



REFERENCE 1 : GUIDELINES ON BIONEXUS STATUS

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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.

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1.0 Introduction : BioNexus eligibility criteria

This paper provides an explanation on the BioNexus Status eligibility criteria as outlined below:

- i. There must be a separate legal entity for the BioNexus-qualifying business and activities;
- ii. The applicant is a provider of a product or services based on life sciences, or substantially utilise biotechnology processes;
- iii. The applicant must undertake continuous developmental research work with access or capability to carry said activity.
- iv. The applicant employs a significant percentage of knowledge workers as part of its total workforce; and
- v. The applicant complies with applicable and related laws, regulations, and guidelines.
- vi. Minimum paid-up capital requirement of RM 250,000. (This requirement must be complied at the Application Processing Stage)

2.0 Separate legal entity

2.1 Eligible Applicant:

- i. A new company incorporated in accordance with the Companies Act 1965.
- ii. An existing company undertaking biotechnology/and or life sciences activity.
- iii. A separate legal entity must be incorporated to undertake the proposed BioNexus activity in the event that the company has diverse business activities.
- iv. Individuals, sole-proprietors and partnerships are NOT eligible to apply.

2.2 Incorporation of a Local Company in Malaysia

There are three (3) types of companies that can be incorporated under the Companies Act 1965:

- a. A company limited by shares;
- b. An unlimited company; and
- c. A company limited by guarantee.

For the purpose of conducting business in Malaysia, the most common type is a company limited by shares. However, applicants may use any of the 3 types above.

2.2.1 Company Limited by Shares

A company having a share capital may be incorporated as a private company (identified by the words 'Sendirian Berhad' or 'Sdn Bhd' appearing together with the company's name) or public company (identified by the words 'Berhad' or 'Bhd' appearing together with the company's name). The requirements to form a company are:

- i. A minimum of two (2) subscribers to the shares of the company;
- ii. A minimum of two (2) directors; and
- iii. A company secretary who can either be :

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- An individual who is a member of a professional body prescribed by the Ministry of Domestic Trade and Consumer Affairs; or
- An individual licensed by the Companies Commission of Malaysia (CCM).

One of the director and company secretary shall have their principal or only place of residence within Malaysia.

2.2.2 Incorporation Procedures

a) Name Search with CCM and Application for Company Name

- i. A name search must be conducted to determine whether the proposed name of the company is available. The steps involved are :
 - Completion and submission of Form 13A – Request for Availability of Name to CCM; and
 - Payment of a RM30.00 fee for each name applied;
- ii. When the proposed company's name is approved by CCM, it shall be valid for three (3) months from the date of approval.

b) Lodgement of Incorporation Documents

Incorporation documents as listed below must be submitted to CCM within three (3) months from the date of approval of the company's name by CCM, failing which a fresh application for a name search must be done.

i. Memorandum and Articles of Association

- An original copy of the Memorandum and Articles of Association shall be stamped at RM100.00. Stamps are affixed at the Inland Revenue Board's stamp office;
- The directors and secretaries shall be named in the Memorandum and Articles of Association;
- The subscribers to the company's shares shall sign the Memorandum and Articles of Association in front of a witness; and
- Table A of the Fourth Schedule in the Companies Act 1965 can be adopted as the Articles of Association of the company;

ii. Form 48A (Statutory Declaration by a Director or Promoter before Appointment)

The director or promoter declares under oath that :

- He/ She is not a bankrupt; and
- He/ She has not been convicted and/or imprisoned for any of the prescribed offences;

iii. Form 6 (Declaration of Compliance)

This declaration states that all the requirements of the Companies Act 1965 have been complied with. It must be signed by the company secretary who handles the registration and is named in the Memorandum and Articles of Association;

iv. Original Form 13A;

- v. A copy of the letter from CCM approving the name of the company; and
- vi. A copy of the identity card of each director and company secretary.

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2.2.3 Registration Fees

Each application for the incorporation of a company shall be accompanied with payment as per the schedule below:

AUTHORISED SHARE CAPITAL (RM)	FEES (RM)
Up to 100,000	1,000
100,001 – 500,000	3,000
500,0001 – 1,000,000	5,000
1,000,001 – 5,000,000	8,000
5,000,001 – 10,000,000	10,000
10,000,001 – 25,000,000	20,000
25,000,001 – 50,000,000	40,000
50,000,001 – 100,000,000	50,000
100,000,001 and above	70,000

2.2.4 Certification of Incorporation

A Certificate of Incorporation will be issued by CCM upon compliance with the incorporation procedures and submission of duly completed incorporation documents.

Source: www.ssm.com.my

3.0 BIOTECHNOLOGY AND/ OR LIFE SCIENCES RELATED ACTIVITIES

3.1 Stage of Project

- Project must be **READY** for production or commercialisation.
- Pre-commercialisation projects comprising of a pilot plant development, projects beyond proof of concept stage and commercial ready prototypes may be considered based on the merits of the application.
- Projects in the conceptual or research stage are **NOT** eligible for BioNexus Status application.

3.2 Focus areas

A project proposal eligible for consideration must be within the purview of the National Biotechnology Policy (NBP) and falls into the following 3 focus areas:

- Agricultural Biotechnology;
- Healthcare Biotechnology; and
- Industrial Biotechnology.

3.3 Qualifying Activities

- Project must have a biotechnology and/ or life sciences element in the activity.
- Companies merely undertaking repackaging, distributing or trading of biotechnology products and consultancy do not qualify for BioNexus Status
- The proposed project must be commercially viable and ready for commercialization.
- The proposed project must be undertaken in Malaysia.

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3.4 Technology and Intellectual Property (IP) Ownership

- a) The technology to be utilised can be developed in-house, acquired or licensed from a third party, either local or foreign
- b) Applicant must demonstrate that it has legal rights/access to the technology. If the technology is acquired or licensed from a third party, the applicant must show the following:
 - i. A concluded and signed technology acquisition agreement, licensing agreement or deed of assignment;
 - ii. The applicant must be a party to the agreement. If the agreement is entered into by the applicant's holding company or sister companies, a proper deed of transfer of the rights must be executed; and
 - iii. The fees stipulated in the technology acquisition, licensing or deed of assignment must have been paid in accordance with the terms stipulated in the said agreement.
- c) In the case of a technology licensing agreement, the terms of the agreement should contain the following:
 - i. Indicate clearly the rights granted to the Applicant company;
 - ii. Preferably allow the applicant to undertake further development and improvement;
 - iii. Indicate and stipulate the ownership of newly developed IP, if any;
 - iv. Indicate and stipulate clearly the territories for which the license is being granted;
- d) In the case of a researcher commercialising research projects while attached to the institutes, written consent/ permission must be obtained from the respective institutes.
- e) Results of trials, scientific publications and journals, commercialization of products/ services using similar technology elsewhere and other supporting documents should be provided to indicate the utilisation and effectiveness of the technology developed or licensed.

4.0 RESEARCH AND DEVELOPMENT

4.1 Research and Development (R&D) Framework

- a) The company must demonstrate that it has the access or capability to undertake continuous R&D activities in relation to the proposed activities submitted for the BioNexus Status application the exception being companies undertaking contract research services for third parties as it is a BioNexus Status qualifying activity..
- b) The proposed R&D project must be within the focus areas and demonstrate commercial potential.
- c) The proposed R&D must be relevant to market needs and requirements, enhancing the biotechnology and life sciences industry.
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- e) The R&D project must at least encompass the following (subject to further evaluation):
 - i. Functional improvement of the current product/s being commercialised;
 - ii. Process improvement to increase yield and efficiency;
 - iii. Development of new product/ services utilizing existing technology;
 - iv. Design, development and testing of new prototypes;
 - v. Design and development of new products or services involving new technology;
 - vi. Efficacy and safety of product or treatment (ie medication, device, procedure or method) through clinical trials or validation process; and
 - vii. Design and development of procedures for scaling-up of commercial production.

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- f) R&D activities involving aesthetic changes to the current product/s or improvement on packaging will not be considered.
- g) The R&D undertaken must be towards the development of Intellectual Property (IP) and the applicant must have ownership of the IP necessary to commercialise the research outcome.
- h) Applicant should demonstrate capability to undertake the proposed R & D project:
 - i. An appropriate research team led by a qualified scientific expert in the related area for R&D projects undertaken in-house;
 - ii. An internal scientific expert in the related area to oversee R&D projects undertaken in collaboration with third parties;
 - iii. Capability to finance the proposed R&D project;
- i) The R&D can be undertaken in-house or in collaboration with third parties, foreign or local.
- j) If the R&D is undertaken in collaboration with third parties, applicant is required to submit documentary evidence of concluded arrangements
- k) Applicants are required to invest at least 3% of its annual revenue into R&D activities

5.0 RULES AND REGULATIONS

The applicant must comply with the following:

- a) All applicable laws including, without limitation, statutory, regulatory and/or licensing requirements;
- b) Obtain and maintain all other necessary licences, permits, approvals and authorisation relating to the undertaking of the proposed activities;
- c) All environmental, ethical and other policies, rules, regulations and guidelines as imposed by the relevant government authorities;
- d) The applicant must also not infringe any intellectual property rights of any third party.

6.0 OTHER MATTERS

- a) Companies that have already been awarded other special statuses or incentives by the Government e.g. by MIDA, MDEC, HDC, Iskandar Malaysia, NCER, ECER etc **may not be eligible** for BioNexus Status. The above applies also to related companies for the same or similar activities.
- b) Applicants are encouraged to contact BiotechCorp for clarification/verification.