memorandum and Articles of Association, Form 9, 13, 24 and 49;
 - v. Application fee
 - vi. Last three (3) years Audited Accounts (if any);
 - vii. Latest Management Account;
 - viii. Technology Licensing Agreement, Technology Acquisition Agreement, Deed of Assignments etc (if any); and
 - ix. Such additional information or document as may be requested by BiotechCorp;
- b) All the above mentioned documents should be submitted in both hardcopy (1 copy only) and softcopy format;
- c) The Business Plan and Financial Projection must be written in English; and
- d) All photocopies of the company statutory documents and any agreements must be certified by the Company Commission of Malaysia (CCM). Photocopy submission of any agreement must be certified by a Director or the Company Secretary.

3.5 Application Fee

- a) An application fee of RM2,000 will be charged to the applicant company.

- b) The application fee is payable upon submission of the BioNexus Status Application Form.
- c) A refund of the application fee will be made to unsuccessful applicants.
- d) The payment must be made payable to “**MALAYSIAN BIOTECHNOLOGY CORPORATION SDN BHD**” via bank draft only.

For further information or clarification, please contact:

Vice President
BioNexus Development Division
Malaysian Biotechnology Corporation Sdn Bhd
Level 23 Menara Atlan
161 Jalan Ampang
50450 Kuala Lumpur

T: 03 2116 5588

F: 03 2116 5528

E: info@biotechcorp.com.my

APPENDIX

BioNexus Application Process Flow

