(**Unofficial Translation**)

Information Relating to Application for BOI Investment Promotion Privileges for Biotechnology-related Businesses (7.30)

In accordance with the Board of Investment Announcement Sor 2/2550 on Promotion of Biotechnology dated 9 April 2007, in order for the Office of the Board of Investment to implement the aforementioned policy effectively, it is deemed appropriate to repeal and replace the Explanatory Note on Application for Investment Promotion under Category 7.30 Biotechnology dated 10 September 2007 with the following:

1. **Application procedures for investment promotion privileges:**

1.1 Applicant must submit "**Investment Promotion application Form" (F PA PP 01-04)** and "**Supplemental Form for Application for Investment Promotion under Category 7.30 Biotechnology" (F PA PP 19-00)** to Investment Promotion Bureau 4, Office of the Board of Investment.

1.2 Regarding **Supplemental Form for Application for Investment Promotion under Category 7.30 Biotechnology (F PA PP 19-00)**, if the company does not have any R&D project or the R&D project has already finished, the applicant will 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), certification 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 following regular procedures.

1.5 Proposals not considered for approval by the National Science and Technology Development Agency or the Thailand Center of Excellence for Life Sciences will be reviewed by a Biotechnology Proposal Screening Committee, and if approved by this committee, will be considered following regular procedures.

1.6 Projects undergoing significant change or revision following approval must submit a **"Request for Project Revision"** for further consideration by the Office of the Board of Investment.

2. Projects under Category 7.30: Biotechnology-Related Business comprises the following:

2.1 Projects can be R&D projects using advanced biotechnology and/or manufacture products using advanced biotechnology to upgrade the industrial productivity. With regard to R&D projects, applicants 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.

2.2 Projects relating to product manufacturing must incorporate activities utilizing advanced biotechnology to improve production processes and to promote the application of R&D in industry.

2.3 Advanced biotechnology applications eligible for promotion comprise, for example genetics, genetic engineering, genetic marker assisted technology, bioinformatics, fermentation technology, and extraction/distillation technologies that utilize biotechnology processes; as well as the use of living matter or organic parts in production to create value added products. Scientific information must be provided to describe, in detail, the living matter, including the origin, genetic characteristics, physical characteristics, and benefits to be derived, and caution must be paid to bio-safety.

2.4 Projects that have been approved for promotion under other categories and which involve advanced biotechnology for R&D and for industrial manufacturing may apply for promotion under Category 7.30.

2.5 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. Activities falling under each of the four sub-categories for promotion are as follows:

3.1 R&D and industrial manufacturing activities related to seed production or plant and animal strain improvement that utilize biotechnology-related processes

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, 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 or 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 improved quality, higher yield seeds and tubers that are disease resistance and/or compatible with the environmental change; *i.e.*, resistant to disease, pests, and drought conditions

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 such as orchids and water plants

3.2 R&D and industrial manufacturing of pharmaceuticals utilizing biotechnology, such as medicines, vaccines, and therapeutic proteins

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

Advanced fermentation technology refers to 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 pure strains of starter culture. These starters are to be described in detail, giving complete scientific information regarding strain types, physiological properties and characteristics, as well as genetic qualities

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 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 develop pharmaceuticals efficiently on an industrial level

3.3 R&D and industrial manufacturing of diagnostic equipment for medicine, agriculture, food, and environmental conditions; for example, equipment to measure the preciseness of plant and animal breed lines, and for medical examinations, as well as diagnostic kits, biosensors and gene chips.

3.3.1 Activities that utilize biotechnology in the production of diagnostic tools for medicine, agriculture, foods, and environmental conditions 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 immuno-assay, to detect antigens, antibodies, enzymes, or hormones; principles inhibiting cell division of bacteria in test tubes; or principles of biosensors to detect enzymes, diseases, or chemical substances.

2) Gene technology, such as microsatellite technology

3.3.3 Examples of activities that should be incorporated include:

1) Biological studies/DNA fingerprinting of microbes in order to examine genetic attributes 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 manufacturing of 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) Testing and analysis services

2) Production of animal feed diagnostic kits

3) Production of diagnostic kits for food exports, such as analysis of freshness, testing for contaminants, testing for chemical residue

4) Exporting, for example orchid disease test kits

3.4 R&D and industrial manufacturing utilizing microbial cells and plant and animal cells in the production of biomolecules and bioactive compounds; for example, hormones, probiotics, and flavor compounds for food production, as well as production of monoclonal antibodies and recombinant proteins

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

Advanced 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 extracts 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.

3.4.3 Examples of related businesses include:

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

2) Production engineering R&D 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 those 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 techniques for selection and production of enzymes, and to evolve means of discovering uses of various organic substances

3.4.4 Related business includes:

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) Businesses manufacturing high-value substances extracted from plants, animals, or organic matter

3) Businesses related to manufacture of substances from organic matter or organic substances to eliminate animal and plant pests

Office of the Board of Investment
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