MALAYSIAN BIOECONOMY
DEVELOPMENT CORPORATION SDN BHD

GUIDELINES On BIONEXUS STATUS

Version 1.0 (July 2025)

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 these Guidelines 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.

Malaysian Bioeconomy Development Corporation Sdn Bhd (Bioeconomy Corporation) does not hold out, warrant or guarantee that reliance on the information contained herein will result in granting or approval of the matters applied for.

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Reference: Promoted sectors for BioNexus Status

1. INTRODUCTION

1.1 The National Biotechnology Policy 2.0 (NBP 2.0), launched in September 2022 as a continuation of NBP 1.0, aspires to create a bio-innovation society by 2030 aimed at generating wealth, enhancing social well-being and promoting sustainable development.

1.2 NBP 2.0 is a policy developed by Ministry of Science, Technology and Innovation (MOSTI) to complete the Science, Technology, Innovation and Economy (STIE) ecosystem which aims to boost the country to become a high tech nation by 2030. It focuses on three (3) focus areas which are biotechnology in agriculture & food security, biotechnology in healthcare & well-being and biotechnology in industrial & circular economy.

1.3 The NBP 2.0 has been designed with the strategic objective of driving biotechnology growth, aiming to contribute 5% to the nation's Gross Domestic Product (GDP) by 2030.

2. BIONEXUS STATUS

2.1 "BioNexus Status" is a special Status awarded by the Government of Malaysia through Bioeconomy Corporation, to qualified biotechnology companies undertaking value-added biotechnology activities.

2.2 Once granted, a BioNexus Status Company is eligible for incentives[Note 1] and privileges as outlined in the BioNexus Bill of Guarantees (BoGs), which represents the commitment of the Government of Malaysia in establishing a promising atmosphere that stimulates the advancement of the biotechnology sector.

Note 1: Under these Guidelines, the BioNexus Status tax incentives are not applicable.

3. BENEFITS OF THE BIONEXUS STATUS

3.1 The BioNexus Status Company is guaranteed the privileges aimed at fostering a supportive environment for research and business development. The following are the BoGs under the BioNexus Status:

a. Freedom of ownership;

b. Freedom to source funds globally subject to prevailing Government's policies;

c. Freedom to bring in knowledge workers, subject to prevailing Government's policies;

d. Eligibility for the BioNexus Status incentives[Note 1];

e. Facilitation of international accreditation and standards; and

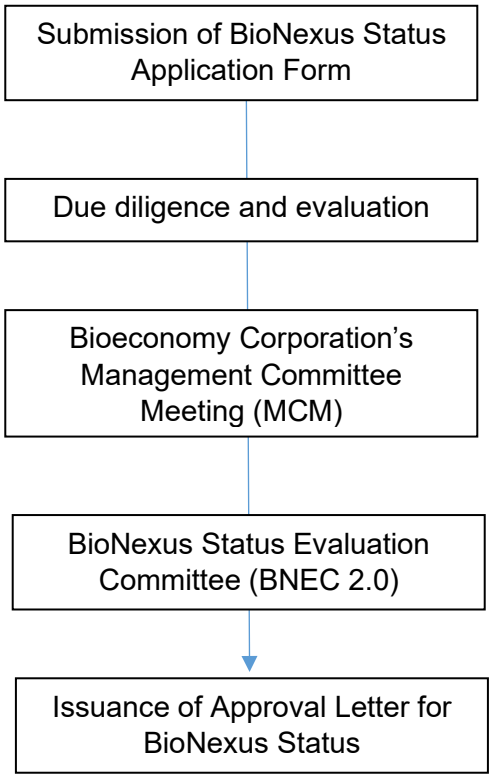
f. Access to BioNexus Partners Programme for shared laboratories and other related facilities.

3.2 The approvals for incentives or benefits under the BoGs shall remain valid, subject to continued compliance with the terms and conditions of the BioNexus Status. These benefits may also require separate approvals, where applicable, and are contingent upon meeting relevant eligibility criteria, fulfilling specified conditions and complying with all applicable laws and regulations.

3.3 The BioNexus Status Company is also eligible for additional benefits, including opportunities for business matching, partnership development and participation in programmes organised by Bioeconomy Corporation. These benefits are subject to the applicable eligibility criteria and conditions of the respective programmes.

4. APPLICATION PROCESS FLOW

4.1 Application process flow



4.2 MCM

MCM is a committee comprising of Bioeconomy Corporation's senior management. It is responsible for the review, evaluation, assessment and recommending the approval of BioNexus Status application to BNEC 2.0.

4.3 BNEC 2.0

BNEC 2.0 is an approving committee comprising representatives from various ministries and government agencies. It is primarily responsible for the review, evaluation, assessment and approval of BioNexus Status, as well as recommending the approval of tax incentives[Note 1] to National Committee on Investment (NCI).

Note 1: Under these Guidelines, the BioNexus Status tax incentives are not applicable.

5. ELIGIBILITY CRITERIA

5.1 The eligibility criteria for granting of BioNexus Status are as follows:

a. A legal entity incorporated pursuant to the Companies Act 2016 to undertake the qualifying activity (QA);

b. Conducts the QA under the BioNexus Status promoted sectors;

c. Must possess the legal rights to the technology, which must be ready for commercialisation;

d. The QA must be undertaken in Malaysia; and

e. A minimum paid-up capital of Ringgit Malaysia One Hundred and Fifty Thousand (RM150,000).

5.2 A company that has been awarded and/or utilised other incentives offered by the Government or other Investment Promotion Agencies (IPAs) to conduct the same QA, may still be eligible for BioNexus Status.

5.3 If a company has a related company that has been awarded and/or has utilised other incentives offered by the Government or other IPAs to conduct the same or different QA, the company may still be eligible for BioNexus Status.

5.4 The BioNexus Status is open to both new and existing companies. For avoidance of doubt, definitions of “new company” and “existing company” are as follows:

a. A new company is a company that has not generated any revenue related to its QA.

b. An existing company refers to a company that has generated revenue from its QA under the following scenarios:

- Has its own manufacturing or services facilities;
- Outsources manufacturing to a third party (allowed for up to twenty-four (24) months from the date of BioNexus Status); and/or
- Has co-sharing arrangements with either manufacturing or service provider companies.

6. COMPLIANCE TO THE BIONEXUS STATUS TERMS AND CONDITIONS

6.1 The BioNexus Status Company is obligated to comply with the terms and conditions (T&C) of the BioNexus Status, effective from the Effective Date as defined in the Letter of Approval issued by Bioeconomy Corporation, including any subsequently approved variations to those conditions.

6.2 A company that has been granted the BioNexus Status must comply with the respective commencement date of QA as follows:

a. A new or existing BioNexus Status Company undertaking **manufacturing activity** must commence its QA within **twenty-four (24) months** from the Effective Date. "Commencement" refers to the first paid purchase of raw materials for the QA; or

b. A new or existing BioNexus Status Company providing **services** must commence its QA within **twelve (12) months** from the Effective Date. "Commencement" here refers to first sales invoice generated; or

c. An existing company that **outsources** its production prior to the BioNexus Status application must commence in-house manufacturing activity **within twenty-four (24) months** from the Effective Date. "Commencement" here refers to the first paid purchase of raw material for the QA.

6.3 The obligation to comply with the T&C shall commence as outlined below:

a. For both new and existing companies, compliance shall commence in the same year of assessment (YA) as the BioNexus Status Company's commencement date of the QA.

b. In the event that the company commences its QA in the fourth (4^{th}) quarter of the YA, compliance requirements shall begin in the following YA.

6.4 The BioNexus Status Company may request an extension, prior to the commencement deadline, if it anticipates being unable to commence the QA.

6.5 The T&C may also include the following:

a. A minimum number of full time employees, as proposed;

b. Investment in research and development, innovation and/or commercialisation. This condition does not apply to Contract Research Organisation (CRO) companies; and

c. Any other applicable conditions as may be advised by Bioeconomy Corporation to the BioNexus Status Company from time to time.

6.6 Any variation of conditions shall be subject to the approval from BNEC 2.0.

6.7 In the event of non-compliance of the T&C, the BioNexus Status may be withdrawn and the effective date of such withdrawal shall be determined by BNEC 2.0.

7. OTHER GENERAL CONDITIONS

7.1 The BioNexus Status Company must comply with all applicable permit and licensing requirements and ensure that the necessary permits or licenses are obtained from the relevant authorities for the implementation of its QA.

7.2 The BioNexus Status Company shall not transfer or assign the BioNexus Status or any benefits, rights and/or obligations thereunder to any third party.

8. POST APPROVAL MATTERS

8.1 The BioNexus Status Company may apply to add new QA by submitting a Variation Request Form to Bioeconomy Corporation. Each application will be assessed by Bioeconomy Corporation and subsequently presented to BNEC 2.0 for deliberation and approval.

8.2 <u>Post approval changes</u>

a. The BioNexus Status Company is required to promptly notify Bioeconomy Corporation of **any changes** to the following, by submitting a Notification Request Form:

- Change in the company's paid-up capital;
- Change in the list of shareholders or shareholding structure;
- Change in the company's name; and/or
- Change in business operating address, contact person(s) or contact details.

b. The BioNexus Status Company will receive an acknowledgement from Bioeconomy Corporation once the changes have been recorded.

c. Any variation to the T&C (as specified in the Letter of Approval), other than the changes listed above, will require the approval from BNEC 2.0.

9. REPORTING AND MONITORING

9.1 The BioNexus Status Company is required to:

a. submit the following reports, including but not limited to:
- Audited Accounts;
- Management Accounts; and
- Compliance Reports.

b. provide any additional information and/or documents as requested by Bioeconomy Corporation for the purpose of:
- Monitoring the progress of the QA; and
- Ensuring compliance with applicable conditions.

9.2 Compliance with the conditions by the BioNexus Status Company is subject to assessment and final determination by Bioeconomy Corporation.

10. WITHDRAWAL OF THE BIONEXUS STATUS

10.1 The BioNexus Status may be withdrawn in the event of non-compliance or breach of the T&C by the BioNexus Status Company.

10.2 The withdrawal of the BioNexus Status shall take effect on a date to be determined by BNEC 2.0.

10.3 With the withdrawal of BioNexus Status, all incentives and benefits granted under the BoGs may also be revoked, subject to applicable laws and regulations.

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Promoted Sectors for BioNexus Status

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1.0 AGRICULTURE BIOTECHNOLOGY

1.1 CROP BIOTECHNOLOGY

(a) Planting materials

Research, development and production of high quality planting materials (true-to-type, nursery and plantlets) utilising **ANY** of the following:

- Plant tissue culture:
  Starting from *in-vitro* micro propagation of plants under controlled environment;
- Molecular tools:
  Examples are marker-assisted selection (MAS), sequencing, CRISPR etc.;
- Other genetic improvement methodologies:
  Not limited to genetic transformation using chromosomal and RNA/DNA manipulations, proteomics and metabolomics.

(b) Crop nutrition / Enhancers

Research, development and production of bio-fertilisers, organic fertilisers, soil enhancers etc. utilising **ANY** of the following:

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Other biotechnology

AND conduct validation procedures on its products.

The applicant must be able to proof that the products and services to be provided are based on reasonably sound scientific validation and methodologies. Refer **Appendix 2a**.

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(c) Crop protection

Research, development and production of bio-pesticide, biochemical pesticides (e.g. insect sex pheromones), bio-herbicide, bio-control, bio-insecticides, bio-fungicides etc. utilising **ANY** of the following:

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Other biotechnology

AND to conduct validation procedures on its products.

The applicant must be able to proof that the products and services to be provided are based on reasonably sound scientific validation and methodologies. Refer **Appendix 2a**.

(d) Emerging areas

- Genetically Modified Organisms (GMO):
  Research, development and production of plants or microbes using recombinant DNA technology to obtain trait(s) of interest; or
- Polyploidisation:
  Research, development and production of plants, microbes or other living organisms using chromosome numbers doubling technology for enhancement of selected trait(s).
- RNA technology:
  Research, development and production of desired products through RNA interference process.

1.2 NATURAL PRODUCT DISCOVERY

Research and development and manufacturing of nutraceuticals, cosmetic products, functional ingredients, botanical extracts, food / functional food, dietary supplement etc. derived from natural products utilising **ANY** of the following (must be conducted in-house):

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Other biotechnology

AND to conduct validations procedures on its standardised extracts/products (may be conducted in- house / third party). Refer **Appendix 2b**.

Note: The sector classification (either Agriculture or Healthcare) will be determined based on the applicant's activity at the point of the BioNexus Status application. Below are the activities involved in natural product discovery development.

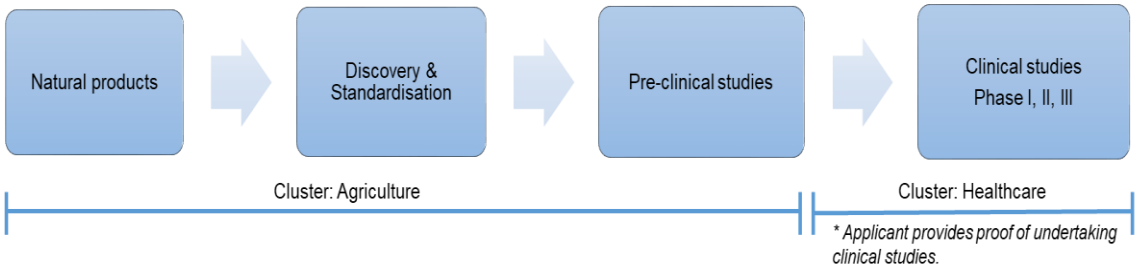

Figure 1: Natural Product Discovery

1.3 LIVESTOCK BIOTECHNOLOGY

(a) Breeding and nucleus farm

Livestock breeding and nucleus farm activities utilising **ANY** of the following:

- Estrus synchronisation (Ovulation induction)
- Artificial insemination
- Embryo transfer
- *In-vitro* fertilisation
- Embryo sexing
- Production, storage and commercialisation of animal semen and embryo;
- Marker-assisted selection (MAS)
- Validated genetically improved breeding materials and the use of integrated biotechnology processes for multiplier farm.

(b) Animal feed and nutrition

Research, development and manufacturing of animal feed and additives such as probiotics, vitamins, protein supplements etc. utilising **ANY** of the following (must be conducted in-house):

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Other biotechnology

(c) Animal health, diagnostic and biologics

Research, development and manufacturing of animal health (e.g. vaccines, biologics, antibiotics, antiviral), diagnostics kits, animal protection products (e.g. biocontrol of pests and diseases) utilising **ANY** of the following (must be conducted in-house):

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Molecular biotechnology
- Other biotechnology

(d) Remediation of animal waste

Research, development and production of high value products utilising **ANY** of the following:

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Other biotechnology

(e) Emerging areas

(i) Research, development and manufacturing of biomaterials from livestock products (e.g. proteins, peptides, enzymes, therapeutics) from livestock products (e.g. skin bones, other organs) utilising biotechnology processes; or

(ii) Research, development and manufacturing of alternative protein and its derivatives (e.g. meat production) utilising cellular agriculture technology; or

(iii) Research, development and manufacturing of alternative protein and its derivatives (e.g. animal feed) utilising insect protein / vegan protein technology.

(iv) Research, development and production of desired products utilising RNA technology.

1.4 AQUACULTURE BIOTECHNOLOGY

(a) Aquaculture breeding

(i) Research, development and production of freshwater and marine species utilising **ANY** of the following:

- Biotechnology reproduction techniques:
  Techniques such as sexing, polyploidy, *in-vitro* fertilisation, spawning or induction techniques; or
- Cultivation of live feed:
  The use of biotechnology aided techniques for the cultivation of live feeds for aquaculture e.g. artemia, copepods, rotifers etc.
- Cultivation of algae:
  - The use of biotechnology aided techniques for cultivation of algae in a controlled environment such as in ponds and photo-bioreactors;
  - In vitro cultivation of the starting materials for micro and macro-algae;
  - Cultivation system using biotechnology aided techniques for the maintenance of an SPF environment.

(b) Aquaculture feed and nutrition

Research, development and manufacturing of aquaculture feed and additives such as probiotics, vitamin & protein supplements, planktons, algae, spirulina, seaweed, single cell protein etc. utilising **ANY** of the following (must be conducted in house):

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Other biotechnology

(c) Aquaculture health diagnostics and biologics

Research, development and manufacturing of aquaculture vaccines, biologics, antibiotics, antiviral or molecular-based diagnostic kits for food safety and aquaculture testing utilising **ANY** of the following (must be conducted in house):

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Other biotechnology

(d) Emerging areas

(i) Research, development and manufacturing of biomaterials (e.g. proteins, peptides, enzymes, therapeutics) from livestock products (e.g. skin bones, other organs) utilising biotechnology processes; or

(ii) Research, development and manufacturing of alternative protein and its derivatives (e.g. meat production) utilising cellular agriculture technology; or

(iii) Research, development and manufacturing of alternative protein and its derivatives (e.g. animal feed) utilising insect protein / vegan protein technology.

(iv) Research, development and production of desired products utilising RNA technology.

1.5 SERVICES PROVIDER

(a) Services provider in agriculture

Provision of research services in agriculture sectors. Research services includes the following:

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

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(b) Contract research and manufacturing services (CRAMS)

Provision of contract research and manufacturing services to third parties. Research services may include the followings:

- Provision of contractual R&D services to third parties.
- Internal R&D conducted by the company in order to provide its contract manufacturing services to third parties.

The above activities is applicable for the following sub-sectors under Agriculture Biotechnology:

- Crop Biotechnology
- Natural Product Discovery
- Livestock Biotechnology
- Aquaculture and Marine Biotechnology

(c) Contract manufacturing services (CMS)

Provision of contract manufacturing services involving biotechnology process to third parties.

The above activities is applicable for the following sub-sectors under Agriculture Biotechnology:

- Crop Biotechnology
- Natural Product Discovery
- Livestock Biotechnology
- Aquaculture and Marine Biotechnology

Note: Activities in the Promoted Sectors may also include value-added enablers to biotechnology, such as the adoption of Fourth Industrial Revolution (4IR) technologies. These include additive manufacturing, artificial intelligence, autonomous robots, big data analytics, cloud computing, cybersecurity, horizontal and vertical system integration, the Industrial Internet of Things (IIoT), new business models, simulated and augmented reality, and supply chain optimisation.

2.0 HEALTHCARE BIOTECHONOLOGY

2.1 SERVICES PROVIDER

(includes business-to-business (B2B) and business-to-consumer (B2C) models).

(a) Discovery and development services

Provision of services in researching human microbiome, developing active pharmaceutical ingredients (APIs), drug discovery and/ or drug delivery systems. Examples of services offered can range from the followings:

- Target discovery (e.g. in vitro research is performed to identify targets involved in specific diseases).
- Target validation (e.g. conducting careful and precise target validation experiments are essential for the success of drug development)
- Lead compound identification (e.g. testing the mechanism of action of the drug, initial safety tests are conducted in cell culture. Both the pharmacokinetics and pharmacodynamics of the drug are also tested)
- Lead compound optimisation (e.g. optimisation of the compound for efficacy and safety study)
- Pre-clinical development / studies (e.g. in-vivo using animal models and in vitro studies)

(b) Bioinformatics and scientific data analysis

Provision of services in the fields of molecular medicine, precision medicine, gene therapy and drug development which comprises **ANY** tools of computation and analysis in order to capture and interpret biological data such as:

- Computational analysis on -omics study (e.g. genomics, transcriptomics, proteomics, or metabolomics)
- Clinical trial results analysis

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(c) Cell tissue technology

Provision of services in the field of human stem cells and tissue for therapeutic purposes utilising **ANY** of the following:

- Proliferation and differentiation of cells
- Acquiring of appropriate source of cells (e.g. autologous cells, allogenic cells, stem cells)
- Genetically engineered cells
- Immunological manipulation
- Cell-based therapeutics
- Other methods

(d) Clinical research organisations (CRO)

Provision of services to the pharmaceutical, biotechnology, generic drug, OTC/consumer healthcare and medical device companies which comprises of **ANY** of the following services:

- Comprehensive clinical trial management services for designing, managing, monitoring and reporting on Bioavailability (BA) and Bioequivalence (BE) studies.
- Phase 1–4 clinical trials research.

(e) Contract research and manufacturing services (CRAMS)

Activities relating to the provision of contract research and manufacturing services to third parties (B2B model only). Research includes the following:

- Provision of contractual R&D services to third parties.
- Internal R&D conducted by the company in order to provide its contract manufacturing services to third parties.

The above activities is applicable for the following sub-sectors under Healthcare Biotechnology:

- Biopharmaceuticals and pharmaceuticals
- Medical device, in vitro diagnostics and biosensors
- Regenerative medicine
- Natural product development with therapeutic claim

(f) Contract manufacturing services (CMS)

Activities relating to contract manufacturing services to third parties that is applicable for the following sub-sectors under Healthcare Biotechnology:

- Biopharmaceuticals and pharmaceuticals
- Medical device, in vitro diagnostics and biosensors
- Regenerative medicine
- Natural product development with therapeutic claim

2.2 BIOPHARMACEUTICALS AND PHARMACEUTICALS

(i) Activities relating to the research, development, commercialisation of drugs (i.e biologics, biosimilars, biobetters, pharmaceuticals), active ingredients and vaccines; or

(ii) Activities relating to fill and finish of drugs.

2.3 MEDICAL DEVICES, IN VITRO DIAGNOSTICS AND BIOSENSORS

(a) Medical devices

i. Activities relating to research, development and manufacturing of Class B, C and D medical devices, as defined by Medical Device Authority (MDA), Ministry of Health, as follows:

Class	Risk Level	Device Examples
B	Low-mode rate	Hypodermic needle, suction equipment
C	High-moderate	Lung ventilator, orthopaedic implants, baby incubator, blood oxygenator, 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

ii. Activities relating to research, development and manufacturing of health tech devices with targeted parameters (e.g. wearable devices that can accurately read cholesterol level, strap that can detect sugar level, continuous glucose monitoring), excluding general parameters (e.g. heart rate detection).

(b) In vitro diagnostics

Activities relating to research, development and manufacturing of all classes (A, B, C & D) in vitro diagnostics as defined by Medical Device Authority (MDA), 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

(c) Biosensors

Activities relating to research, development and manufacturing of biosensors (an analytical device involving biological sensing element with wide range of applications such as drug discovery, diagnosis, biomedicine, food safety and processing, environmental monitoring, defence and security) utilising **ANY** of the following bio-element:

- Enzyme
- Antibody
- Aptamers
- Cell receptor
- Reagents
- Metabolites
- DNA construct
- Sensing element
- Transducer

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2.4 REGENERATIVE MEDICINES

(a) Tissue engineering

Activities relating to research, development and manufacturing of 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

Activities relating to research, development and manufacturing of human stem cells and tissue for therapeutic products utilising **ANY** of the following:

- Proliferation and differentiation of cells
- Acquiring of appropriate source of cells (e.g. autologous cells, allogenic cells, stem cells)
- Genetically engineered cells
- Immunological manipulation
- Cell-based therapeutics
- Other methodologies

(c) Biomolecules

Activities relating to research, development and manufacturing of angiogenic factors, growth factors, differentiation factors and bone morphogenic proteins utilising **ANY** of the following:

- Recombinant DNA technology
- Microbial technology **(Appendix 1b)**
- Cell culture technology
- Extraction / purification technology **(Appendix 1a)**
- Enzymatic technology **(Appendix 1c)**
- Other technologies

(d) Biomechanics in regenerative medicine

Activities related to biomechanics-based approaches in regenerative medicine, encompassing applications from tissue engineering to cell therapy. This approach focuses on understanding and manipulating the mechanical forces and properties of biological tissues to promote regeneration and repair. It involves the application of biomechanical principles to design biomaterials, stimulate cellular responses and develop innovative therapeutic strategies for tissue engineering and regenerative therapies.

(e) Cell genetic engineering

Activities relating to research, development and manufacturing of human stem cells and tissue for therapeutic products and services utilising **ANY** of the following:

- Recombinant DNA technology
- Genetic modification/ manipulation
- Gene splicing (e.g. CRISPR- Cas9 etc.)

2.5 NATURAL PRODUCTS WITH THERAPEUTICS CLAIMS

Activities relating to research, development and manufacturing of cosmetic products, botanical products, wellness and pharma-nutrition products utilising **ANY** of the following (must be conducted in-house):

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Other biotechnology

AND with proven to have medical benefits / medical claims.

Note: The sectors (either Agriculture or Healthcare) will be determined based on the applicant's activity at the point of BioNexus Status application. Below are the activities involved in natural product discovery:

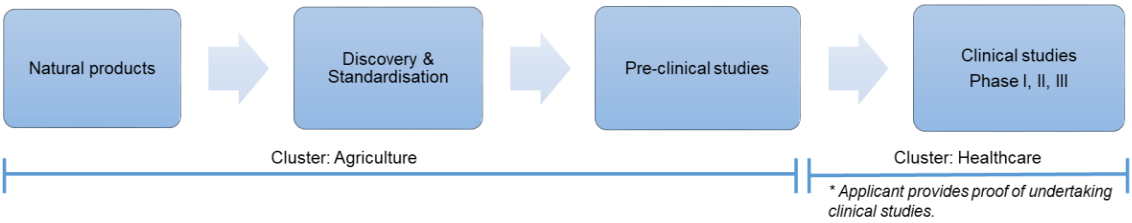

Figure 1: Natural Product Discovery

Note: Activities in the Promoted Sectors may also include value-added enablers to biotechnology, such as the adoption of Fourth Industrial Revolution (4IR) technologies. These include additive manufacturing, artificial intelligence, autonomous robots, big data analytics, cloud computing, cybersecurity, horizontal and vertical system integration, the Industrial Internet of Things (IIoT), new business models, simulated and augmented reality, and supply chain optimisation.

3.0 INDUSTRIAL BIOTECHNOLOGY

3.1 FINE & SPECIALTY CHEMICALS (BIOCHEMICALS)

(a) Fine, specialty and bulk chemicals

Research, development and manufacturing of biochemicals from bio-based and/or renewable feedstocks and are used as base chemicals for industrial manufacturing processes (e.g. organic acids, amino acids, alcohols & ketones) utilising **ANY** of the following:

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Bio-based or renewable sources
- Any component of the circular economy in the production process
- Other biotechnology processes

(b) Active ingredient/compound

Research, development and manufacturing of extracts or ingredients (e.g. standardised herbal extract, food ingredients, natural flavour and fragrance) from natural resources utilising **ANY** of the following:

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Bio-based or renewable sources
- Any component of the circular economy in the production process
- Other biotechnology processes

(c) Secondary metabolites

Research, development and manufacturing of secondary metabolites utilising **ANY** of the following:

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Others, including and not limited to genetic modification of organisms to enhance or introduce secondary metabolite production

Example of secondary metabolites:

- Prebiotics:

  A group of nutrients and ingredients of functional food. Prebiotics include and are not limited to fructans, galacto-oligosaccharides and starch and glucose-derived oligosaccharides; or

- Probiotics:

  Live microorganisms that confer beneficial health effects to the host when administered in adequate amounts. The most common species used in probiotics research and development belong to *Lactobacillus* spp. and *Bifidobacterium* spp.; or

- Postbiotics:

  Also known as metabiotics, biogenics, or simply metabolites. They are soluble factors (metabolic products or by-products), secreted by live bacteria, or released after bacterial lysis providing physiological benefits to the host.

3.2 BIOFUEL & BIOENERGY

(a) Biofuels

i. Research, development, and production of any type of fuels or energy sources (solid, liquid or gas) (e.g. bioethanol, biogas, biobutanol, biomethanol, biodiesel) derived from biomass (e.g. oilseeds, bio-circular waste, sugars, residues) utilising **ANY** of the following:

   - Thermal reactions
   - Microbes **(Appendix 1b)**
   - Enzymes **(Appendix 1c)**
   - Chemical reactions
   - Solvents

ii. Research, development and production of bio-based utilities (e.g. electricity, hydrogen, bio compressed natural gas, heat) using renewable raw materials (e.g. biogas and industrial wastes (gas and solids).

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(b) Bioenergy

i. Research, development and production of renewable energy composed of or produced from bio-based feedstocks or biofuel (e.g. biogas power plant, biomass power plant) utilising **ANY** of the following:

- Thermal reactions
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Chemical reactions
- Solvents

ii. Research, development and production of bio-energy (e.g. electricity, sustainable fuels) using renewable raw materials (e.g. biogas and industrial waste such as gas and solids).

3.3 BIOMATERIALS

(a) Biomaterials

Research, development and manufacturing of bioplastics, biopolymers and biocomposites materials made from renewable bio-based resources utilising **ANY** of the following:

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Other biotechnology

(b) Renewable and biodegradable products

Research, development and manufacturing of products (e.g. biodegradable packaging, bio-based panel) made from renewable bio-based resources (e.g. cellulose, starch, natural fibres) utilising **ANY** of the following:

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Other biotechnology

(c) Biosensors

Research, development and manufacturing of biosensors (an analytical device involving biological sensing element with wide range of applications such as drug discovery, diagnosis, biomedicine, food safety and processing, environmental monitoring, defence and security) utilising bio-elements such as:

- Enzyme
- Antibody
- Aptamers
- Cell receptor
- Reagents
- Metabolites
- DNA construct
- Sensing element
- Transducer

3.4 BIOCATALYST

Research, development and production of biocatalyst (e.g. industrial enzyme, effective microbes) utilising **ANY** of the following:

- Extraction **(Appendix 1a)**
- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Other biotechnology

3.5 BIOREMEDIATION

(a) Microbial solution

Research, development and production of biological agents (e.g. microbes, fungi and plants) to remove, degrade or detoxify pollutants from contaminated environmental sites (e.g. municipal solid waste, hydrocarbons, industrial waste) utilising **ANY** of the following:

- Microbes **(Appendix 1b)**
- Enzymes **(Appendix 1c)**
- Phytoremediation (with proven data on its efficacy)
- Other biotechnology processes

(b) Equipment and microbes total solution

Research, development and manufacturing of equipment in-house (e.g. bioreactors) and packaged with in-house produced biological agent.

3.6 SERVICES PROVIDER

(a) Research services provider in industrial

Provision of research services in industrial. Research services includes the following:

- Screening and identification of active components
- Process and technology development
- Analytical profile and standardisation protocol development
- Storage and stability profiling
- Protocol development
- Toxicity and safety profiling
- Good Laboratory Practices (GLP) & Good Manufacturing Practices (GMP) standards for product development
- Pilot plant production, feasibility studies and services

(b) Contract research and manufacturing services (CRAMS)

Provision of contract research and manufacturing services to third parties. Research services includes the following:

- Provision of contractual R&D services to third parties.
- Internal R&D conducted by the company in order to provide its contract manufacturing services to third parties.

The above activities is applicable for the following sub-sectors under Industrial Biotechnology:

- Biochemicals
- Biofuel
- Biomaterials
- Biocatalysts

(c) Contract manufacturing services (CMS)

Activities relating to contract manufacturing services to third parties that is applicable for the following sub-sectors under Industrial Biotechnology:

- Biochemicals
- Biofuel
- Biomaterials
- Biocatalysts

Note: Activities in the Promoted Sectors may also include value-added enablers to biotechnology, such as the adoption of Fourth Industrial Revolution (4IR) technologies. These include additive manufacturing, artificial intelligence, autonomous robots, big data analytics, cloud computing, cybersecurity, horizontal and vertical system integration, the Industrial Internet of Things (IIoT), new business models, simulated and augmented reality, and supply chain optimisation.

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Appendix 1: Technologies

(a) Extraction

Activities relating to the use of extraction technologies to produce bio-active components. Examples of extraction method are as follows:

- Water extraction
- Solvent extraction
- Hydro distillation
- Steam distillation
- Supercritical fluid extraction
- Enzyme assisted extraction
- Ultrasonic extraction
- Pressurised liquid extraction
- Mixing, heating techniques
- Physical separations
- Microwave assisted extractions
- Mechanical extractions (such as pressing, phase-change technology and homogenisation that can cause large scale of cell disruption)
- Hydrolysis

(b) Microbes

Activities relating to the use of in vitro methods to produce secondary plant and microbial metabolites or extracts. Examples of in vitro methods are the use of bio-reactors and fermenters to cultivate or to mass propagate cells and tissues of plants, animals or microbes to produce their secondary metabolites or extracts for the nutraceutical and functional ingredient applications.

Regardless of whether the microbes are purchased from a third party or produced in-house, as long as the fermentation process takes place in-house, the company is eligible for BioNexus Status.

(c) Enzymes

Activities relating to the use of enzyme to speed up (i.e. catalyse) chemical reactions. Regardless of whether the enzymes are purchased from a third party or produced in-house, the company is eligible for BioNexus Status.

Appendix 2: Scientific Validations

(a) Crop nutrition and protection or relevant sub-sectors:

- The identification of the microbes involved at least to genus level;
- The cultivation / multiplication of microbes;
- The validation of the biological activities of microbes involved based on documented evidence or third party laboratory;
- The quantification or any quality assurance measurements denoting the potency of the preparation; and
- The results of greenhouse or field trials involving at least a case control design showing the effectiveness and specific intended roles of the biofertilisers on target crops.

(b) Natural products or relevant sub-sectors:

- Activities related to the discovery, selection and screening of natural products for the identification of leads (bioactivity) for various nutraceuticals, cosmeceuticals, functional ingredients and pharmaceutical applications; or
- Validation activities related to the development of quality, safety and efficacy profiles of the extracts and also to identify possible bioactivity(ies) of the extracts. Validation activities include analytical profiling, toxicity/safety assays and bioactivity assays on the extracts; or
- Activities related towards validating the natural products for various nutraceuticals, cosmeceuticals and functional ingredient applications; or
- The extracts produced must be standardised to certain molecular markers or other standardisation methods practiced industry-wide to ensure consistency and quality.

ENQUIRIES AND SUPPORT

For enquiries and clarification, please refer to:
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