

(Unofficial Translation)

Explanatory Notes on applying for investment promotion for Category 7.12 Biotechnology

For further clarification of investment promotion in biotechnology stated in the BOI Announcement No. 2/2557 dated December 3, 2014 on Policies and Criteria for Investment Promotion, the Office of the Board of Investment terminate the Explanatory Note on applying for investment promotion for Category 7.19 Biotechnology dated November 26, 2014 and hereby issues the following explanatory note:

1. Investment Promotion Procedures
 - 1.1 Applicant must submit “Application for Investment Promotion” with “Supplement Form for investment promotion in Category 7.12 Biotechnology”
 - 1.2 In case there is no R&D project or the R&D project has ended, applicant must fill in information for only no. 1, 2, 3 and 5 of the aforementioned Supplement Form.
 - 1.3 If the project has been approved by the the National Science and Technology Development Agency (NSTDA) or the Thailand Centre of Excellence for Life Sciences (TCELS), a letter of proof must be submitted together with the aforementioned application form.
 - 1.4 If the project has been approved by NSTDA or TCELS, the Office of the Board of Investment will consider the project accordingly through its normal procedures
 - 1.5 If the project has not been approved by NSTDA or TCELS, the Office of the Board of Investment will present the project to a Screening Committee on Biotechnology Projects to grant approvals prior to normal project consideration procedures.
 - 1.6 In case of major changes or amendments of the approved project, a request for changes must be submitted to the Office of the Board of Investment for further consideration.
2. Projects eligible for investment promotion under Category 7.12 Biotechnology are as follow:
 - 2.1 R&D project using advanced biotechnology and/or project manufacturing products using advanced biotechnology in order to enhance production competitiveness to the industry. R&D activity in the project can be conducted by the company or partner research with other agencies which could be an agency in Thailand or foreign agencies in order to promote development of researchers, as well as to support biotechnological businesses to conduct R&D, and utilize molecular technology. The coverage of the promotion will be from manufacturing of raw materials and/or essentials for the purpose of R&D, experiment, test and quality control and/or production of biological substances and projects using biological substance analysis and/or synthesis services and/or quality control services and/or product validation services.
 - 2.2 Applicant must submit complete details and/or other supplemental documents as specified by the Office of the Board of Investment, otherwise the Office of the Board of Investment will not accept the application.
3. Details on activities eligible for investment promotion in accordance with the 6 Sub-Category are as follows:
 - 3.1 R&D business and/or manufacturing of seed industry, improvement of plants, animals or microorganisms using biotechnology (Category 7.12.1)**
 - 3.1.1 The business must use biotechnology to select suitable traits, to improve strains and production of plants, animals, and microbes as well as to apply precision breeding to create an organism with the special characteristics e.g. tolerating

certain unwanted disease and insects tolerance or inducing organism to produce bio-substances with required qualifications.

3.1.2 Examples of technologies include genetic engineering technology, biomarkers technology and tissue culture with radiation treatment/suitable genes transplant.

3.1.3 Examples of activities that should be carried out in the Category are as follows:

- 1) Genetic study and study of RNA interference (RNAi) for improving reproduction and immune systems.
- 2) Genetic engineering
- 3) R&D on biomarkers/genetic markers/ molecular markers or protein markers for screening or evaluating economic traits for breed improvement, fast-growing, or disease tolerance breed selection with good immune system.
- 4) R&D on direct alteration of gene e.g. using hormones to induce specific gender and radiation treatment/suitable genes transplant together with tissue culture.

3.1.4 Possible businesses include:

- 1) Production of disease-free seed or disease-free cuttings
- 2) Plant propagation, development and animal breeding e.g. tiger prawns, giant river prawns, Nile tilapia, Ornamental fish, cow
- 3) Production of flower plant, decorative plants e.g. orchid, water plant

3.2 R&D business and/or manufacturing of biopharmaceutical agents using biotechnology (Category 7.12.2)

3.2.1 The business must use biotechnology to effectively produce medical supplies and meets the standards.

3.2.2 Examples of technologies include fermentation using advanced technology, genetically modified microbe to produce specified substances, bioinformatics, screening technology and synthetic technology for active pharmaceutical ingredients

3.2.3 Examples of activities that the business should have:

- 1) Study of molecular level e.g. comparative study on human genes and medicinal reaction, the symptoms of genetic disease.
- 2) R&D on technology to search for protein or to develop detection device for vaccine production
- 3) Use of molecular technology e.g. proteomics, genomics to improve production process
- 4) Research on synthesizing active pharmaceutical ingredients from bio-based materials.
- 5) Clinical research, bio-similar, pharmacokinetics, bioavailability to study the effect of medicine on cells, and toxicity on cells.
- 6) Design research on production process to efficiently produce medicine in industrial level.

3.3 R&D business and/or manufacturing of diagnostic kits for health, agriculture, food and environment (Category 3.12.3)

3.3.1 The business must utilize biotechnology to develop diagnostic devices for screening, monitoring, and confirming the results in health, agriculture, food and environment.

3.3.2 Examples of technologies include:

- 1) Diagnostic Technology such as immunochromatography, ELISA, microarray, and microsatellite to produce diagnostic kits, both rapid diagnostic and well-plate used in standard laboratory.
- 2) Technology to connect the biological substance and electronic device such as screen printing, microfluidic to develop the biosensor and bio-chip

3.3.3 Examples of activities that the business should have include:

- 1) Study of biology/DNA fingerprinting of organism in order to analyse the genetic profile, contamination, disease diagnostic and genetic epidemiology e.g. human DNA fingerprinting, pharmacogenetic.
- 2) R&D on raw materials to develop specific detector e.g. antigen, antibody, enzyme, DNA probe/primer or recombinant protein to produce the diagnostic kits
- 3) R&D on biological raw materials used to connect with the electronic device to shift from quality-based detection to quantity-based detection such as bio-sensor
- 4) R&D for enhancing inspection efficiency, to reduce false positive and false negative results e.g. use of nanotechnology or parallel inspection such as use of Array technology.

3.3.4 Related businesses include:

- 1) Manufacturing of diagnostic kits, bio-sensor
- 2) Manufacturing/Synthesizing of active pharmaceutical ingredients
- 3) Outsource research related to analytical inspection/testing

3.4 R&D business and/or manufacturing of bio-molecules and bioactive substances using microorganisms, plant cells and animal cells (Category 7.12.4)

3.4.1 The business must employ advanced technology to produce bio-molecules and/or bioactive substance using recombinant microorganisms, plants cells and animal cells as source of production with specific production process using domestic raw materials, and also study the characteristics of the generated biological substance e.g. active ingredient efficiency, toxicity.

3.4.2 Examples of technology used include advanced fermentation technology, genetic engineering technology, bioinformatics, and extraction technology using biological process.

3.4.3 Examples of activities that the business should have:

- 1) R&D on production process engineering for extracting sufficient amount of substance at high standard.
- 2) Molecular Study of bioactive substance to observe the chemical structure, to detect the suitable fit of active ingredients and targeted bacteria, to design the computing system for forecasting drug activity.
- 3) Develop the transgenic microorganism for industrial scale production.
- 4) Testing of extracted natural substance for the benefit of qualification, quantity and application method.
- 5) Research on selection and production of enzyme and develop a diagnostic method for efficiently utilizing the microorganism.

3.4.4 Related businesses include:

- 1) Production of enzymes/starter cultures to produce food supplement e.g. probiotics
- 2) Production of starter cultures for pesticide production and water treatment

- 3) Production of enzymes to act as a bio-catalyst that can replace chemical substance in the production process e.g. dyeing process and manufacturing of plastic.
- 4) Production of high quality biological substance extracted from plant, animals and microorganism.

3.5 Manufacture of raw materials and/or essential materials for molecular biological research and development, experiment, testing or quality control services and/or production of biological substances (Category 7.12.5)

3.5.1 The business must produce raw materials and/or materials needed for R&D, experiment/test, quality control or manufacture of bio-products, mainly for utilizing domestic raw materials.

3.5.2 Examples of manufactured products include

- 1) Raw materials such as
 - Hygienic eggs
 - Laboratory animals
 - Microorganism e.g. host cells, genetically modified microorganism
 - Antigen, antibody
- 2) Related materials such as
 - Standardized substance e.g. standard DNA, standard RNA and labelling substance.
 - Oligonucleotides e.g. short DNA molecules synthesized to use as a primer or probe or vector for DNA cloning.
 - Biomarker for improvement of breed or biological indicator.
 - culture medium for cells and tissues
 - ready-to-use reagents

3.5.3 Related businesses include:

- 1) Production of raw materials for research, experiment, test or bio-products e.g. disease-free eggs, laboratory animal
- 2) Production of required materials for research, experiment, test or bio-products e.g. standard DNA , culture medium for cells and tissues.

3.6 Business on biological substance analysis and/or synthesis services and/or quality control services and/or product validation services (Category 7.12.6)

3.6.1 The business must provide services on analysing and/or subcontracting production of biological substance and/or validating quality control matched with international standards

3.6.2 Examples of technologies used include:

- 1) DNA sequencing
- 2) Identification of specific protein for the purpose of analysing or study the function of organism e.g. mechanism to produce biological substance and pathology of disease.
- 3) Using bioinformatics to manage biological knowledge, develop informatic tools to efficiently solve computational problems.

3.6.3 Examples of activities that the business should have include:

- 1) Inspecting the contamination and verifying breed integrity by means of DNA sequencing .
- 2) Perform pharmaceutical testing, bio-similar testing, pharmaceutical equivalence when comparing with original.

3.6.4 Related business include:

- 1) Laboratory examination service for the production of bio-products
- 2) Production of biological substance
- 3) Quality control services of products in accordance with international standard
- 4) clinical research service

The above explanatory note is made for information to all concerns.

The Office of the Board of Investment
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