

(Unofficial Translation)

Explanatory Note on Application for Investment Promotion under Category 7.19

Biotechnology

In accordance with the Board of Investment Announcement 10/2552 dated 15 October 2009, the office of the Board of Investment announces the Explanatory Note on Application for Investment Promotion under Category 7.30 Biotechnology dated 6 May 2008 be amended and replaced with the following:

1. Application procedures for investment promotion privileges:

- 1.1 Applicant must submit “Investment Promotion application Form” (F PA PP 01) and “Supplementary Form for Application for investment Promotion under Category 7.19 Biotechnology” (F PA PP 19) to Investment Promotion Bureau 4, Office of the Board of Investment.
- 1.2 Regarding Supplementary Form for Application for Investment Promotion under Category 7.19 Biotechnology (F PA PP 19), if the company does not have any R&D project or the R&D project has already finished, the applicant shall fill in details only No. 1,2,3 and 5.
- 1.3 If the project has already received approval from the national Science and Technology Development Agency (NSTDA) or the Thailand Center of Excellence for Life Sciences (TCELS), letter of such approval should be submitted along with the application.
- 1.4 Proposals receiving approval from the National Science and Technology Development Agency or the Thailand Center of Excellence for life Sciences will be considered by the Office of the Board of Investment according to normal procedures.
- 1.5 Proposals not yet approved by considered for approval by the national Science and Technology Development Agency or the Thailand Center of Excellence for

Life Sciences will be first considered by a Biotechnology Proposal Screening Committee, and if approved by this committee, will be considered according to the Office of the Board of Investment's normal procedures.

1.6 Project undergoing significant change or revision following the approval must submit a "Request for project Revision" for further consideration by office of the Board of investment.

2. Project under Category 7.19: Biotechnology-Related Business comprises the following:

2.1 Project can be R&D project using advanced biotechnology and/or manufacturing products using advanced biotechnology to upgrade the industrial productivity. With regard to R&D project, applicant may operate the R&D activity by themselves or cooperate with other foreign or domestic agencies in order to enhance the research capabilities of human resources. Besides, in order to promote R&D and application of technology in molecular level, promotion shall include manufacture of raw material and/or essential materials used in molecular biological experiments and/or tests as well as analysis and/or synthesis services for biological substances.

2.2 Details of the R&D project or the product manufacturing project, as well as all other documentation required by the Office of Board of Investment must be attached to the application in order to be considered.

3. The activities falling under each of the six sub-categories for promotion are as follows:

3.1 R&D activity and/or industrial manufacturing of seeds or improvement of plant and animal breeds using biotechnology (Sub-category 7.19.1)

3.1.1 Activities utilizing biotechnology-related processes for speed and accuracy in selection, improvement, and production of plant and animal strains to derive desired characteristics; e.g., adaptability to unfavorable

environmental conditions, reducing the need for pesticides and insecticides, etc.

3.1.2 Examples of technology used include genetics engineering (gene modification), genetic marker assisted technology, technology for protein, enzyme or DNA research.

3.1.3 Examples of activities that should be incorporated include:

1) Study and research of molecular genetic data to determine the genetic of hereditary derivatives for each type of lineage; study of genes and distinguishing features related to reproductive and immune systems.

2) R&D into various kinds of genetic markers (biomarkers, molecular markers, or protein markers) and use all kinds of genetic information to improve plant and animal strain such as productive activities, disease free or high immune.

3) R&D into direct genetic modification; for example, use of hormones to select desired gender, use of radiation or genetic transformation with tissue culture and gene modification/gene splicing.

4) Assessment of potential or genetic quality of selected plants and animals through the identification of molecular markers, along with assessment of the economic potential of their external characteristics.

3.1.4 Related businesses include:

1) Propagation of seeds, stocks or tubers

2) Breeding, improvement and production of animal lines such as Black Tiger Prawn, fresh water lobster, Nile Tilapia, carp and cows.

3) Propagation of flowers and decorative plants as orchids and water plants

3.2 R&D activity and/or industrial manufacturing of pharmaceuticals using biotechnology, such as medicines, vaccines, and therapeutic proteins (Sub-category 7.19.2)

3.2.1 Application of biotechnology in the efficient production of pharmaceuticals with high standard

3.2.2 Examples of technology include: advanced fermentation technology; genetic engineering technology to enable microbes to produce desired substances; bioinformatics technology; as well as extraction and synthesis technology to derive active pharmaceutical ingredients.

3.2.3 Examples of appropriate activities include:

- 1) Study of molecular genetics data to assist in creating or prescribing medicines, such as comparisons of the effects of medication on human genes or the level of hereditary disease indications in order to develop medications or prescribe medications for treatment
- 2) R&D to find proteins or sensors for vaccine production
- 3) Development of vaccine production process using DNA technology
- 4) Research to develop models of active pharmaceutical ingredients in producing medicine prototype.
- 5) Clinical research into bioequivalence, pharmacokinetics, and bioavailability, to study effects and cytotoxicity of pharmaceuticals in cells
- 6) Research into models of production processes to efficiently develop pharmaceuticals on an industrial level.

3.3 R&D activity and/or industrial manufacturing of diagnostic test kits equipment for medical diagnoses, agriculture, foods, and environmental conditions. (Sub-category 7.19.3)

3.3.1 Activities that utilize biotechnology in the production of diagnostic tools for medical, agriculture, foods, and environmental conditions for screening and confirming results and to confirm results.

3.3.2 Examples of the kinds of biotechnology used include:

- 1) Application of proteomic technology, for example, principles of immuno-chromatography or Microarray, to detect antigens, antibodies, enzymes, or hormones: principles of inhibiting cell division of bacteria in test tubes: or principles of biosensors to detect enzymes, diseases, or chemical substances.
- 2) Genetic technology, such as microsatellite technology or nucleotide array.

3.3.3 Examples of appropriate activities include;

- 1) Biological studies/DNA fingerprinting of microbes in order to examine genetic attribute or contamination, and to diagnose diseases and epidemiology: for example, the study of human heredity, or the production of screening tests for viruses prior to populating shrimp ponds.
- 2) R&D of raw materials to create primers for microbes, antigens, antibodies, or enzymes: or DNA probes/primers for use in producing diagnostic kits
- 3) R&D of microsatellite markers to examine the purity of breed lines
- 4) Development of the production of recombinant protein for use in producing diagnostic kits

5) Development of models for improved diagnoses: for example greater speed, improved accuracy, or capacity for simultaneous diagnoses

3.3.4 Related businesses include;

1) Manufacture of diagnostic kits

2) Research service of upstream raw materials used in analysis and testing

3.4 R&D activity and/or industrial manufacturing utilizing microbial, plant and animal cells in the production of biomolecular material and substances giving bio-molecule. (Sub-category 7.19.4)

3.4.1 Use of advanced technology: for example, advanced fermentation technology or extraction technology using bio-processes and microbial, animal and plant cells, to effect modification of genes and/or metabolism to produce desired biological substances

3.4.2 Example of technologies used include: advanced fermentation technology: genetic engineering to splice genes to enable microbes to produce desired substances: and bioinformatics technology.

3.4.3 Examples of appropriate activities include:

1) Molecular studies of active ingredients to determine their chemical structure, their effect on targets, computation to forecast effects

2) Study and improvement of Production engineering to generate industrial levels of high standard extracted substances of sufficient quantity

3) Development of genetically modified organisms to evolve microbes with special characteristics that produce desired products that are safe.

4) Study, research and experimentation of the effects of natural, laboratory, or field-experimental substances to define their properties, amount, and uses

5) Research to develop technology for selection and production of enzymes, and to evolve means of discovering uses of various organic substances.

3.4.4 Related businesses include:

1) Animal feed production that utilizes enzymes originating from fermentation of organic matter, or that utilizes organisms such as bacteria, yeast, and molds as probiotics

2) Manufacture to be used as dietary supplements of high-value extracts from plants, animals, or organic matter

3) Manufacture of starter Inoculum to be used as plant pesticide and waste water treatment.

3.5 Manufacture of raw materials and/or essential materials used in molecular biological experiments or test (Sub-category 7.19.5)

3.5.1 Manufacture of raw materials and/or essential material used to support molecular biological activity or experiments with emphasis on using domestic raw materials.

3.5.2 Examples of the appropriate activities include:

1) Manufacture of DNA standard marker in various sizes for comparison to estimate the sizes of sizes of DNA to be studied.

2) Manufacture of oligonucleotides in genetic lines or short DNA synthesized for research and analysis such as that used as primer in DNA synthesis or probe in detecting genetic abnormality.

3) Manufacture of culture media specialized in culturing microorganism using domestic raw materials.

4) Manufacture of reagent used in analysis and testing in molecular level using domestic raw materials.

3.5.3 Related businesses include:

1. Manufacture of upstream raw materials or essential materials used in scientific research, experiments and testing such as culture media, reagent, lagging strand DNA.

3.6 Analysis and/or synthesis service for biological substances (Sub-category 7.19.6)

3.6.1 Analysis and/or synthesis service of biological substances to support fast, efficient and accurate application of molecular technology in biotechnology business.

3.6.2 Examples of the technology include:

1) DNA sequencing

2) Search of proteomics used in diagnosis or study of mechanism in organism such as mechanism in synthesis of biological substances, mechanism of disease

3) Application of bioinformatics to manage biological data, to formulate programs, tools for faster data processing.

3.6.3 Examples of activities include:

1) DNA base sequencing to diagnose contamination and breed line matching.

2) Diagnoses of germ contamination in working places, using genetically modified microbe to specify pollution.

3) Analysis of pharmaceutical property, pharmaceutical equivalence, bioequivalence of medicine, treatment and safety evaluation in comparison with original drug.

3.6.4 Related activities include:

1. Analysis and testing services that use biotechnology in molecular level.

2. Synthesis service of biological substances.

Remarks:

Advance fermentation technology means the biological processes of fermentation of varying types, incorporating control systems to ensure appropriate conditions, such as batch fermentation, fed batch fermentation, and continuous fermentation. Other types of technology can be included, such as cell recycling and cell fixing, which require completely unadulterated fermentation starters. These starters are to be described in detail, giving complete scientific information regarding the breed of starter, its physiological properties and characteristics as well as its genetic qualities.

Extraction technology using bio-processes refers to the processes of separating substances through the use of an organic solvent, for example ethanol, acetone, or organic acids, which extract a pure substance with bio-effects. In the case of herbal substance extraction, the project proposal must include scientific information to support the efficacy of the desired chemical elements of the plant.

Genetic engineering refers to editing genetic materials such as gene, DNA of various organisms to create desired genetic property.

Bioinformatic technology refers to application of computer technology and statistics in managing biological data such as protein, genetic code, for better efficiency and higher speed of data storage, analysis, synthesis and interpretation .

Office of the Board of Investment

November 26, 2009