BIOTECHNOLOGY POLICY OF HIMACHAL PRADESH

Chapter 1
THE POLICY

1. Introduction:

1.1 Himachal Pradesh towards harnessing the benefits of Biotechnology

Biotechnology is a fast developing field with activities and uses covering the entire spectrum of human life. Biotechnology, which involves the fusion of biology and technology, is the technology based on the understanding of life incorporating various aspects of biology, medicine, chemistry, engineering and informatics. Biotechnology is formally defined as “the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services. It involves manipulating and modifying organisms, often at the molecular level, to create new and practical applications for agriculture, medicine and industry.”

The areas which may be greatly (and positively) impacted by such applications/innovations and research are very wide ranging and may include diverse fields such as agriculture, floriculture and horticulture, medicinal and aromatic plants and forestry sector, soil fertility management, microbial products, traditional fermented foods and beverages, vaccine production, animal health including reproduction and nutrition, as well as gene pool conservation and utilization, IPR related issues and the cleaner environment, to name a few.

Himachal Pradesh has the wide scope to develop various types of BT industries using raw material base of fruits, vegetables, high value cash crops and other naturally growing herbal plants. These industries can be in the sectors such as, bio-pharmaceuticals, phyto-chemicals, bio-prospecting, fermentation, post-harvest processing, bio-processing, pharmaceuticals, biochemical, genetically engineered micro-organisms, enzyme production, environment protection and animal husbandry etc.

Himachal has tremendous potential in horticultural sector. The state needs immediate replacement of old orchards with high yielding, disease free fresh planting stock. Biotechnology can play important role by use of micro propagated plants. With this, the industries for cider, vinegar, wine and juice can come up to international standard. The horticulture sector also needs a facelift using hi-tech biotechnological interventions at nursery, orchard, post harvest, processing, packaging and marketing stages. The Horticulture Technology Mission launched in the State will prove to be a major milestone in strengthening the developmental activities through technological inputs.

In agriculture sector there is need for diversification of farming for economic rehabilitation and self-sufficiency. High yielding improved crop verities and transgenic
especially stress tolerant (cold, rain fed conditions), biofertilizers, biostimulants etc. are other areas where Biotechnology can play major role.

1.2 **Strengths of HP to Support Biotechnology based Industries**

Himachal Pradesh is an ideal destination to invest in biotechnology based industries because of the following advantages over other States:

**Biodiversity:** The State is endowed with rich plant, animal and microbial biodiversity. There are many rare plants, particularly in the upper reaches of Himalayas, which have immense potential for use in the pharmaceutical industry.

**Eco-diversity:** The State is unique in having varied ecological conditions. Depending upon the eco-geographical conditions, different flora and fauna predominates in different areas.

**Pollution-free environment:** Because of low population density and thick vegetative cover, the State is free from the pollution.

**Mild climate:** Unlike the neighbouring plains, the climate of the State remains mild for most part of the year. This is advantageous for those industries, which require controlled environment, especially cooling during summer months.

**Availability of industrial land, water and electricity:** There are three basic requirements to establish and sustain industrial units. There is adequate wasteland, which can be used to setup industries. The State has enough and cheap electricity, available throughout the year. Water, mostly from the natural perennial sources fed by snow melting is in abundance.

**Excellent law and order situation:** Himachal Pradesh is a peaceful State with virtually no law and order problem.

**Pro-active Government facilitation:** The State Government is pro active in promoting the BT enterprise in the State by providing quick facilitation for starting the units.

To expedite the potentials of biotechnological tools, a policy, “Biotechnology Policy of Himachal Pradesh” is being proposed in this document which has been revised taking into consideration the present needs of the State in Biotechnology Sector.

1.4 **Mission Statement:**

To convert Himachal Pradesh into a prosperous Himalayan Biobusiness Hub with Biotechnology as one of the engines of growth through scientific and technological empowerment of human resource for enhancing efficiency, productivity, cost effective products, processes and technologies.
Vision:

Promotion of Biotechnology through its application in agriculture, animal husbandry, medicine, environment, biodiversity conservation and utilization and bio-industrial development in the State.

Objectives:

- To make Himachal a preferred and globally competitive destination for development of BT products, processes and services.
- To upgrade infrastructural support to R&D and Educational Institutions to generate highly skilled human resource in biotechnology.
- To intensify R&D work in potential areas of biotechnology, including agriculture, animal husbandry, human health, environment and industry.
- To conserve and commercially exploit bio-resources of the State for sustainable development.
- To create awareness about the investment opportunities in biotechnology, genomics, bioinformatics, biofuels, contract research, etc. to entrepreneurial community and promote Biotechnology industrial investment in the State.
- To provide suitable Institutional framework to achieve the objectives.

Strategies:

- Scientific and technological empowerment of human resource for enhancing efficiency, productivity, cost effective products, processes and technologies
- Identification of areas for harnessing the rich bioresource available in the State.
- Ensure an effective scientific base and make strategic investments in R&D to support biotechnology innovation, the regulatory framework and economic development.
- Patenting of research findings using effective patenting regime in the State.
- Creation of infrastructure for up scaling the patented research for commercial production of consumer importance.
- Outline a number of incentives for setting up of enterprises based on local resources and commercialization of research base.
- Promotion of industries for manufacture of end product.
1.5 Institutional Framework to Achieve the Objectives:

The institutional frameworks within which the objectives of the Biotechnology Policy of the Government of Himachal Pradesh will be met are outlined below.

State Department of Environment, Science & Technology and rules governing the incentives to the Biotechnology Industries:

The Department of Environment, Science & Technology will be the Nodal Department in the State that will deal with matters concerning biotechnology in the State. The Department will promote appropriate research in different sectors, lay more emphasis on fields like bioresource utilization, conservation and industrial promotion that are likely to create employment and will try to bring companies and research centres closer.

As per the provisions of the Notification No. Ind. A(F)6-3/2008) dated 7.2.2009 Biotechnology related Thrust Enterprise(s) covered under Sl. No. 27 of Annexure-II of the Rules will be governed by:-

a) the procedure of the Department, as applicable to other Industrial Enterprises with regard to approval/acknowledgement, processing of applications for the purchase of private land, allotment and transfer of industrial plots/lands/sheds in the Industrial Area/Estate including Biotechnology Parks/Estates etc. of the State, release of electricity & water connections and other infrastructural requirements. The Department of Environment, Science and Technology of the State Government will be the Nodal Department for receiving, processing and recommending the applications of such Thrust Enterprise(s) to concerned Departments/ Boards/ Corporations of the State and Central Government, as the case may be, wherever required and

b) the Schemes of Incentives, Concessions and Facilities under these Rules as provided to Industrial Enterprises:-

- Ensure that incentives provided to manufacturing units are performance linked.
- Number of incentives in the form of subsidies, concessions and tax deferments provided by the State Government and Govt. of India which included tax related concessions, power concessions, availability of developed plots at no profit no loss basis.
- Additional incentives to special category entrepreneurs and incentives for quality, technology upgradation and installation of pollution control devices.
- Special incentives like Central Freight Subsidy Scheme are also provided to thrust enterprises.

Regulatory Mechanism

The regulatory mechanism in Biotechnology shall be followed in line with that of the Acts and Rules as notified by the Central Government under Environment Protection Act, 1986 under Rule for Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms,
Genetically Engineered Organisms or Cells Rules, 1989 for GMOs and product thereof. These Rules shall be executed by the Department of Environment, Science and Technology in the State.

The Rules for Ethical Policies on the Human Genome, Genetic Research & Services as notified by the government of India shall also be employed by the State Government. Beside this the r-DNA Vaccines Guidelines and Ethical issues and contest process pertaining to stem cell Research shall also be followed in the State in line with that of GoI instructions as given in the official website of Department of Biotechnology, Government of India.

Beside this, the Department will:

- Link the policy with the existing policies of the line Departments such as Organic Farming Policy of Agriculture Department; Technical Education Policy of Technical Education Department to modify course curricula in Biotechnology Sector, etc.
- Support R&D Institutions/Universities by providing funds through national and international funding.
- Execute and monitor commercial exploitation of biotechnological tools.
- Establish liaison among R&D Institutions/Universities, Industry, farming community and NGOs.
- Help in establishing ‘Biotechnology Parks’ for promoting biotechnology based industry and R&D Centers in the State.
- Help in managing intellectual property and patenting issues related to Biotechnology.

**Area of Operation**

The Biotechnology Policy will be operational in the State of Himachal Pradesh.

**Registration:**

The Biotechnology Industries and R&D Institutes engaged in the manufacture and R&D of BT products/HRD programmes in the State, need to register their units/Institutions with Department of Environment, Science & Technology (DEST). For this purpose, application in the prescribed format may be made to DEST, GoHP and Registration Certificate shall be issued in the prescribed format. In case of claiming benefit(s) under different policies of the Government, companies may be required to register separately with concerned department. The same shall be facilitated and coordinated by DEST. The companies will be able to claim any incentives or relaxations/concessions only on production of such certificate under the prescribed Rules.

**Definition:**

**Biotechnology Industry:** Government has included Biotechnology in the list of thrust industrial enterprises vide Notification No. Ind. A(F)6-3/2008 dated 7.2.2009 which envisages enterprises to manufacture industrial products by any biotechnology process and Processing Laboratories or Research and Development activity related to processing, scale-up, other
innovations and products in the field of Biotechnology, as approved by State Level Single Window Clearance and Monitoring Authority on the recommendation of Department of Environment, Science and Technology of the State Government. However, a Biotechnology (BT) industry refers to inter alia a company engaged in any of the following activities, using living things, and components of living things, involving manipulating and modifying organisms, often at the molecular level, to create any products (finished and semi-finished) having practical applications for agriculture, environment, medicine, industry, etc. Besides above, any commercial or research product manufactured or devised using the following techniques shall fall under the classification of BT Industry.

- Environmental biotechnologies: Bioremediation, biosensing, biological control, any other process biotechnology techniques, etc.
- Metabolomics/ metabonomics.
- Systems biology –biosystems–ecological sanitation. Composting/digestion, etc.
- Synthetic biology.
- Biodiscovery.
- DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling and use of anti-sense technology, etc.
- Proteins and other Molecules: Sequencing/synthesis/engineering of proteins and peptides (Including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signaling, identification of cell receptors, etc.
- Cell and Tissue Engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation, etc.
- Process Biotechnology Techniques: Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, biofiltration and phytoremediation, etc.
- Gene and RNA Vectors: Gene therapy, viral vectors, etc.
- Bioinformatics: Construction of databases on genomes, protein sequences, modeling complex biological processes, including systems biology, etc.
- Nanobiotechnology: Applied tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics, etc.

The Biotechnology Industry/Company using the process/techniques as described above is classified as follows:
- Medical/Human and Animal Healthcare both manufacturing and R&D
- Agriculture and Food both manufacturing and R&D
- Environment both manufacturing and R&D
- Industrial BT Products both manufacturing and R&D
- Bioinformatics

**Medical**
- Diagnostics
- Vaccines
- Therapeutics
- Veterinary Drugs (including vaccines)
- Natural drugs/Biopharmaceuticals

**Agriculture–Food**
- Biopesticides & Biofertilizers
- Natural Products in Healthcare/Food Industry
- Animal Feeds Supplements from Agriculture Products
- Flavors/Fine Chemicals/Amino Acids/ Nutrient Supplements from plant and animal waste
- Transgenics, Cell/Tissue Engineering (improved biotic and a biotic stresses, agronomic and nutritive qualitative characteristics)
- Diagnostics – Disease
- Technologically aided fruit processing
- Commercial Micro propagation
- Cell/Tissue culture and Engineering

**Environment**
- Methods/Apparatus/Techniques for Biosensors
- Microbial strain development of cultures for waste management
- Bioremediation
- Effluents and waste water treatment plants
- Creation of value-added germplasms including microbial germplasms.
- Commercial cultivation, value addition and processing of Medicinal and Aromatic Plants

**Industrial Products**
- Food and Industrial enzyme
- Classical Fermentation products (antibiotics, immuno modulators, etc.) for yield improvements
- Bio-energy/Biofuels
- Surface and additives
- Biopolymers
• Other categories

Biosimilars, Bioproducts, bioplastics, biodetergents, biolubricants, etc.

However, any BT units involving GMOs shall be covered under the guidelines and regulations as notified by Government from time to time to this effect in the State.

**Regulatory guidelines for GMOs in India**

The legislative framework on agro-biotechnology is provided under the Environment (Protection) Act 1986. The Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Modified Organisms or Cells formulated under the Environment (Protection) Act provide the multi-tiered regulatory framework to assess and ensure bio safety of genetically engineered organisms.

1.6 **The State Industrial Policy (Draft):**

1.6.1 **Vision**

To promote and incentivize industry led sustainable economic growth by creating a conducive climate which enables environmentally sustainable inclusive development, generates income and employment opportunities, and encourages skill development thereby establishing Himachal as a model industrial hill State, or

To establish Himachal as a model industrial hill State that promotes and incentivizes industrial growth through sustainable inclusive development, generating income and employment opportunities, and encouraging skill development, all in harmony with the State’s environment and ecology, or

To achieve environmentally sustainable and balanced industrial growth leading to more employment opportunities, income generation and overall economic development of the State.

1.6.2 **Mission**

To make Himachal a model Hill State to by promoting and developing micro, small, medium and large industries with emphasis on eco-compatible and local resource based industries thereby creating opportunities of employment and increasing the share of industries in the State Gross Domestic Product.

1.6.3 **Objectives**

a) To achieve an average annual industrial growth rate of 15% per annum, aligned with the target of 9% per annum growth in State GDP as envisaged in the 12th Five Year plan, with the manufacturing sector contributes at least 25% of the State GDP by the year 2022.
b) Promoting Himachal Pradesh as the most preferred investment destination to ensure uniform industrial growth throughout the State.
c) Creating additional employment opportunities for about 3 lakh persons by the year 2022 through enhancement of skills and entrepreneurs.
d) Encouraging eco-friendly and environmentally sustainable industrial growth through adoption of cleaner technologies and environmental management systems and promoting public disclosure of pollution status at the unit and cluster level.
e) Continuing thrust on creation and provision of state of the art industrial and related infrastructure.
f) Creating a congenial investment climate by ensuring ease of business and time bound delivery of services.

1.6.2 Incentives to the Biotechnology Industry

A new set of Rules to govern incentives, concessions and facilities are being announced as a part of this Policy which will remain operative till the next Rules governing the incentives, concessions and facilities are announced or these rules amended. While doing so, it will be our effort to enable existing units to avail of the incentives they are already availing for the periods they are entitled to.

The salient features of Schemes of Incentives, Concessions and Facilities as provided to Biotechnology Industrial Enterprises in the State is as follows:

- Number of incentives in the form of subsidies, concessions and tax deferments provided by the State Government and Govt. of India which included tax related concessions, power concessions, availability of developed plots at no profit no loss basis.
- Additional incentives to special category entrepreneurs and incentives for quality, technology up gradation and installation of pollution control devices.
- Special incentives like Central Freight Subsidy Scheme are also provided to thrust enterprises.
- Ensure that incentives provided to manufacturing units are performance linked.
- Special Incentives would be provided to encourage local employment generation entrepreneurship and for setting up of environment friendly industry, especially industry based on local skills, raw materials and employing local people.
- Incentives would also be provided to enterprises for improving productivity through technological and process improvements, patenting their inventions and its commercialization.
- Fiscal incentive by the State Government would also be provided to certain specific categories of entrepreneurs and enterprises identified as “Thrust industries”.
- State taxes to be paid by new undustrial units would be rationalized and streamlined.
- Tax incentives would be graded in accordance to the category of areas where the Industrial unit is located.

Note: The BT industries located in rural areas are also eligible for all incentives and exemptions available to other BT industries in BT Park and elsewhere in the State.
1.7 DEVELOPING BIOTECHNOLOGY INFRASTRUCTURE

Development of Biotechnology infrastructure in the State shall be precisely based on the State Land Policy and Planning keeping in view the land availability utilizing barren land, un-irrigated cultivable waste land lying unutilized for long time shall be taken into consideration and the land development shall be done by the Industries Department and finally shall be allocated to Biotechnology Industries in the State.

The State Government, through collaborative partnerships and provisions of incentives/concessions, proposes to encourage and facilitate the private sector, in developing necessary Biotechnology infrastructure such as Biotechnology Parks and other supporting infrastructure for research, training, testing, accreditation, etc.

State’s varied regional characteristics such as geographic location; agro-climatic conditions, distribution of industries, academic institutes, research centre etc. provide comparative advantage to a particular biotech sector. In view of such comparative advantages the State Government proposes to encourage the development of dedicated clusters in the following areas:


1.7.1 Establishment of Biotechnology Parks

The State is already in the process of setting up a Biotechnology Park at Aduwal, Teh. Nalagarh, Dist. Solan. It is proposed to setup Biotechnology Parks/ BT Industrial Cluster in Himachal Pradesh in association with the private sector to boost biotechnology based ventures. Biotechnology based and other auxiliary industries will be located in these Parks. It is proposed to locate these Parks on the Solan and Sirmour districts. The Biotechnology Park will have the following salient features:

- Biotechnology Incubation Centre (BTIC)
- Industrial Plots for starter companies
- Auction/Procurement Centre for raw material of medicinal and aromatic plants and horticultural produce.
- Auction/Procurement Centre for biotechnology based products.
- Availability of genetically improved planting material.
- Facility for on-line trading.
- Cold storage facility for perishable products, like flowers
- Information Technology cell.
- Consultancy for biotechnology based industries.
- Demonstration plots.
Benefits from the Biotechnology Parks

- Employment generation
- Investment opportunities in Biotechnology in the State
- Conservation of biodiversity as only the produce of cultivated medicinal and aromatic plants will be purchased and utilized in industry.
- Boost to economy of the State.
- Increase in land utilization due to diversification of farming.
- Meeting the challenges of WTO
- Direct buyer seller contact
- Good buyer and grower base

1.7.2 R&D Infrastructure

More and more R&D support shall be created by the Government for improving the R&D Infrastructure of the Research Institutions by creating a Corpus Fund in Biotechnology Sector and suitably rewarding the best Research work in the State as an encouragement to the Research Scientist in Biotechnology.

Operational Mechanism

A linkage needs to be established among farmers and industry including, R&D Institutions. This will allow continuous supply of raw material required for the industry with a buy-back facility needs to be ensured to the farmers for supplying the raw material. This is especially true for herbal, aromatic and horticulture based industries.

1.8 Biotechnology Task Force

A Task Force has already been constituted to advise the State Government on making biotechnology related policies and implementing them. The Task Force will also formulate norms for setting up biotechnology based industry.

1.9 Single Window Clearance Agency

A Single Window Clearance Agency will be constituted to clear all the projects related to biotechnology.