



BioNexus Status 3.0 Framework Guideline (Non-IP Income)

BioNexus Evaluation

BIONEXUS 3.0 FRAMEWORK GUIDELINE

Version 3.0 (December 2019)

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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Chapter 1: Introduction and background

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1.1 Introduction of BioNexus Status

- Bioeconomy Corp is a one-stop agency to develop the biotechnology and bio-based industries in Malaysia.
- BioNexus is a special status awarded to qualified international and Malaysian biotechnology companies. The status bestows fiscal incentives, grants and other guarantees to assist growth. This status is awarded to qualified companies undertaking biotechnology activities.
- A BioNexus Status company is assured a list of privileges as stipulated in the BioNexus Bill of Guarantees (“BoGs”) 2018^{Note 1} which includes:
 - i. Freedom of ownership;
 - ii. Freedom to source funds globally subject to prevailing Government’s policies;
 - iii. Freedom to bring in knowledge workers subject to prevailing Government’s policies;
 - iv. Eligibility for BioNexus Status incentives;
 - v. Facilitation of international accreditation and standards; and
 - vi. Access to BioNexus Partners Programme for shared laboratories and other related facilities.
- **The BioNexus Status incentives shall be in effect until 31 December 2020 in accordance with the National Biotechnology Policy.**

Note 1: BioNexus Bill of Guarantees 2018 is a revised BoGs for BioNexus Status companies

1.2 BioNexus 3.0 Framework: Continuous changes

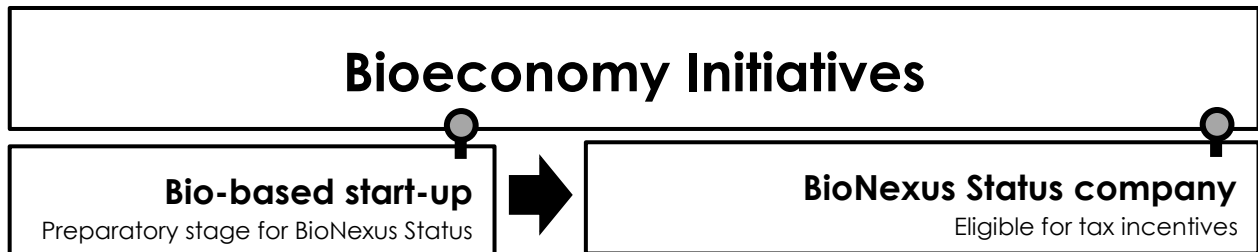
- Throughout the previous 2 phases of the National Biotechnology Policy (NBP), BioNexus Status was reviewed and improved several times in ensuring the content and operational practices remained relevant to the development of the biotechnology industry.
- Certified under ISO 9001:2008, the quality operational procedure (“QOP”) for BioNexus Status application was reviewed and improved several times amongst others to cater to major changes relating to the implementation of BioNexus 3.0 Framework replacing BioNexus 2.0 Framework. Under the BioNexus 3.0 Framework, new standard operating procedures have been introduced with the objective to reduce the QOP timeline from the previously set forty-two (42) working days to thirty (30) working days.
- A new comprehensive BioNexus application form has also been introduced replacing the need for submission of the business plan from the applicant. Available online at Bioeconomy Corp’s website, the applicant is required to submit the online Registration of Interest prior to downloading the BioNexus Application Form.
- The continuous evolution of BioNexus 3.0 Framework is a recognition and commitment from the Government in ensuring the growth of the biotechnology industry and to strengthen the BioNexus Status brand.
- The BioNexus 3.0 Framework is in line with Base Erosion and Profit Shifting (“BEPS”) Action Plan, under the Organisation for Economic Co-operation and Development (“OECD”). Malaysia’s commitment to the implementation of the BEPS Action Plan, OECD is amongst others, marked with the completion and implementation of the BioNexus 3.0 Framework.

Chapter 2: Overview of Bioeconomy Initiatives and BioNexus 3.0 Framework

Chapter 2: Overview of Bioeconomy Initiatives and BioNexus 3.0 Framework

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2.1 Overview: Bioeconomy Initiatives



Biotechnology is an important element in creating a comprehensive bioeconomy framework. Targeted to be the engine of growth for bioeconomy, BioNexus 3.0 Framework not only focuses on value creation from the Intellectual Property (“IP”) but also acknowledges the economic contribution from bio-based start-up companies. Bio-based start-up is a newly introduced category under the bioeconomy initiatives with an objective to prepare the bio-based companies to qualify for BioNexus Status. Summary of the bio-based start-up and the BioNexus 3.0 Framework are as follows:

- a. Bio-based start-up : A preparatory stage for bio-based start-up companies to qualify for BioNexus Status. Nurturing and facilitation programmes under Bioeconomy Corp will be provided within two (2) year period, at the end of which the company is ready to be graduated as a BioNexus Status company. Bio-based start-up is not eligible for tax exemption incentives.
- b. BioNexus Status : BioNexus 3.0 Framework separates the tax exemption incentives into as follows:
 - i. Non-IP income^{Note 2}:
A category where the income is generated from knowledge/technology/processes/etc. other than IP assets, in undertaking the commercialisation of QA.

Note 2: Non-IP income can only be generated from the approved QA

Note 3: Only three (3) types of IP assets are eligible namely Patent, Copyrighted software and trade secret (refer to Chapter 4)

2.2 Tax incentives available under BioNexus Status

The following are the summary of tax incentives available for BioNexus Status company categorised based on the tax treatment:

Tax treatment	Summary			
i. Tax exemption (on statutory income)	Exemption period:			
	<p>A company awarded with BioNexus Status will enjoy tax exemption on statutory income (“SI”) derived from the approved QA:</p> <ol style="list-style-type: none"> a. For a period of ten (10) consecutive years of assessment commencing from the first (1st) year of assessment the company derived SI from the new business; or b. For a period of five (5) consecutive years of assessment commencing from the first (1st) year of assessment^{Note 4} the company derived SI from the existing business and expansion project. <p><i>Note 4: The first (1st) year of assessment begins once the company derives SI after receiving the BioNexus Status.</i></p>			
	Exemption percentage:			
	<p>Tax exemption treatment is:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Category</th> <th style="text-align: center;">Tax exemption percentage</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Non-IP income</td> <td>The percentage of exemption awarded is based on activity classification.</td> </tr> </tbody> </table>	Category	Tax exemption percentage	Non-IP income
Category	Tax exemption percentage			
Non-IP income	The percentage of exemption awarded is based on activity classification.			

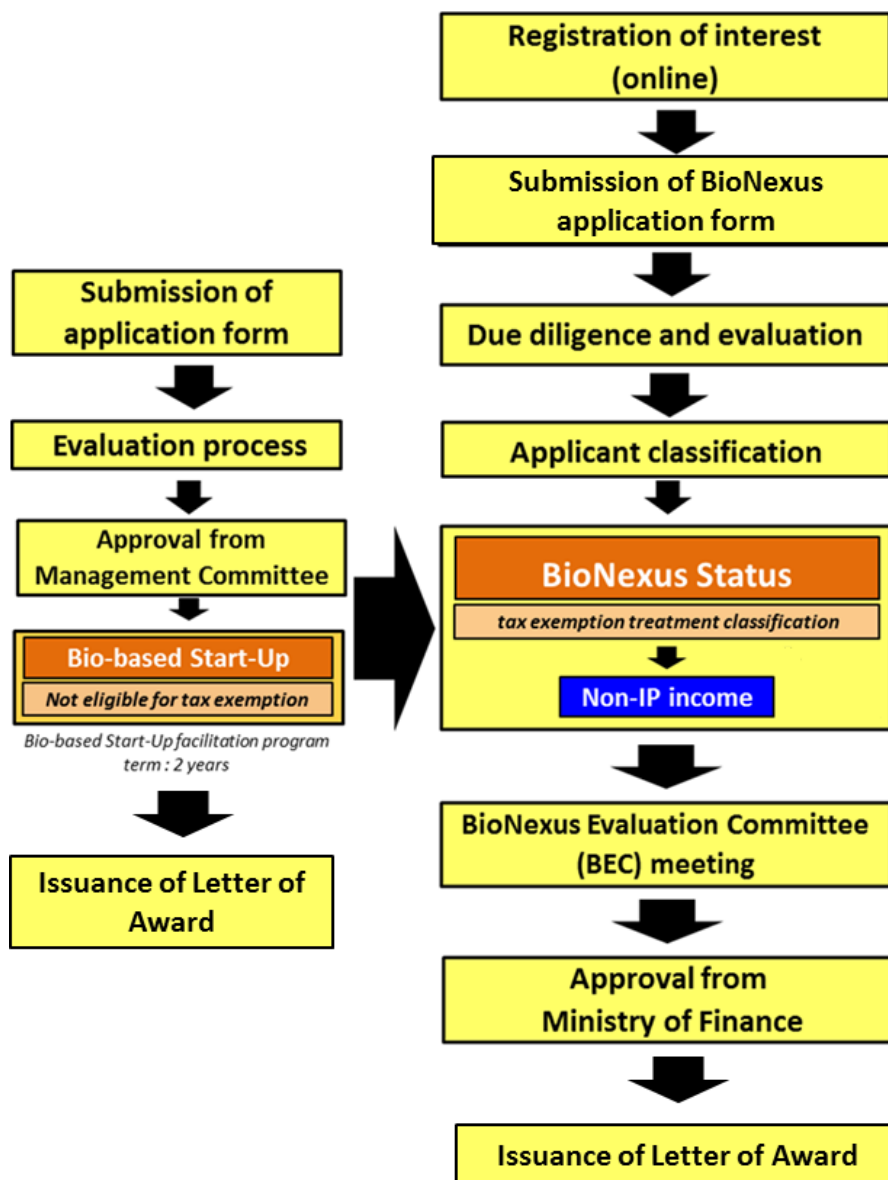
Overview of Bioeconomy Initiatives and BioNexus 3.0 Framework

Tax treatment	Summary
i. Tax exemption (Investment Tax Allowance)	A tax exemption of seventy percent (70%) on statutory income derived from a new business or an expansion project that is equivalent to an allowance of one-hundred percent (100%) of qualifying capital expenditure incurred for a period of five (5) years.
ii. Tax rate	A BioNexus Status company is entitled to a concessionary tax rate of 20% on statutory income from QA for ten (10) years upon the expiry of the tax exemption period
iii. Tax deduction	<ul style="list-style-type: none"> a. Tax deduction for investors; b. Double deduction on expenditure incurred for R&D; and c. Double deduction for R&D expenditure and promotion for exports.
iv. Others	A BioNexus Status company is entitled to: <ul style="list-style-type: none"> a. Exemption of import duty on raw materials/components and machinery and equipment; and b. Industrial building allowance.

Refer to **Chapter 4** for details on the tax incentives available under BioNexus Status.

2.3 BioNexus Status application

2.3.1 Application process flow



2.3.2 BioNexus Evaluation Committee (BEC)

BEC is a committee of the Board of Directors (the Board) of Bioeconomy Corp comprising relevant representatives from various ministries and government agencies. It is primarily responsible for the review, evaluation, assessment and recommendation to the Ministry of Finance (“MoF”) for its approval relating to the following:

- i. Application, variation and revocation for BioNexus Status; and
- ii. Application and variation of the tax incentives.

Chapter 3: BioNexus 3.0 Framework

Chapter 3.0 BioNexus 3.0 Framework

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3.0 BioNexus 3.0 Framework

3.1 Eligibility criteria

Applicant must fulfil all the following eligibility criteria at the point of application for BioNexus Status:

- a. A separate legal entity to undertake QA with minimum paid-up capital of RM250,000;
- b. Proposed QA (product/services) must have biotechnology element;
- c. Projection of full-time employment, knowledge workers percentage and R&D projects; and
- d. Complies with applicable laws, regulations and guidelines.

3.1.1 Separate Legal Entity

3.1.1.1 Incorporation of a local company in Malaysia

- A separate legal entity to undertake QA with minimum paid-up capital of RM250,000.
- Must be incorporated under the Malaysian Companies Act 2016.
- A Certificate of Incorporation will be issued by the Companies Commission of Malaysia (CCM) upon compliance with the incorporation procedures and submission of duly completed incorporation documents.

3.1.1.2 New or existing business

- New business is eligible for ten (10) years of tax exemption period.
- However, for a company already commenced its operation^{Note 5}, can be considered as a new business subject to the following criteria:
 - i. Proposed QA have commenced not more than one (1) year from the date of application received; and
 - ii. Malaysian equity ownership of at least sixty percent (60%).
(as per Malaysian Investment Development Authority's ("MIDA") "Desirous Clause" criteria for tax exemption)
- Existing business (expansion project) is eligible for five (5) years of tax exemption subject to the following criteria:
 - i. The applicant has been in operation for more than twenty-four (24) months and the business has generated revenue either from qualifying activities or non-qualifying activities; and
 - ii. The applicant must undertake new investment equivalent to a minimum of thirty percent (30%) of total fixed assets^{Note 6} involved in the production process. For services companies, a minimum of thirty percent (30%) of the total fixed asset^{Note 6} involved in the business; and

Note 5: Commencement of business means the date the BioNexus Status company commences its operation, i.e. upon issuance of its first (1st) sales invoice.

Note 6: Total fixed assets at net book value

- iii. The new investment will increase the business capacity equivalent to a minimum thirty percent (30%) of current production capacity **or current services (sales/revenue) capacity**; or
 - iv. The new investment will produce new related product **or services** equivalent to a minimum thirty percent (30%) of current production capacity **or current services (sales/revenue) capacity**.
- Upon approval:
 - i. BioNexus Status company undertaking manufacturing activity must commence its QA within twenty-four (24) months from the approval date; or
 - ii. BioNexus Status company providing services must commence its QA within twelve (12) months from the approval date.
 - iii. BioNexus Status company undertaking expansion project must complete within twenty-four (24) months from the approval date.

3.1.1.3 Ownership limitation

- Holding or related company is restricted to a maximum number of two (2) BioNexus Status companies in each cluster, **(Agriculture, Healthcare and Industrial)** and the qualifying activities must be under different sub-clusters.
- “Related company” is defined as:
 - i. the operations of which are or can be controlled, either directly or indirectly, by the first (1st) mentioned company;
 - ii. which controls or can control, either directly or indirectly, the operations of the first-mentioned company; or
 - iii. the operations of which are or can be controlled, either directly or indirectly, by a person who controls or can control, either directly or indirectly, the operations of the first-mentioned company;
- Provided that a company shall be deemed to be a related company of another company if:
 - i. at least twenty percent (20%) of its issued share capital is beneficially owned, either directly or indirectly, by that other company; or
 - ii. at least twenty percent (20%) of its issued share capital of that other company is beneficially owned, either directly or indirectly, by the first-mentioned company.
- The technology must reside with the applicant which legal rights have been obtained from the technology owner.
- A BioNexus Status company is not allowed to use/share the facility/resources of another BioNexus Status company without legal rights agreement.

3.1.2 Proposed QA

The proposed QA must have biotechnology element.

3.1.2.1 Biotechnology related activity

- An applicant who is merely repackaging, distributing, trading biotechnology products or providing consultation does not qualify for BioNexus Status.
- The proposed project must be commercially viable and ready for commercialisation.
- The proposed project must be undertaken in Malaysia.
- A BioNexus Status company must at all-time undertake the approved QA as stipulated in the BioNexus Letter of Award (“LOA”) and Terms and Conditions.

3.1.2.2 Limitation to undertake Non-QA

- A BioNexus Status company is allowed to generate revenue from non-QA up to ten percent (10%) of its annual revenue and subject to tax.
- Similarly, a BioNexus Status company is allowed to generate revenue from downstream products/services and/or by-products/services limited to ten percent (10%) of its annual revenue and subjected to tax.

Example:

QA	Biotechnology Element	Eligible Revenue Stream
Commercialisation of marine fish species	Cultivation of microalgae as aquaculture feed	1. Sale of microalgae as aquaculture feed; 2. Sale of fingerlings; and 3. Sale of grown-out fish - <i>(limited to 10% of annual revenue)</i>
Commercialisation of fruit plantlets through tissue culture technology	Tissue culture technology	1. Sale of tissue culture plantlets; 2. Sale of planting materials; and 3. Sale of fruits e.g. banana, pineapple etc. - <i>(limited to 10% of annual revenue)</i>

3.1.2.3 Location of operation

- BioNexus Status company must locate its operations and undertake the QA at the Location of Operations as defined and specified in the LOA.
- Where there is a change in the location of its operations from the address specified in the LOA, the BioNexus Status company must immediately notify Bioeconomy Corp in writing within ninety (90) days as stated in the BioNexus Status Terms and Conditions.

3.1.3 Complies with applicable laws, regulations and guidelines

The applicant must:

- Comply with all applicable laws including, without limitation, statutory, regulatory and/or licensing requirements;
- Obtain and maintain all other necessary licenses, permits, approvals and authorisation relating to the undertaking of the proposed activities;
- Comply with all environmental, ethical and other policies, rules, regulations and guidelines as imposed by the relevant government authorities; and
- Not infringe any intellectual property rights of any third party.

3.2 Post-approval monitoring and compliance requirement

Upon approval of the BioNexus Status, the company must comply with several compliance requirements, including but not limited to the following:

- Continuous Research & Development;
- Full-time employment and knowledge workers;
- Approved investment and annual business spending requirement; and
- Reporting, notification and review process.

3.2.1 Continuous Research & Development requirement

The applicant must undertake continuous research and development work with access or capability to perform said activities.

3.2.1.1 Definition of R&D

“A systematic study undertaken in the field of science or technology to gain knowledge and insight with the objective to devise new or improved products or services”

- The applicant must submit the proposed R&D project in relation to the proposed activities for the BioNexus Status application.
- Contract Research Organisation (CRO) is excluded from the requirement to conduct R&D.
- The proposed R&D project must be within the QA and demonstrate commercial potential.
- R&D activities can be undertaken in-house or in collaboration with third parties, whether foreign or local. If the R&D is undertaken in collaboration with third parties, the applicant is required to submit documentary evidence of concluded arrangements.
- R&D activities such as pre-clinical and clinical trials can be conducted out of Malaysia provided that such services are unavailable in the country.

3.2.1.2 Limitation on the R&D activities

The following do not qualify as R&D activities:

- R&D activities involving aesthetic changes to the current product(s) or improvement on the packaging.
- R&D in quality control or routine testing of materials, devices, products or produce.
- R&D in the social sciences or humanities.
- Routine data collections for any purposes.
- Efficiency surveys of management studies.
- Market research or sales promotion.

3.2.1.3 Minimum R&D Investment Requirement

- A BioNexus Status company must invest at least three percent (3%) of its annual revenue into R&D activities.
- Qualifying R&D expenditures may include, but not limited to the following:
 - i. Patent registration costs
 - ii. R&D raw materials and related consumables
 - iii. R&D lab maintenance costs and lab equipment
 - iv. Field trial and prototyping cost
 - v. Payroll on R&D staffs, seminars, travelling, etc.
 - vi. Utilities related to R&D
 - vii. Calibration and validation cost
 - viii. Clinical trial (up to Phase III^{Note 7})
 - ix. Transportation and lab rental
- However, qualifying expenditures will not include interest payments, building costs, acquisition costs or any cost that could not be directly linked to a specific IP asset.
- Capital expenditures for R&D are not considered as qualifying expenditures.

Note 7:

Phase I - studies to assess the safety of a drug or device.

Phase II - studies to test the efficacy of a drug or device.

Phase III - studies involve randomised and blind testing in several hundred to several thousand patients.

Phase IV - studies, often called Post Marketing Surveillance Trials, are conducted after a drug or device has been approved for consumer sale.

3.2.2 Full-time and knowledge workers employment requirement

- Upon approval, BioNexus Status company must at all times comply with Bioeconomy Corp's minimum full-time employment and knowledge workers requirements.
- A projection for five (5) years on full-time employment (Malaysians and non-Malaysians) and knowledge workers must be submitted at the point of application and to be committed solely for the purpose of undertaking the QA.

- BioNexus Status companies must re-submit a new 5 years projection of full-time employment (Malaysians and non-Malaysians) and knowledge workers by the end of the 5th financial year.
- A BioNexus Status company must employ the minimum number or percentage of knowledge workers respective to its sector, which will be determined by BEC. The benchmark is as stated in Reference 2.

3.2.2.1 Definition of Knowledge Workers

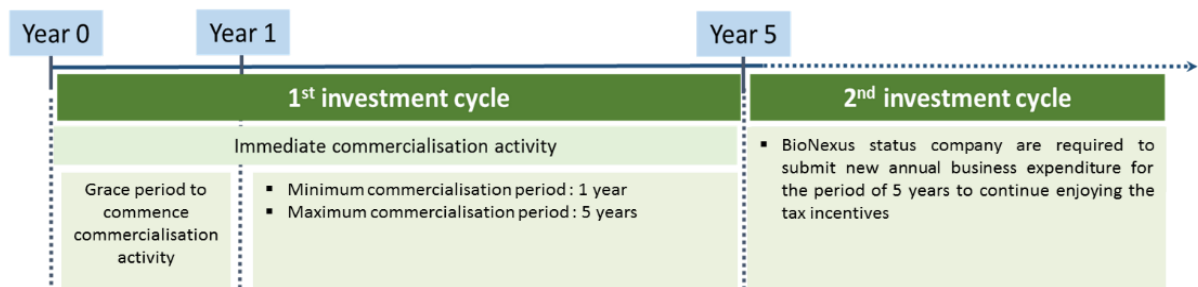
For the purposes of the BioNexus Status, “knowledge workers” mean the persons who are:

- i. directly involved in the technical development and deployment of biotechnology products and services; or
- ii. involved in important business function in undertaking the QA; and
- iii. possess the following qualifications:

Eligible education level	Working experience
1. Master’s Degree or higher in;	
a. Life sciences or biotechnology-related field	N/A
b. Other majors	1-year relevant working experience
2. Bachelor’s Degree :	
a. Life sciences or biotechnology-related field	1-year relevant working experience
b. Other majors	3 years of relevant working experience
3. Diploma	
a. Diploma in life sciences or biotechnology-related field	3 years of relevant working experience
b. Other majors	5 years of relevant working experience
4. Others qualifications	
Individuals with 10 years of relevant working experience in the biotechnology industry	

3.2.3 Approved investment and annual business spending requirement

- A company generating non-IP income must comply with the minimum investment and annual operating expenditure requirement as approved by the BEC (as stated in the BioNexus Letter of Award).
- A projection of approved investment for five (5) years must be submitted at the point of application and to be committed solely for the purpose of undertaking the QA.
- The applicant must be able to undertake the committed proposed investment.
- The projection of approved investment and annual business spending will be deliberated by the BEC. The approved investment^{Note8} is for 1st investment cycle whilst annual business spending is for 2nd investment cycle as follows:



- BioNexus Status companies must re-submit a new 5 years projection of annual business spending by end of the 5th financial year.

Note 8: For an existing business, the company is required to submit 2 years of approved investment and 3 years of annual business spending at the point of application.

3.2.3.1 Definition of eligible approved investment

- Approved investment is defined as the planned investment (or project cost) in the proposed QA, by BioNexus Status company.
- The planned investment or project cost include working capital, capital expenditure (CAPEX) purchases or other operating and activities of the companies. Sources of investment excluding land are as listed below:
 - i. Long-term liabilities (bank loan or mortgage);
 - ii. Paid-up capital and other securities;
 - iii. Capital reserve; or
 - iv. Any other forms of funding or investment for the purpose of raising funds.

3.2.4 Reporting, notification and review process

BioNexus Status company is required to comply with the reporting, notification and review process as stated in the BioNexus Terms and Conditions.

Refer to **Reference 3**: BioNexus Terms and Conditions.

3.3 Re-application and Non-eligibility clause

3.3.1 Re-application

The applicant is not allowed to resubmit the BioNexus Status application within six (6) months upon date of rejection of its earlier application.

3.3.2 Non-eligibility

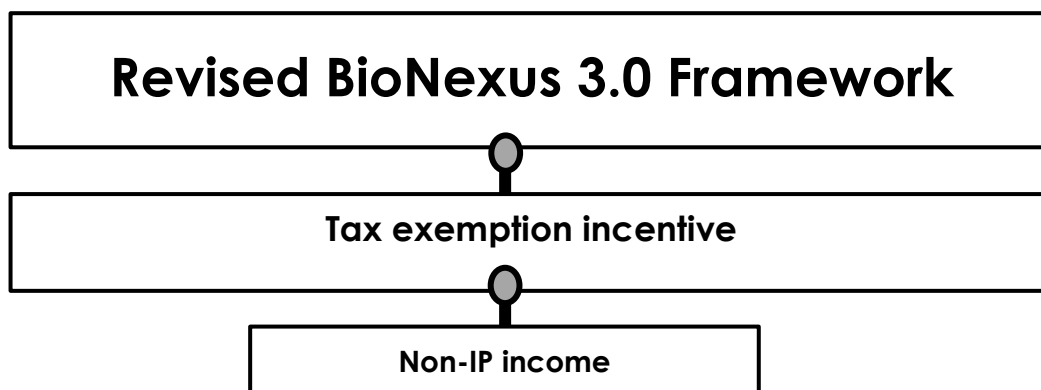
Companies that have already been awarded, utilised other special statuses and/or incentives offered by the Government [e.g. by MIDA, Malaysia Digital Economy Corporation Sdn Bhd (MDEC), Halal Industry Development Corporation (HDC), Iskandar Regional Development Authority Malaysia (IRDA), Northern Corridor Implementation Authority (NCIA), East Coast Economic Region Development Council (ECERDC) etc.] for the same qualifying activity are not eligible to apply for the BioNexus Status.

Chapter 4: Details on Tax Incentives Available Under BioNexus Status

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4.0 Overview

The major variation/amendment of the BioNexus 3.0 Framework is the tax exemption treatment awarded to the BioNexus Status company. Under the revised framework, tax exemption will be awarded based on IP or Non-IP income. Details on the tax exemption incentives can be summarised as follows:



Eligibility criteria:

Utilises knowledge/ technology/processes/etc. other than IP asset in its approved qualifying activity

Tax exemption percentage:

Based on BioNexus ecosystem promoted clusters segmentation

4.1 Tax exemption incentives for income on approved QA

4.1.1 Tax exemption treatment on Non-IP income

Non-IP income derives from commercialisation activities undertaken by the applicant within the BioNexus Status promoted clusters, which is generated from knowledge/technology/processes/etc. other than IP assets.

The proposed activity must be within the purview of the NBP and falls into the following three (3) focus clusters:

- i. Agricultural Biotechnology;
- ii. Healthcare Biotechnology; and
- iii. Industrial Biotechnology.

4.1.1.1 Eligible Non-IP income

For the purpose of tax exemption, eligible applicant undertaking commercialisation activities with Non-IP income will be evaluated and classified in accordance with the following ecosystem classification:

i. **Ecosystem Anchor:**

- Percentage of tax exemption for Non-IP income will be awarded based on in-house manufacturing/production activities or which are outsourced to third (3rd) party.
- An applicant is allowed to outsource the manufacturing/production activities (partially/wholly) only for its in-house developed technology.
- An applicant who has obtained technology licenses from third (3rd) parties must undertake the manufacturing/production activities in-house. For ease of reference, the summary is as follows:

Technology	Manufacturing/Production activity
In-house developed	Activity can be undertaken in-house or outsourced
Licensed from 3 rd parties	Activity must be undertaken in-house

- An applicant is only allowed to partially/wholly outsource its manufacturing/production activities for a maximum period of two (2) years.

ii. **Ecosystem Support:**

Applicant involved in the provision of services based activity utilising biotechnology processes. Different tax exemption percentages will be awarded based on the following categories:

- a. Contract research and manufacturing services (“CRAMS”); and
- b. Contract research services (“CRO”).

4.1.1.2 Tax exemption percentage for non-IP income

Categories	Tax exemption		
	%	New Business	Existing Business
		Years	Years
Ecosystem Anchor (Manufacturing)			
Manufacturing/production activities conducted in-house <i>Manufacturing/production activities are allowed to be outsourced to the third (3rd) party for a maximum period of 2 years (Only applicable to New Business).</i>	70	10	5
Ecosystem Support (Services)			
Contract Research and Manufacturing Services (“CRAMS”)	70	10	5
Contract Research Organisation (“CRO”)	70	10	5

4.1.2 Tax exemption – Investment Tax Allowance

A tax exemption of **seventy percent (70%)** on statutory income derived from a new business or an expansion project that is equivalent to an allowance of one-hundred percent (100%) of qualifying capital expenditure incurred for a period of five (5) years.

4.1.3 Application and evaluation process

4.1.3.1 Application process

- The applicant must submit an application for tax exemption together with its BioNexus Status application. This must be submitted to Bioeconomy Corp by completing the 'BioNexus Status Application Form'.
- The applicant needs to select, either:
 - i. An exemption of statutory income in respect of a new business or an expansion project (this is for a company with low capital expenditure and making high profit); or
 - ii. An exemption on statutory income equivalent to an allowance of qualifying capital expenditure incurred within a period of five (5) years (this is for a capital-intensive company with long gestation period).

4.1.3.2 Evaluation and approval process

- All applications will be processed by an Account Manager from Bioeconomy Corp for recommendation to BEC.

4.1.4 Separate Accounts

A BioNexus Status company which qualifies for tax exemption must maintain a separate account for the IP and Non-IP income derived from QA and non-QA.

4.2 Concessionary tax rate of 20% incentive

Segregation of IP and Non-IP Income and the calculation of tax payable:

- Under existing P.U (A) 156, there is no separation between IP and Non-IP income.
- Under the new framework, the segregation between IP income and Non-IP Income is continued and applied in the post exempt period (after the tax exemption period expired).

4.2.1 Eligibility criteria

- The applicant will be assessed on the two general eligibility criteria as follows:
 - i. The company must retain the BioNexus Status at the point of application;
 - ii. The company must comply with the current BioNexus Terms & Conditions as per the latest compliance review from Bioeconomy Corp's Monitoring & Compliance department.
 - iii. Tax compliance checks (tax return form and payment) by Inland Revenue Board.

4.2.2 Exemption Amount

The total exemption amount will be as follows:

a = IP Income: 20% x [SI x Nexus Ratio]

The same Nexus ratio will be used in the calculation of the concessionary tax rate.

b = Non-IP Income: 20% x [SI x Non-IP tax exemption percentage]

The same Non-IP tax exemption percentage is still applicable.

Total tax exemption amount is a + b

For Non-IP income, the company is required to comply with the substantial activity requirements as stated in Para 3.2.2 and 3.2.3 (only annual business spending requirement) to qualify for the Concessionary Tax Rate incentive.

4.2.3 Application process

- Application must be submitted to Bioeconomy Corp **during the final year** of tax exemption period (the 10th or 5th year). The application must be submitted **at least six (6) months before the end of the financial year**.
- The documents required from the applicant are as follows:
 - i. Official Letter to request for the concessionary tax rate;
 - ii. Application Form for Concessionary Tax Rate; and
 - iii. Statutory Declaration Form.
- Evaluation process will be conducted by an Account Manager from the Tax Advisory Services Unit, BioNexus Evaluation Department and will make a recommendation to the BEC members and decision will be forwarded to Ministry of Finance for final approval.
- The Account Manager may request additional information or documentation to support the application for the deliberation by the BEC members.

4.3 Tax deduction incentives

4.3.1 Tax deduction for investors

4.3.1.1 Definition of Investment for Investing Company

- This rule is effective from the year of assessment 2016;
- It is provided in the Guidelines on Income Tax (Deduction for Investment in a BioNexus Status Company) Rules 2016;
- Tax deduction eligible for investors is equivalent to the value of the investment made in a BioNexus Status company for the sole purpose of financing activities at the initiation of commercialisation stage of a new business in arriving at the adjusted income of a qualifying person;
- “Investment” means an investment in the form of cash for which there is no obligation to repay by BioNexus Status company or holding of paid-up shares in cash in respect of ordinary shares in a BioNexus Status company; and
- “Initiation of commercialisation stage” means the stage of research, assessment and development of an initial concept or prototype before the technology or product is commercialised excluding increasing product capacity, product development or product marketing.

4.3.1.2 Condition for Deduction

The deduction allowed under these Rules is subject to the following conditions:

- The qualifying person has submitted the application for approval to the Minister through the Bioeconomy Corp for a period not earlier than 1 January 2016 and not later than 31 December 2020;
- If the qualifying person is a company, no related company has been allowed the deduction under these Rules or the Income Tax (Deduction for Investment in a BioNexus Status Company);
- If the qualifying person is an individual:
 - i. Only three applications shall be allowed under these Rules;
 - ii. Each approval shall be given in respect of investment made in three different activities of a new business which are agriculture, healthcare and industrial;
 - iii. The investment shall be made in a BioNexus Status Company which any of its paid-up capital is not owned by the following:
 - a. The spouse of the individual;
 - b. The brother or sister of the individual or of the spouse of the individual;

- c. The parent of the individual or of the spouse of the individual;
- d. The child including a stepchild or child adopted in accordance with any law, of the individual;
- e. The grandparent or grandchild of the individual or of the spouse of the individual;
- f. The spouse of any of the individual referred to in sub-subparagraph (b); or
- g. The uncle, aunt or cousin of the individual or of the spouse of the individual.

4.3.1.3 Eligibility criteria

The following are the criteria to be met by investors in claiming tax deduction:

- The investment made must be in the form of cash and converted into ordinary shares only. Any investment in the form of “in-kind” is not qualified for the incentive;
- It is for the sole purpose of financing activities at the initiation of the commercialisation stage of a new business approved by the Minister;
- For investments in the form of share capital, it must not be disposed of within five (5) years from the date of last investment. If the disposal is made within five (5) years, any proceeds on disposal will be added back in ascertaining the adjusted income;
- If the investor is a company, it must be incorporated under the Companies Act, 1965;
- If the investor is an individual, he must be a Malaysian citizen, resident and has business income source;
- The investment must only be made after the investee company has obtained BioNexus Status;
- If the investment is made prior to the commencement of a new business, it is deemed to be incurred on the date of the new business commences. This date shall be determined by Bioeconomy Corp;
- The deduction on the investment would be applicable at all phases within the initiation of commercialisation stage. The amount of investment made for each phase has to be approved by the Minister of Finance before a deduction can be claimed;
- The deduction is equivalent to the total investment made at the pre-commercialisation stage to set off against investor’s statutory income.

- The investment must be utilised to purchase capital expenditure only. Any amount utilised on operating expenditure will be considered only if it is directly related to the approved QA.
- The tax deduction for investors will cease when a BioNexus Status company commences its operation which is based on the issuance of the first sales invoice.

4.3.1.4 Application and approval process flow

The application must be submitted to Bioeconomy Corp and to be deliberated by BEC for the recommendation of approval from MoF.

4.3 Tax deduction incentives

4.3.2 Industrial Building Allowance

4.3.2.1 Definition of Qualifying Building Expenditure

- This allowance is provided in the Guideline for Income Tax (Industrial Building Allowance) (BioNexus Status Company) Rules 2007.
- This is effective for applications submitted to Bioeconomy Corp on or after 2 September 2006.
- In accordance with the guideline mentioned above, 'qualifying building expenditure' means capital expenditure incurred on the construction or purchase of a building but does not include capital expenditure incurred on buildings used for storage or as living accommodation which are provided wholly and partly for the use of a director or an individual who is a member of the management, administrative or clerical staff.
- A claim to be made by a BioNexus Status company is equivalent to one-tenth of qualifying building expenditure incurred in the basis period of the year of assessment and for each of the following nine (9) years of assessment.

4.3.2.2 General Rules on Claiming IBA

The following are the criteria to be met in claiming IBA:

- Qualifying building expenditure is incurred by a company resident in Malaysia;
- A company must have BioNexus Status in the basis period for the year of assessment used for the sole purpose of its new business or expansion project;
- An allowance to be made is equivalent to one-tenth of qualifying building expenditure incurred in the basis period of a year of assessment and for each of the following nine (9) years of assessment;
- If the qualifying building expenditure is incurred prior to the commencement of new business or expansion project, it is deemed to be incurred on the date the business or project commences;
- The first qualifying building expenditure incurred will be on a date determined by Bioeconomy Corp and the date will not be earlier than 2 September 2006;

Chapter 4: Details on tax incentives available under BioNexus Status

- For the purpose of determination on first qualifying building expenditure, the company must inform Bioeconomy Corp in writing and support with evidence e.g. Sales and Purchase agreement, invoices from the contractor for constructing a building, etc.;
- Bioeconomy Corp will issue an approval letter on the commencement date of first qualifying building expenditure incurred; and
- Where a building qualifies for the allowance is disposed within two (2) years from the date of completion or acquisition of the building, the allowance which has been made by the company shall be withdrawn in the basis period for the year of assessment that the building is disposed of.

4.3 Tax deduction incentives

4.3.3 Double Deduction for Expenditure Incurred for R&D

- A BioNexus Status company is eligible to claim a double deduction on expenditure (non-capital expenditure in nature) incurred for R&D.
- For example, raw materials used in research, manpower in a research project, technical services, travelling cost, transportation cost, maintenance cost, rental and other revenue expenditure incurred directly for research. This incentive is given for approved research projects.
- Double deduction means further deduction on the same expenses in arriving at adjusted income. Before claiming for the double deduction, the research project must be approved by the Inland Revenue Board (“IRB”).
- In the case of a claim during the tax-exempt period, a further amount of deduction of the R&D expenditure (non-capital expenditure in nature) will be accumulated and can be utilised in the first year of assessment after the tax-exempt period.

4.3.3.1 Eligibility criteria

- Double deduction is given to a person resident in Malaysia who directly incurs revenue expenditure on research;
- “Person” as defined under Section 2 of Income Tax Act, 1967 includes a company, a body of persons and a corporation sole;
- The expenses must be incurred specifically for undertaking in-house research in relation to the business;
- The research project must be approved by the IRB;
- The expenditure for the approved research project must be incurred in the basis period; and
- For further details, please refer to the Public Ruling No. 5/2004 – Double Deduction Incentive on Research Expenditure and its addendum.

4.3.3.2 Application process flow

This must be submitted with relevant supporting documents six (6) months before the financial year-end of the business to Technical Division, IRB.

4.3 Tax deduction incentives

4.3.4 Double Deduction for Expenditure Incurred for Promotion for Exports

- This incentive is available to resident manufacturing, trading and agricultural companies which have incurred expenses primarily and principally for the purpose of seeking opportunities or in creating or increasing demand for the export of goods or agricultural products manufactured or produced in Malaysia.
- This incentive is available to resident manufacturing, trading and agricultural companies which have incurred expenses for the export of goods or agricultural products manufactured or produced in Malaysia.
- During the tax-exempt period, the company qualify for a deduction on expenditure incurred on the promotion for exports. However, the deduction can only be claimed after the tax-exempt period.
- The duplicate copy (without any supporting documents) is to be sent to the Technical Division, IRB for record-keeping upon submission of the income tax return which is within seven (7) months from the financial year-end.

4.4 Other tax incentives

4.4.1 Import Duty Exemption on raw materials/components, machinery and equipment

The applicant is eligible for the following incentives, where applicable:

- i. Import Duty Exemption on Machinery, Equipment, Spare Parts and Consumables.
- ii. Import Duty Exemption on Raw Materials and Components.
- iii. Import Duty Exemption on Machinery, Equipment and Materials for Selected Services Sub-Sectors.

4.4.1.1 Eligibility Criteria

- Machinery and equipment must not be produced locally;
- It must be imported directly and used in the manufacturing, agricultural and related services sectors;
- Raw materials and components used directly in the production of finished products;
- As a prerequisite, the applicant is required to register with the Department of Occupational Safety and Health (DOSH); and
- Only applications for total duty/tax exemption of RM5,000 and above (per submission) will be considered for exemption.

4.4.1.2 Application Process

- Forms can be downloaded from MIDA's website;
- MIDA will evaluate and assess the application;
- Upon approval by the MoF, MIDA will issue a letter of approval to the applicant; and
- For further details of the application procedures and sample of the application forms, please refer to the "Import Duty and Sales Tax Exemption on Imported **Raw Materials and Machinery – Process and Procedures**".

References

Reference 1: Promoted clusters under BioNexus 3.0 Framework

Reference 2: Knowledge workers percentage requirement

Reference 3: BioNexus Status Terms and Conditions

**Reference 1:
Promoted Clusters under BioNexus 3.0 Framework**

1.1 AGRICULTURE BIOTECHNOLOGY (AGBIOTECH)

1.1.1 Crop biotechnology

Qualifying activities:

- a) Planting materials
(e.g. plant tissue culture, use of markers/molecular tools/methodologies, etc.)
- b) Crop nutrition/enhancers:
(e.g. bio-fertiliser, soil enhancer, etc.)
- c) Crop protection
(e.g. bio-pesticide, bio-herbicide, bio-control, etc.)
- d) Emerging areas
(e.g. genetically modified organisms, polyploidisation, etc.)

1.1.2 Natural product discovery

Qualifying activities:

- a) Cosmeceuticals
- b) Nutraceuticals
- c) Functional Ingredients
- d) Botanical Extracts
- e) Food / Functional Food
- f) Dietary Supplement

1.1.3 Livestock biotechnology

Qualifying activities:

- a) Breeding and nucleus farms
(e.g. assisted reproductive techniques, marker-assisted techniques, etc.)
- b) Animal feed and nutrition
(e.g. probiotics, vitamin & protein supplements, etc.)
- c) Animal health diagnostics and biologics
(e.g. vaccines, diagnostic kits, etc.)
- d) Remediation of animal waste
(e.g. biogas, bio-fertiliser, etc.)
- e) Emerging areas
(e.g. Embryo sexing, cloning, etc)

1.1.4 Aquaculture & marine biotechnology

Qualifying activities:

- a) Aquaculture breeding and cultivation
(e.g. polyploidy, *in vitro* fertilisation, sexing, etc.)
- b) Aquaculture feed and nutrition
(e.g. probiotics, vitamin & protein supplements, planktons, algae, single-cell protein, etc.)
- c) Aquaculture health diagnostics and biologics
(e.g. vaccines, diagnostic kits, etc.)

1.1 AGRICULTURE BIOTECHNOLOGY (AGBIOTECH)

1.1.5 Contract research services (CRO) providers in agriculture

Qualifying activities:

- a) Screening and identification of active components
- b) Process and technology development
- c) Analytical profile and standardisation protocol development
- d) Storage and stability profiling
- e) Protocol development
- f) Toxicity and safety profiling
- g) Good Laboratory Practices (GLP) & Good Manufacturing Practices (GMP) standards for product development
- h) Pilot plant production and services
- i) Conducting pre-clinical trials

1.1.6 Contract Research and Manufacturing Services (CRAMS)

Companies that provide contract research and manufacturing services to third parties.

Research includes the following:

- a) Provision of contractual R&D services to contracting parties; and/or
- b) Internal R&D conducted by the company in order to provide its contract manufacturing services to third parties.

The above qualifying activities include the following:

- i. Crop biotechnology;
- ii. Natural products;
- iii. Livestock biotechnology; and
- iv. Aquaculture and marine biotechnology

1.2 INDUSTRIAL BIOTECHNOLOGY (BIOINDUSTRIAL)

1.2.1 Fine, bulk & specialty chemicals (biochemicals)

Qualifying activities:

- a) Fine, Specialty and Bulk chemicals:
Produced from bio-based and renewable feedstocks and they are base chemicals for industrial manufacturing processes.
(e.g. Organic acids (Succinic acid, Lactic acid), Amino acids (Lysine, Methionine), Alcohols & Ketones (BDO, Butanol))
- b) Active ingredient/compound:
Extracts from natural resources.
(e.g. Standardised herbal extract, natural flavour and fragrance)

1.2.2 Biofuel & bioenergy

Qualifying activities:

- a) Biofuels:
Fuels produced directly or indirectly from organic material; including plant materials, microorganism, biomass and animal waste.
(e.g. Bioethanol, Biomethane, Biohydrogen)
- b) Bioenergy:
Renewable energy composed of or produced from bio-based feedstocks or biofuel as compared to fossil-based / petroleum-based feedstocks.
(e.g. Biogas power plant, Biomass power plant)

1.2.3 Biomaterials

Qualifying activities:

- a) Biomaterials:
Include Bioplastics, Biopolymers and biocomposites materials made from renewable bio-based resources as compared to fossil-based materials derived from petroleum.
(e.g. Polyhydroxyalkanoates, Polyols, Polyamides)
- b) Renewable and Biodegradable products:
Products made from renewable bio-based resources such as cellulose, starch, natural fibres.
(e.g. Biodegradable packaging, bio-based panel)

1.2.4 Biocatalyst

Natural substances to speed up (or catalyze) chemical reactions. They can be in the form of Enzymatic processes or Microbial processes or the production of the biocatalyst.
(e.g. Industrial enzyme, Effective microbes)

1.2 INDUSTRIAL BIOTECHNOLOGY (BIOINDUSTRIAL)

1.2.5 Bioremediation

Treatment that uses naturally occurring organisms or enzymes to remove or neutralise pollutants from a contaminated site and biological treatment for domestic, municipal and industrial waste.

(e.g. phytoremediation, bioventing, bioleaching, land farming, bioreactor, composting, bioaugmentation, rhizofiltration, and biostimulation, POME treatment, MSW management.)

1.2.6 Bioprospecting

Applicable to all five (5) focus areas, ie biochemicals, biofuel, biomaterials, biocatalysts and bioremediation.

1.2.7 Contract Research and Manufacturing Services (CRAMS)

Companies that provide contract research and manufacturing services to third parties. Research includes the following:

- a) Provision of contractual R&D services to contracting parties; and/or
- b) Internal R&D conducted by the company in order to provide its contract manufacturing services to third parties.

The above qualifying activities include the following:

- i. Biochemicals;
- ii. Biofuel;
- iii. Biomaterials;
- iv. Biocatalysts; and
- v. Bioremediation

1.3 HEALTHCARE BIOTECHNOLOGY (HEALTHCARE BIO)

1.3.1 Contract Research Organisations (CRO)

Conduct non-clinical testing or pre-clinical testing or clinical trials and/or central lab activities related to clinical trials.

Qualifying activities:

- a) **Pre-clinical testing Lab Services:**
Activities of CROs in this category include *in-vivo* and *in-vitro* analyses, toxicology, histopathology, molecular biology, provides animal models for immune responses *etc.*
- b) **Clinical Research Organisations:**
Organisations serving pharmaceutical, biotechnology, generic drug, OTC/consumer healthcare and medical device companies; offering comprehensive clinical trial management services for designing, managing, monitoring and reporting on Phase 1–4 clinical research trials.
- c) **Discovery and Development Services:**
Organisations that offer custom synthesis of APIs and novel compounds, catalogue compound services, route screening, lead optimisation, utilising all developing proprietary drug discovery and/or drug delivery systems. Example: *nucleic acid, RNA interference (RNAi), and nanotechnology.*
- d) **Bioinformatics / Healthcare *Big Data*:**
Activities include computational genomics & proteomics, clinical trial results prediction *etc.*
- e) **Proprietary Technologies Providers (*for new drug discovery etc.*)**
(e.g. microfluidics and mass spectrometry, X-ray crystallography, NMR, in silico protein structure modelling, novel chemical synthesis procedures, small interfering RNA (si RNA), gene sequencing and data mining technology-computer algorithms, hardware, etc.

1.3 HEALTHCARE BIOTECHNOLOGY (HEALTHCARE BIO)

1.3.2 Contract Research and Manufacturing Services (CRAMS)

Companies that provide contract research and manufacturing services to third parties. Research includes the following:

- a) Provision of contractual R&D services to contracting parties; and/or
- b) Internal R&D conducted by the company in order to provide its contract manufacturing services to third parties.

The above qualifying activities also include the following:

- i. Bio-manufacturing;
- ii. Primary manufacturing; and
- iii. Secondary manufacturing

1.3.3 Biopharmaceuticals and pharmaceuticals

Qualifying activities:

- a) Biopharmaceuticals – Innovator Biologics:
- b) Biopharmaceuticals – Biosimilars and Biobetters
- c) Pharmaceuticals – New Chemical Entities (NCE)
- d) Pharmaceuticals – Generics
- e) Vaccines

1.3.4 Medical devices, biosensors, and in vitro diagnostics

Qualifying activities:

- a) Medical Devices:
Research and development and manufacturing activities in line with Class C and D, as defined by the Ministry of Health as follows:

Class	Risk Level	Device examples
C	High	Lung ventilator, orthopaedic implants, baby incubator, blood oxygenator
	Moderate	blood bag, contact lens disinfecting/cleaning products, deep wound dressing, defibrillator, radiological therapy equipment
D	High	Pacemakers and their leads, implantable defibrillators, implantable infusion pumps, heart valves, inter-uterine contraceptive devices, neurological catheters, vascular prostheses, stents

1.3.5 Medical devices, biosensors, and in vitro diagnostics

- a) In Vitro Diagnostics:
Reagents & kits, devices & instrumentation, research & development and manufacturing activities in line with all classes (A, B, C & D) as defined by the Ministry of Health as follows:

Class	Risk Level
A	Low Individual Risk and Low Public Health Risk
B	Moderate Individual Risk and/or Low Public Health Risk
C	High Individual Risk and/or Moderate Public Health Risk
D	High Individual Risk and High Public Health Risk

- b) Biosensors:
Analytical devices, used for the detection of an analyte that combines a biological component with a physicochemical detector.

1.3.6 Stem cell, cellular medicine, and cellular and gene therapy products (cgtp)

Qualifying activities:

- a) Biomaterials:
This includes novel biomaterials that are designed to direct the organisation, growth and differentiation of cells in the process of forming functional tissue by providing both physical and chemical cues.
- b) Cell-based Technology:
This includes enabling methodologies for the proliferation and differentiation of cells, acquiring the appropriate source of cells such as autologous cells, allogeneic cells, stem cells genetically engineered cells, immunological manipulation and cell-based therapeutics.
- c) Biomolecules:
This includes angiogenic factors, growth factors, differentiation factors and bone morphogenic proteins.
- d) Biomechanical aspects of design:
This includes properties of native tissues, identification of minimum properties required of engineered tissues, mechanical signals regulating engineered tissues and efficacy and safety of engineered tissues.
- e) Tissue engineering and Related Support Informatics
(e.g. gene and protein sequencing, gene expression analysis, protein expression and interaction analysis, quantitative cellular image analysis, quantitative tissue analysis, in silico tissue and cell modelling, digital tissue manufacturing, automated quality assurance systems, data mining tools and clinical informatics interfaces).

1.3 Healthcare biotechnology (Healthcare Bio)

1.3.7 Biocosmeceuticals, wellness, and pharma nutrition

Qualifying activities:

- a) **Bio-Cosmeceuticals:**
Cosmetic products with biologically active ingredients purporting to have medical or drug-like benefits.
- b) **Phytomedicine:**
Herbal-based traditional medical practice that uses various plant materials in modalities considered both preventive and therapeutic. Practices that are registered and have proven medical claims are included in this category.
- c) **Botanical Drugs:**
Botanical product that proven by medical research for diagnosing, mitigating, treating, or curing disease; it is a finished, labelled product that contains ingredients from plants.
- d) **Wellness and Pharma-Nutrition:**
Medical nutrition products with proven medical claim used in patient treatment and disease management.

**Reference 2:
Knowledge workers percentage requirement**

2.1 AGRICULTURE BIOTECHNOLOGY (AGBIOTECH)

2.1.1 Aquaculture & Marine Biotechnology

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Aquaculture & Marine Biotechnology	Aquaculture Feed and Nutrition	40%
	Aquaculture Breeding and Cultivation	30%
	Aquaculture Health Diagnostics and Biologics	50%
	Emerging Areas	10%

2.1.2 Crop Biotechnology

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Crop Biotechnology	Crop Nutrition/ Enhancers	30%
	Crop Protection	30%
	Emerging Areas	40%
	Planting Materials	30%

2.1.3 Livestock

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Livestock	Animal Feed & Nutrition	30%
	Animal Health Diagnostics & Biologics	40%
	Breeding & Nucleus Farms	40%
	Emerging Areas	10%
	Remediation of Animal Waste	30%

Reference 2:
Knowledge workers percentage requirement

2.1 AGRICULTURE BIOTECHNOLOGY (AGBIOTECH)

2.1.4 Natural Product Discovery and Commercialisation

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Natural Product Discovery & Commercialisation	Cosmeceuticals	30%
	Nutraceuticals	50%
	Dietary Supplement	40%
	Food/ Functional Food	30%
	Functional Ingredients	30%
	Pharmaceuticals/Botanical Drugs	40%

2.1.5 Contract Research Organisation

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Contract Research Organisation (CRO)	Contract Research Services	20%

2.1.6 Contract Research and Manufacturing Services (CRAMS)

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Contract Research and Manufacturing Services (CRAMS)	Crop biotechnology	<i>To follow the respective sub-clusters or categories percentage</i>
	Natural products	
	Livestock biotechnology	
	Aquaculture & marine biotechnology	

Reference 2:
Knowledge workers percentage requirement

2.2 HEALTHCARE BIOTECHNOLOGY (HEALTHCARE BIO)

2.2.1 Bio-Informatics

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Bio-Informatics	Bio-Informatics	50%

2.2.2 Biopharmaceuticals & pharmaceuticals

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Biopharmaceuticals & pharmaceuticals	Biopharmaceuticals	50%
	Vaccines	50%
	Biosimilar	50%
	Pharmaceuticals- New Chemical Entities (NCE)	50%

2.2.3 Contract Research Organisation (CRO)

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Contract Research Organisation (CRO)	Clinical research organisations	50%

2.2.4 Contract Research and Manufacturing Services (CRAMS)

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Contract Research and Manufacturing Services (CRAMS)	Bio-manufacturing	50%
	Primary manufacturing	40%
	Secondary manufacturing	40%

Reference 2:
Knowledge workers percentage requirement

2.2 HEALTHCARE BIOTECHNOLOGY (HEALTHCARE BIO)

2.2.5 Drug Discovery & Drug Delivery System

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Drug Discovery & Drug Delivery System	Drug Discovery and Drug Delivery System	50%

2.2.6 Medical Devices & In Vitro Diagnostics

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Medical Devices & In Vitro Diagnostics	In vitro Diagnostics - Reagents & Kits, Devices & Instrumentation	50%
	Medical Devices	50%

2.2.7 Natural Product Discovery & Commercialisation

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Natural Product Discovery & Commercialisation	Pharmaceuticals/Botanical Drugs	50%

2.2.8 Stem Cell, Tissue Engineering and Genetic Engineering

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Stem cell, tissue engineering & Genetic Engineering	Stem Cell	50%
	Tissue Engineering	50%
	Genetic Engineering	50%

Reference 2:
Knowledge workers percentage requirement

2.3 INDUSTRIAL BIOTECHNOLOGY (BIOINDUSTRIAL)

2.3.1 Biocatalyst Enzymes

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Biocatalyst Enzymes	Biocatalyst Enzymes	30%

2.3.2 Biofuel

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Biofuel	Biogas	20%
	Bioethanol	10%
	Biobutanol	10%
	Biodiesel	10%
	Biomethanol	10%

2.3.3 Biomaterials

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Biomaterials	Biodegradable polymers using agricultural biomass	30%
	Polylactic acid (PLA) from lactic acid generated by fermentation	60%
	Starch-based polymers	10%
	Polyhydroxylalkanoate (PHA) variants	10%
	Intermediate monomers	10%

2.3.4 Bioremediation

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Bioremediation	Industrial wastes	30%
	Municipal wastes	30%
	Hydrocarbons	30%
	Photoremediation	30%

2.3 INDUSTRIAL BIOTECHNOLOGY (BIOINDUSTRIAL)

2.3.5 Fine & Specialty Chemicals (Biochemicals)

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Fine & Specialty Chemicals (Biochemicals)	Enzymatic processes	30%
	Extraction method to obtain the active compounds/ markers	30%
	Microbial processes	55%
	Using bio-based or renewable sources	30%
	Validation method	40%
	Standardised method	30%

2.3.6 Others

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Others	Bioprospecting (Microbes prospecting)	30%

2.3.7 Contract Research and Manufacturing Services (CRAMS)

Sub-Cluster	Qualifying activities	Employment of Knowledge Workers of Total Workforce (%)
Contract Research and Manufacturing Services (CRAMS)	Biochemicals	<i>To follow the respective sub-clusters or categories percentage</i>
	Biofuel	
	Biomaterials	
	Biocatalysts	
	Bioremediation	



**Reference 3:
BioNexus Status Terms and Conditions**



Terms and Conditions of BioNexus Status

..... SDN BHD (company registration no xxxxx)

("The BioNexus Status Company") must at all times fully comply with the terms specified in the attached Letter of Award and these Terms and Conditions.

1 Qualifying Activities ("QA")

1.1 Scope

QA. The BioNexus Status Company must conduct the QA specified and detailed in the attached Letter of Award.

Non-QA. The BioNexus Status company is allowed to undertake 10% of the annual revenue from the non-qualifying activity and the 10% of the annual revenue is subject to tax.

Business Plan. The QA must be performed in accordance with the Business Plan and any other documents (hereinafter collectively referred to as the "Business Plan") submitted to (in support of the Company's application for BioNexus Status) and received by Bioeconomy Corp from the Company prior to the date of the attached Letter of Award.

Changes. No change to the QA or Business Plan may be made without the prior written approval of Bioeconomy Corp.

1.2 Commencement

The BioNexus Status Company conducting manufacturing activity must commence its QA within twenty-four (24) months from the Effective Date and BioNexus Status Company providing services must commence the QA within twelve (12) months from the Effective Date as defined in the Letter of Award.

A BioNexus Status company is considered to have commenced its business upon the issuance of its first (1st.) sales invoice.

1.3 Diligence

The BioNexus Status Company must act diligently in performing the QA and do all things necessary to achieve or fulfil its objectives, financial projections or assurances as contained in the Application Documents (including but not limited to the Business Plan) and/or any subsequent update documents.



2 Location of Operations

The BioNexus Status Company is required to locate its operations and undertake the QA at the Location of Operations specified in the Letter of Award. Any changes to the Location of Operations shall be notified to Bioeconomy Corp within ninety (90) days after such relocation.

Where there are justifiable reasons for any intended relocation of the entire or a part of the QA on a temporary basis outside of Malaysia, the BioNexus Status Company must seek prior written approval of Bioeconomy Corp. Bioeconomy Corp may, in its sole discretion, evaluate the proposal for a temporary relocation and attach any conditions to any approval granted for the intended relocation.

Any permanent relocation of the QA or any part thereof outside of Malaysia will result in the revocation of the BioNexus Status.

3 Research and Development (R&D)

For the purposes of these Terms and Conditions, the term “Research and Development” is defined any systematic or intensive study carried out in the field of science or technology with the objective of using the results of the study for the production or improvement of materials, devices, products, produce or processes.

As stipulated in the Letter of Award, the BioNexus Status Company is required to undertake continuous R&D on the approved QA; and in performing the R&D activities, the BioNexus Status Company is required to comply with the definition provided above.

4 Knowledge Workers

BioNexus Status Company must at all times comply and employ the number of “knowledge workers” as set out in the Letter of Award or as prescribed by Bioeconomy Corp and notified to the BioNexus Status Company from time to time.

Knowledge workers are to be recruited, employed and appointed solely for the purpose of undertaking the QA. The recruitment, employment and appointment of foreign knowledge workers (if any) are the sole responsibility of the BioNexus Status Company concerned. Bioeconomy Corp is neither responsible nor liable for any expenses or liability arising from such recruitment, employment or appointment.

4 *Knowledge workers - cont'd*

For the purposes of this clause, to qualify as “knowledge workers” they must possess either of the following:

4.1 Master’s Degree or higher:

- a) Master’s degree or higher qualification in life sciences or biotechnology-related field; or
- b) Other Master’s degree or higher qualification with 1-year relevant working experience;

OR

4.2 Bachelor’s Degree:

- a) Degree in life sciences or biotechnology-related field with 1-year relevant working experience in the biotechnology or biotechnology-related industry; or
- b) Other degrees with 3 years of relevant working experience;

OR

4.3 Diploma:

- a) Diploma in life sciences or biotechnology-related field with 3 years relevant working experience in the biotechnology or biotechnology-related industry;
- b) Other diploma with 5 years of relevant working experience;

OR

4.4 Others qualifications:

- a) Individuals with 10 years of relevant working experience in the biotechnology industry

5 Compliance

The BioNexus Status Company shall at all times:

- a) comply with all applicable laws, including, without limitation, statutory, regulatory and/or licensing requirements;
- b) acquire and maintain the validity of all other necessary licences, permits, approvals and authorisations relating to the carrying out the QA and its business;

5 *Compliance - cont'd*

- c) comply with all prevailing and applicable environmental, ethical and other policies, rules, regulations and guidelines as determined by the relevant governmental authorities; and
- d) ensure that it does NOT at any material time whatsoever infringe or violate any intellectual property rights of Bioeconomy Corp or any third party whether registered or otherwise;
- e) comply with all Special Condition(s) and all other terms and conditions spelt out in the Letter of Award

6 Reporting

6.1 General

The BioNexus Status Company is required to submit the following reports to Bioeconomy Corp:

- a) **Audited Financial Statements.** As soon as they become available (and in any event within 180 days after the end of each of its financial year) a copy of its audited Financial Statements for that period which shall contain a profit and loss account and a balance sheet. Detail of the R&D expenses incurred must be reflected in the “notes to the financial statements” in the audited financial statement. The Financial Statements must be prepared in accordance with the Companies Act 1965 and the Malaysian Accounting Standards Board approved accounting standards in Malaysia and the Financial Statements must give a true and fair view of the results of the operations and the state of affairs of the BioNexus Status Company for the period for which the Financial Statements are made up.
- b) **Management accounts.** As soon as they become available (and in any event within 60 days after the end of each quarter of each financial year). The submission shall be made via Bioeconomy Corp’s Online Submission System (OSS) and shall contain full particulars of the business of the BioNexus Status Company together with its income statement and balance sheet.
- c) **Progress report.** The BioNexus Status Company is required to attend to and submits on an annual basis a progress report (in the format as forwarded by Bioeconomy Corp from time to time).
- d) **Other relevant documents** as may be requested by Government of Malaysia and Bioeconomy Corp from time to time.



6 Reporting - cont'd

6.2 Notification

The BioNexus Status Company **must immediately notify** Bioeconomy Corp of:

- a) any circumstance (s) that has occurred which affects or is reasonably expected to affect the BioNexus Status Company or its performance of the QA;
- b) any change which is reasonably expected to affect the nature of the operations of the BioNexus Status Company or the manner in which the BioNexus Status Company implements and operates the QA;
- c) any constructive or actual knowledge of any claim, allegation, action or prosecution in respect of any improper or wrongful use or possible infringement of any intellectual property rights of any third party; and
- d) any event which it anticipates or should reasonably anticipate will affect the interests of Bioeconomy Corp or the biotechnology industry.

7 Review Process

7.1 Right of Access and Inspection and Monitor

The BioNexus Status Company agrees that Bioeconomy Corp shall have the right, in its absolute discretion, to reasonable access to the premises of the BioNexus Status Company where the QA are performed and to monitor the activities and operations of the BioNexus Status Company. The BioNexus Status Company shall render all reasonable and necessary assistance to Bioeconomy Corp for the above purpose.

7.2 Process and Procedures

Bioeconomy Corp may from time to time, at its absolute discretion, establish applicable monitoring processes and procedure and conduct a compliance review, which **MUST** be complied by the BioNexus Status Company. The BioNexus Status Company shall also provide to Bioeconomy Corp, including but not limited to the following:

- a) standard update forms or other documents, with sufficient details, as may be requested by Bioeconomy Corp from time to time;
- b) detailed progress reports and/or such other information and documentation in relation to its activities and operations which may be requested by Bioeconomy Corp from time to time;
- c) cooperation through means of discussions or meetings with Bioeconomy Corp's employees or representatives/agents in relation to any monitoring activities or processes;



7 *Review Process – cont'd*

- d) reasonable access to Bioeconomy Corp's employees or representatives/agents to inspect its operations, equipment, research facilities, company records, accounts and books; and
- e) access to inspect and audit its records, books and accounts or have them inspected or audited by an independent firm of accountants appointed by Bioeconomy Corp.

8 Confidentiality

Any written information, unless expressly marked as "confidential", submitted by the BioNexus Status Company to Bioeconomy Corp, will not qualify as "confidential or privileged information" and Bioeconomy Corp will assume no responsibility to protect the information from disclosure.

Bioeconomy Corp shall treat written information clearly marked "confidential" in the same manner and use such reasonable care as it would treat its own confidential information.

Please do note that Bioeconomy Corp reserves the right to utilise confidential information released by the BioNexus Status Company for the purpose of compiling data or statistics and/or for evaluation by Bioeconomy Corp, its professional advisers and/or agents.

Bioeconomy Corp will not be liable for disclosure of any information provided by the BioNexus Status Company which has been identified as "confidential" if Bioeconomy Corp is required by law or obliged pursuant to a court order or by any governmental authority to make such disclosure.

9 Tax Liabilities

The tax projections and computations submitted in the BioNexus Status Company's Business Plan are for Bioeconomy Corp's internal assessment and reporting purposes only and in no way does the award of BioNexus Status relieve the BioNexus Status Company of any of its legal and/or statutory responsibilities or obligations under any law or governmental regulations pertaining to income or taxation.

The adjudication and final decision on actual tax computations lie with the Inland Revenue Board Malaysia.

10 Non-Compliance

Bioeconomy Corp reserves the right, in its absolute discretion, to recommend revocation of the BioNexus Status awarded under the attached Letter of Award in the event of any of the following:

- a) **Non-compliance or Breach.** Failure to comply with any of the terms and conditions stipulated herein (*including any amendments thereto made by Bioeconomy Corp from time to time*) or in the attached Letter of Award including but not limited to failure to comply with any of the processes and procedures described herein; or
- b) **Failure to perform.** The BioNexus Status Company fails or is unable to achieve or fulfil its objectives or assurances as contained in the Application Documents (including but not limited to the Business Plan) and/or any subsequent update documents; or
- c) **Unsatisfactory Performance.** The BioNexus Status Company is, in Bioeconomy Corp's opinion, assessment and/or evaluation, unable to undertake or perform the QA; or
- d) **Reputation.** Any act or omission on the part of the BioNexus Status Company which, in the opinion of Bioeconomy Corp, has or may tarnish, harm, damage or adversely affect the reputation of the Government of Malaysia, Bioeconomy Corp or the biotechnology industry; or
- e) **Insolvency.** The BioNexus Status Company becomes insolvent or is unable to pay its debts when due, or enters into any arrangement or composition with its creditors generally, or a receiver or manager is appointed for the BioNexus Status Company, or where the BioNexus Status Company goes into liquidation or passes a resolution for its winding-up (other than pursuant to an approved scheme of reconstruction, amalgamation or re-organisation);
- f) **Distress.** The BioNexus Status Company suffers any distress or where execution is levied against any assets of the BioNexus Status Company which, in Bioeconomy Corp's opinion, would render the company unable to undertake or continue to undertake the QA, or to comply or continue to comply with the terms and conditions of the BioNexus Status awarded; or
- g) **Misrepresentation.** Breach of any representation, warranty or statement which is made (or acknowledged in writing to have been made) by the BioNexus Status Company in the Application Documents or any other documents furnished to Bioeconomy Corp, or if repeated at any time with reference to the facts and circumstances subsisting at such time would not be accurate in all material respects; or
- h) **Defunct.** The BioNexus Status Company is deregistered or struck off the Register of Companies for any reason whatsoever.



11 Remediation

In the event that the BioNexus Status Company defaults in any of its obligations under these terms and conditions, Bioeconomy Corp may at its absolute discretion allow for remediative action to be taken by the BioNexus Status Company within a time period to be stipulated by Bioeconomy Corp. If the BioNexus Status Company still fails to remedy the default upon the expiry of the stipulated time period, Bioeconomy Corp may then at any time revoke the BioNexus Status previously granted to the BioNexus Status Company.

GENERAL

12 Waiver

No delay or failure by Bioeconomy Corp to exercise or enforce at any time any right or provision under the attached Letter of Award and/or these Terms and Conditions shall be considered a waiver unless expressly made in writing. No single waiver constitutes a continuing or subsequent waiver.

13 Contra Proferentem Rule

No rule of construction shall apply to the detriment of either party by reason of that party having control and/or being responsible for the preparation of these Terms and Conditions or any part thereof.

14 Status Cannot Be Assigned

The award of the BioNexus Status is personal to the BioNexus Status Company, and cannot be assigned, pledged or otherwise transferred, in whole or in part, to any other entity person or body corporate. Any assignment, pledge or transfer or any attempted assignment, pledge or transfer is null and void and of no effect whatsoever.

15 Variation

Bioeconomy Corp may, by written notice to the BioNexus Status Company amend, vary, modify any of the terms specified in the Letter of Award and these Terms and Conditions.

16 Acknowledgement of Liability

The BioNexus Status award referred to in the attached Letter of Award is conferred by the Government of Malaysia. For this reason, notwithstanding anything herein to the contrary, Bioeconomy Corp accepts no liability whatsoever, to the BioNexus Status Company nor shall the BioNexus Status Company have any claim against Bioeconomy Corp in respect of any loss or damage suffered by the BioNexus Status Company or any other person at any time as a result of or arising out of the award of the BioNexus Status or the revocation of the BioNexus Status.

In this connection, Bioeconomy Corp is unable to make any representation nor provide any guarantee that the benefits attached to the BioNexus Status or any part thereof will not be withdrawn revoked suspended or terminated by the Government of Malaysia.

17 Revocation

The BioNexus Status granted under the Letter of Award may be revoked for breach of the terms and conditions of the Letter of Award and/or non-compliance with these Terms and Conditions of BioNexus Status.

Upon the revocation of the award of the BioNexus Status:

- (a) all benefits, incentives and privileges awarded by Bioeconomy Corp or any relevant governmental authorities to the BioNexus Status company shall be immediately withdrawn;
- (b) the BioNexus Status company shall immediately surrender its BioNexus Status certificate to Bioeconomy Corp; and
- (c) the BioNexus Status company shall immediately cease holding itself as having BioNexus Status.

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