

GOVERNMENT OF UTTARAKHAND

BIOTECHNOLOGY

POLICY

2018-23

CONTENTS

A. UTTARAKHAND: AN OVERVIEW	3
B. BIOTECHNOLOGY SECTOR	(3-5)
B.1 Definitions	3
B.2 Indian Scenario	4
B.3 Indian Government Initiatives	5
C. UTTARAKHAND: POLICY STATEMENTS FOR BIOTECH SECTOR	(6)
C.1 Vision	6
C.2 Mission	6
C.3 Policy Objectives	6
C.4 Policy Targets	6
D. WHY UTTARAKHAND: TACTICAL ADVANTAGES WHICH STATE OFFERS ?	(6-12)
D.1 Favorable location and abundant resources	6
D.2 Policy and infrastructure	7
D.3 Stable political environment & statistics	7
D.4 Large base of adequate Scientific & Technical Manpower	8
D.5 Technology Convergence	8
D.6 Single–Window Clearance Mechanism	8
D.7 Fiscal Incentives	8
D.7.1 Incentives for Manufacturing Activities	9
D.7.2 Mega Industrial & Investment Policy- 2015 (MIIP- 2015)	9
D.8 Special financial incentives and other assistance proposed for R&D	10
D.9 Incentives for Biotech Park/ Incubators	11
D.10 Scientific Regulatory Approvals	12
E. UTTARAKHAND BIOTECHNOLOGY COMMITTEE (UKBC)	(12)



A. UTTARAKHAND

Uttarakhand is 27th State of India, which was carved out of northern Uttar Pradesh on 9th November, 2000. Located in midst of Himalayan mountain ranges, it is largely a hilly State, having international boundaries with China in the north and Nepal in the east.

It has almost all major climatic zones, making it amenable to a variety of commercial opportunities in horticulture, floriculture and agriculture. The number of small scale industries is 25,294 providing employment to 63,599 persons. As many as 1802 heavy and medium industries with an investment of Rs 20,000 crore employ 5 lakh persons. Besides, there are a total of 54,047 handicraft units in the state.

With levels of literacy rate (79.63% with 88.33% males and 70.70% females) higher than the national average, Uttarakhand has abundant availability of quality human resources. It harbors 14 Govt Universities, 15 Private Universities and 15 Research Institutions of National & International repute.

Uttarakhand has witnessed massive growth in capital investments due to a conducive industrial policy and generous tax benefits. Therefore, Uttarakhand is one of the fastest growing states in India. Within 17 years of its existence and resource development, Uttarakhand has emerged as a significant destination for investments in manufacturing industry, tourism and infrastructure.

A. BIOTECHNOLOGY SECTOR

B.1 Definitions

'Biotechnology' is defined as the application of Science & Technology to living organisms as well as parts, products and model thereof, to alter living or non-living materials for the production of knowledge, goods and services.

'Biotechnology Product' include a product, which uses or is derived by using (a) living systems, (b) enzymes, (c) Proteins (d) Bio-molecules and by any of the biotechnological tools and techniques including genetic engineering.

'Biotechnology Unit/Company' is any company (product development and/or service oriented such as clinical research and biotech contract research organizations) initiating and carrying out work utilizing 'Living Systems' including genetic engineering with an objective to develop via R&D a product (proteins, enzymes, lipids and other biological molecules) or a process of benefit to the society in the areas of Agriculture, Health, Energy and Environment.

'Biotechnology Park/Incubator' means an organization registered as a Park/Incubator, engaged in accelerating the growth of start-ups through host of support services and resources such as space, funding support, mentoring, market linkages and business management services.

'Biotech Startup company' as defined under terms and conditions outlined in the Startup Policy of Uttarakhand-2018 (<https://www.siidcul.com/industrial-policy/startup-policy-uttarakhand-2017>). An entity shall be considered as a 'startup',



1. Up to five years from the date of its incorporation/registration [07 years for Biotechnology Units/Company on approval Uttarakhand Biotechnology Committee (UKBC)]
2. If its turnover for any of the financial years has not exceeded Rs. 25 crores, and
3. It is working towards innovation, development, deployment or commercialization of new products, processes or services driven by technology or intellectual property; Provided that any such entity formed by splitting up or reconstruction of a business already in existence shall not be considered a 'start-up'; Provided further that in order to obtain tax benefits a startup so identified under the above definition shall be required to obtain a certificate of an eligible business from SLIC (State Level Innovation Council) or Gol.

MAJOR PRODUCT SERVICES OF THE INDIAN BIOTECH INDUSTRY

And priority focus areas for Uttarakhand

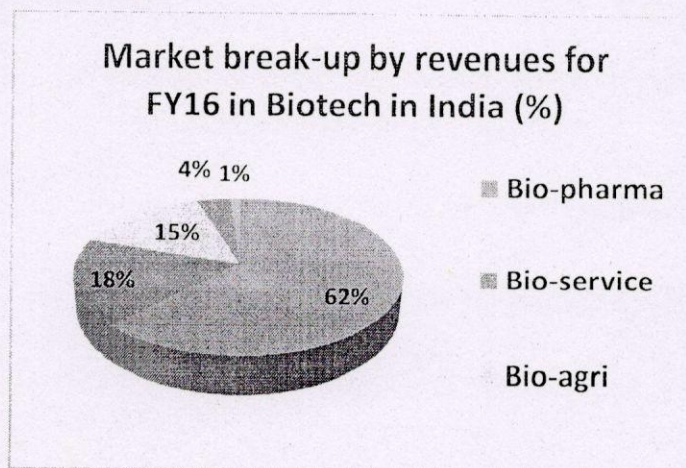
Biopharma	Bio-Agri	Bio-industrial	Bio-service Bioinformatics
<ul style="list-style-type: none"> • Vaccines ✓ • Medical devices & biosensor based diagnostic Kits • Therapeutics • Bio-similars 	<ul style="list-style-type: none"> ✓ • Hybrid Seeds ✓ • Bio-fertilizer, Bio-pesticide ✓ • Animal Husbandry & Organic meat ✓ • Contract-farming 	<ul style="list-style-type: none"> • Enzymes • Probiotics 	<ul style="list-style-type: none"> • Drug Discovery • Sequencing & Data Analytics • Contract research organizations • Clinical trials

B.2 Indian Scenario: The biotechnology sector of India is highly innovative and is on a strong growth trajectory. India is among the top 12 biotech destinations in the world and ranks third in the Asia-Pacific region, with approximately 3% share in the global biotech industry. The Indian biotech industry, which comprises about 800 companies, is estimated to have grown at a CAGR of 20.3% during 2005-17, to reach USD 11.6 billion in 2016-17. By 2025, Indian Biotech industry is expected to reach USD 100 billion.

India has the second-highest number of US Food and Drug Administration (USFDA) approved plants, after the USA and is the largest producer of recombinant Hepatitis B vaccine. Out of the top 10 biotech companies in India (by revenue), seven have expertise in bio-pharmaceuticals and three specialize in agri-biotech.

Under Indian biotech scenario, Bio-pharma is the largest sector contributing about 62% of the total revenue followed by bio-services (18%), bio-agri (15%), bio-industry (4%), and bio-

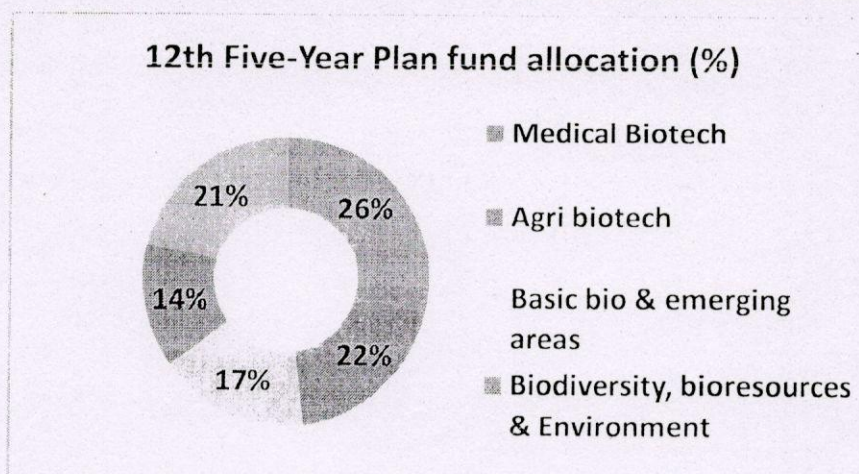
informatics contributing (1%). India is becoming a leading destination for clinical trials, contract research and manufacturing activities which is leading to the growth of bio-services sector. India has a strong institutional support for R&D in Biotechnology. Besides, both government and autonomous institutions has capacity to develop appropriate pool of skilled human resource in biotechnology.



B.3 Indian Government Initiatives

A network of Technology Centers and promotion of start-ups by Small Industries Development Bank of India (SIDBI) are among the steps taken by the Government of India to promote innovation and entrepreneurship in the agro industry proposed by the Ministry of Micro, Small & Medium Enterprises (MSME) in a new scheme. The Government of India has taken several initiatives to improve the biotechnology sector in the country as well as offer enough scope for research in this field. The Department of Biotechnology (DBT) along with other government funded institutions such as National Biotechnology Board (NBTB) and many other autonomous bodies, are working together in order to project India as a global hub for biotech research and business excellence. Some of the recent major initiatives are as follows:

In the Union Budget 2017-18, the DBT received Rs 2,222.11 crore (US\$ 333.31 million), with an increase of 22%, to continue implementing the department's national biotech strategy and target to increase the industrial investment from \$7 billion (2016) to \$100 billion by 2025 from.



C. UTTARAKHAND: POLICY STATEMENTS FOR BIOTECH SECTOR

C.1 Vision

Developing conducive environment for promotion of competent R&D, innovation & commercialization, and harnessing true potential of Biotechnology as one of the key sector for socio-economic growth of Uttarakhand

C.2 Mission

Nurturing innovation, translational capacity and entrepreneurship for Promotion of biotechnology and creation of appropriate ecosystem to attract biotech based industries in Uttarakhand

C.3 Objectives

1. To develop quality infrastructure facility with the required support services for development of human resources and Biotechnology based industrial ventures
2. To make Uttarakhand a preferred destination for Biotechnology Industry by providing proactive, congenial and industry-friendly climate for Biotechnology companies.
3. Simplify administrative and clearance processes to create an enabling environment for the public and private sectors to invest across the biotechnology value chain
4. To promote creation of Intellectual Property (IP) in the biotechnology by facilitating R&D institutions and contributing more funds to R&D in the biotechnology sector.
5. To encourage indigenous bioresource based biotechnological activities for the promotion of village level industries in the state
6. To promote R&D and Innovation in state specific potential issues of agriculture, horticulture, health etc. through biotechnological interventions

C.4 Policy Targets

Policy targets are as follows:

1. Enhance competitiveness of the sector to make Uttarakhand one of the most preferred destinations for biotech investments
2. Attract new investments worth Rs 5,000 crore in the sector by 2023
3. Create additional employment opportunity for 2,000 skilled personnel in the sector by 2020 and 5,000 people by 2023

D. WHY UTTARAKHAND: TACTICAL ADVANTAGES WHICH STATE OFFERS ?

D.1 Favorable location and abundant resources

The state has close proximity to the national capital Delhi, a leading market of the country and excellent connectivity with neighboring states. Almost all agro-climatic conditions prevail in the state due to hilly terrain, which support agriculture and horticulture based industries. State has recorded a remarkable production of fruits (6.7 lakh tone), vegetable (9.5 lakh tone) and spices



(3.7 lakh tone) during 2017-18. The Central Government has planned to provide Rs 1,500 crore (US\$ 231.69 million) for development of 'Organic Farming' in the state of Uttarakhand. Almost 10,000 new clusters are expected to be developed in this project. State provides vegetables during off seasons.

D.2 Policy and infrastructure

The state offers a wide range of benefits in terms of interest incentives, financial assistance, subsidies and concessions. Uttarakhand has a strong social and industrial infrastructure, virtual connectivity with over 39,000 km of road network, two domestic airports, 339.80 km of rail routes and an installed power capacity of 3,356.23 MW.

State has formulated some promising innovative policies, such as MSME Policy-2015; Special Integrated Industrial Incentive Policy (Hill Policy) (As Amended/As Modified)-2011; Central Capital Investment Subsidy Scheme; Mega Industrial & Investment Policy-2015; Purchase Preference Policy-2014; Start-up Policy-2017; Freight Subsidy Scheme Gazette; Central Capital Investment Subsidy Scheme; *Mahila Udyami Vishesh Protsahan Yojna*, etc. creating inductive environment for ease in doing business.

Besides, institutional support system for information and escort assistance by State Infrastructure and Industrial Development Corporation of Uttarakhand Limited (SIIDCUL), Industries Association of Uttarakhand (IAU), Information Technology Development Agency (ITDA) and Uttarakhand Organic Commodity Board (UOCB) reflects vibrant efforts of state to facilitate investment in Biotechnology.

D.3 Stable political environment & statistics

The state has a stable political environment with successive governments that have been committed towards creating a progressive business environment including fiscal incentives. Following are some economic snapshots of Uttarakhand (Source: Ministry of Statistics and Program Implementation):

- At current prices, gross state domestic product (GSDP) of Uttarakhand stood at around Rs 2.18 trillion or 2.18 lakh crore (US\$ 33.61 billion) in 2017-18 as compared to Nation's GDP for the year 2016-17 Rs 151.84 lakh crore. Between 2011-12 and 2017-18, GSDP of the state grew at a CAGR of 11.16%.
- In 2017-18, the state's per capita GSDP was estimated at around Rs 197,539 (US\$ 3,051). The per capita GSDP increased at a CAGR of 9.68% between 2011-12 and 2017-18.
- At current prices, net state domestic product (NSDP) of Uttarakhand was around Rs 1.95 trillion or 1.95 lakh crore (US\$ 30.18 billion) in 2017-18, as against Nation's Rs 134.08 lakh crore for the year 2016-17. NSDP of the state witnessed growth at a CAGR of 11.45% between 2011-12 and 2017-18.
- In 2017-18, the state's per capita NSDP was about Rs 177,356 (US\$ 2,740) as compared to Nation's Rs 103,219 during 2016-17. The per capita NSDP increased at a CAGR of 9.96% between 2011-12 and 2017-18.



D.4 Large base of adequate Scientific & Technical Manpower

The average literacy level of the state is high. A large pool of trained and talented human resources is available as Uttarakhand has some top-notch R&D institutes and Universities (14 State Universities, 01 Central and 15 Private Universities), 15 R&D institutions including 3-CSIR & 1-ISRO). They foster the need for skilled manpower and Industry-Academia linkages for fruitful technical and R&D assistance.

D.5 Technology Convergence for Biotech R&D

The state government is confident that the effective symbiotic convergence of Information Technology, Biotechnology and Pharma will catapult the State into the forefront of major global biotechnology centers. The State harbors Uttarakhand State Council for Science & Technology (UCOST), Uttarakhand Council for Biotechnology (UCB), AIIMS, Universities, R&D institutions, incubation centers, IT Park, Software Technology Park of India (FTPI) Earth Station and well established 09 different Industrial Estates in plain areas of Tarai-Bhabhar and hilly regions. They will not only breed new technology and foster innovation but also help develop a synergy between IT, Academia, Industry, Hospitals and R&D laboratories.

Technology Business Incubator (TBI) supported by Dept of Science & Technology (DST) at Dehradun and Technology Incubation and Entrepreneurship Development Society (TIEDS) supported by Department of Electronics and Information Technology (Deity), Gol at Roorkee are working to facilitate Start-ups and innovators.

D.6 Single-Window Clearance Mechanism

State announced the implementation of single window clearance system in the MSME (medium, small and micro enterprises) policy introduced in 2015. The IT enabled single-window contract facility is available under a two-tier system:

- The District Industrial Centers (DIC) at the district-level.
- SIIDCUL at the state-level.

These centers are responsible for providing information and escort services to entrepreneurs. Approvals for establishment of ventures are given in 15 days and the deadline for approvals has been set at 30 days. All approvals are provided online. Aspiring companies may visit website of SIIDCUL for Land bank details (<https://www.siidculsmartcity.com/GIS/>).

State government has proposed an investment plan of Rs 554.00 crore (US\$ 85.96 million) through single window system, which will result in employment generation opportunities for around 500 people.

D.7 Fiscal Incentives

While the State offers attractive range of incentives for setting up of new industrial enterprises, it recognizes that the Life Sciences/ Biotechnology industry, characterized by high investments and long gestation periods, needs special focus to help sustenance and growth of the sector. Biotech facilities will get the following special benefits:



D.7.1 Incentives for Manufacturing Activities

Under "MSME Policy-2015", State has been divided into five categories (A, B, B+, C & D) for the purpose of quantum of incentives/ subsidies based on Hilly and plain regions, in which special focus has been given to Biotechnology.

Following is a summary of incentives under "MSME Policy-2015":

- Investment Promotion Assistance (Capital Subsidy): All eligible new and existing industrial units on their substantial expansion, would be eligible for investment promotion assistance @ 40% [Max. up to Rs. 40 lacs] in category A, @ 35% [Max. up to Rs. 35 lacs] in category B and B+, @ 30% [Max. up to Rs. 30 lacs] in category C and @ 15% [Max. Rs. 15 lacs] in category D District/ region, on the fixed capital investment in plant & machinery.
- Interest Subsidy would be eligible @ 10% [Max. up to Rs. 8 lacs/per year] in category A, @ 8% [Max. up to Rs. 6 lacs/per year] in category B and B+, @ 6% [Max. Rs. 4 lacs/per year] in category C and @ 5% [Max. Rs. 3 lacs/per year] in category D District/ region on Term loan/ working Capital.
- SGST after the adjustment of input tax credit on the sale of finished product [B to C] will be reimbursed from the date of commencement of production in the unit (100% for the 5 year and 90% thereafter for Category-A & 100% for the first 5 year and 75% thereafter in category B & B+ District/ region).
- A total of 100% quantum of concession on Stamp Duty will be admissible in Category-A, B, B+, C and 50% in Category D district/ region.
- All eligible Manufacturing industrial units, would be eligible for Reimbursement of electricity bill @ 100% for the first 5 year and 75% thereafter, in category A and 100% for the first 5 year and 60% thereafter in category B & B+ up to 100 KVA sanctioned load. For sanctioned load above 100 KVA, 60% quantum for reimbursement is set for Category-A, while 50% for Category- B & B+.

D.7.2 Mega Industrial & Investment Policy- 2015 (MIIP- 2015)

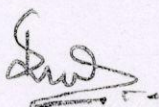
MIIP-2015 [As amended in 2018] is an enabling policy which has been framed to attract investment with an objective to promote industrial development in the state. On the basis of Capital Investment Project shall be classified as large, Mega & Ultra Mega as follows:

1. Large Projects: Capital Investment of Rs 50 crore to Rs 75 crore
2. Mega Projects: Capital Investment of Rs. 75 crore to Rs 200 crores
3. Ultra Mega Projects: Capital Investment of more than Rs 200 crores

Eligible enterprises/ units may avail benefits, incentive and concessions for maximum 5 year from the date of commencement of commercial production within the valid period of the scheme.

Following are the incentive under MIIP- 2015:

1. Interest Subsidy: 7% maximum Rs 25 lacs for large Projects, 7% maximum Rs. 35 lacs for Mega Projects and 7% maximum Rs 50 lacs for Ultra Mega Projects.



2. Reimbursement for SGST after adjustment of input Tax Credit on the sale of finished product (B to C) @ 30% for large units and @ 50% for Mega and Ultra Mega units.
3. Power Assistance/power Bill rebate.
4. Rebate on Stamp Duty: 50% of stamp duty on registration of purchase / Lease Deed on the land.
5. Reimbursement of land Registration Fee.
6. Subsidy on ETP: 30% Maximum Rs 50 Lacs.
7. Rebate on Mandi Tax.
8. Payroll assistance for promoting greater employment generation.
9. Concession on Land Cost in SIIDCUL Industrial areas (on prevailing rates 15% for Large Projects, 25% for Mega Projects & 30% for Ultra Mega Projects).

D.8 Special financial incentives and other assistance proposed under Biotechnology Policy-2018-23

A Biotech Corpus of Rs 5.0 crore has been created to facilitate Biotech Companies/Units/Start-ups, for R&D, Mentorship, Project Report, Standardization Certificate, IPR and Market Incentives. Besides all other legitimate fiscal incentives described in MSME Policy-2015 and MII Policy- 2015, following are the incentives available for the Biotech Companies/Units/Start-ups classified under Biotechnology Policy:

- I. **Co-financing of industry sponsored research:** Co-financing of biotech related research projects of public interest through Biotech corpus on pre-approval of Uttarakhand Biotechnology Committee (UKBC), constituted by the Government.
- II. **Collaborative Research Grant:** The scheme aims at accelerating collaborative research for market driven product development through Biotech corpus among scientists, preferably of Uttarakhand based research institutions and/or academic institutions. This will be approved by the UKBC.
- III. **Introduction of Grand Challenges:** UKBC will launch a Grand Challenges under the Start-up Policy-2017, which will focus on new technologies or innovations that can offer solutions to some longstanding issues pertaining to the state of Uttarakhand. It is aimed to channelize innovations for social impact and, in the process, support the establishment and growth of start-ups. Grand Challenges around five well-defined priority queries will be taken up in the first phase. The funding will be completed in two stages:
Phase I: Up to five innovators will receive Idea to Proof of Concept funding of up to INR 05 lakhs for six months for prototyping and testing innovative solutions in a real-world setting.
Phase II: After six months, the selected candidates will undergo one more round of selection. One of them will be selected for further funding of up to Rs 25 Lakhs for 12 months to scale up the prototype.
 The award agreement will be structured as a grant. The UKBC will provide the winning candidates access to networks and marketing channels to commercialize their innovations.
- IV. **Mentorship Support:** Provides start-ups with business advisory services through Mentorship Support of Rs 5 Lakh per Unit and facilitate access to private investors only

to those projects that are approved by UKBC through Biotech corpus. Mentors will facilitate Idea Validation, Effective Business Plans, Sales and Marketing Strategy, and Start-up/Entrepreneur Education and Training Program.

- V. **Reimbursement of Costs for Preparation of Project Report:** Refund of cost incurred for preparation of project report, up to a maximum of Rs 1 Lakh through Biotech corpus.
- VI. **Standardization Certificate:** Financial assistance of up to 50% of the cost incurred in obtaining a standards certificate such as ISO / BIS / GLP / GMP / NABL (maximum of Rs 5 Lakhs per case) through Biotech corpus.
- VII. **Patent Registration:** Financial assistance towards the cost of filing and prosecution of patent application up to a limit of Rs 0.5 lakh per Indian Patent awarded; and for awarded international patents on a single subject matter up to Rs 2.00 lakhs through MSME Policy-2015 or Biotech corpus.
- VIII. **Marketing Incentives:** Reimbursement of 30% of the actual costs incurred for marketing programs, subject to a maximum of Rs 2 Lakhs per year per company through Biotech corpus.
- IX. **Part Funding & Legal Backing to support preclinical trials of Biopharma & Bioservice Companies/Units** and field trials of hybrid or high yielding seeds varieties. A matching contribution of up to Rs 25 lakhs is proposed for such financial supports after pre-approval of UKBC through Biotech corpus. The government will upgrade/develop a dedicated biological testing facility well-equipped with latest technological equipment at GBPUA&T, Pantnagar for product testing or trials and authorized to provide certification. This testing laboratory would act as a certifying authority similar to the NIB.
- X. **Incentive through EPF Contribution:** Eligible Biotechnology units will be given the benefit of reimbursement of the EPF contribution made for their incremental employees operating out of their facilities in Uttarakhand for a period of five years. This reimbursement would be made subject to the following criteria:
 - i. 100% of EPF amount paid in case of female employees
 - ii. 75% of EPF amount paid in case of male employees
 - iii. The ceiling of EPF amount per employee will be 12% of Employee's basic salary plus applicable DA and retaining allowance.
- XI. **Anchor Unit Subsidy:** Available for the first two manufacturing enterprises with a minimum employment of 70-100 members and a minimum investment of Rs 50 crores.

D.9 Incentives for Biotech Park/Incubators

Besides various subsidies described in MSME Policy-2015 and MII Policy- 2015, the eligible Biotech Park/Incubators (Incubates minimum 10 incubatees at a time and out of which minimum 60% are from Biotechnology sector. For new incubators being setup under this Policy, the incubator should get 06 incubatees within 2 years from the date of application out of which minimum 60% will be from Biotechnology sector) will be entitled for following Incentives:

1. **Mentoring Assistance:** Eligible Incubators will be entitled to a mentoring assistance of Rs. 5 lakhs per annum.



2. **Operating Assistance:** Eligible Incubators will be entitled to a matching grant of 25% of funds mobilized by them from non-governmental sources, subject to a ceiling of Rs One Crore per annum for meeting their operational expenses.
3. **Assistance for Procurement of Software:** Government will support the procurement of key software required for development and testing purpose at the incubator attached with an educational institution or a university as recognized by UGC/ State Government/ AICTE at the rate of 50% of software cost subject to a ceiling of Rs. 50 Lakhs.

D.10 Scientific Regulatory Approvals

Uttarakhand Biotechnology Committee (UKBC) shall set-up a Guidance Cell through Biotech corpus to assist and advise the business units on regulatory compliance and procedures. To effectively deliver the service, an expert with considerable experience in regulatory matters related to biotechnology & life sciences sector will facilitate companies under the aegis of UKBC. The guidance cell will offer advice on the process of filing applications, guidelines, etc. in addition to disseminating information on the different regulations with amendments from time to time.

Since agriculture is a State subject, UKBC will assist companies for No-Objection Certificates (NOC) through single-desk clearance from Agriculture department and to conduct confined field trials. It will also facilitate companies for prior regulatory approvals of Genetic Engineering Appraisal Committee (GEAC) and Review Committee on Genetic Manipulation (RCGM), etc. on genetic engineering R&D.

UKBS will facilitate companies to arrange robust microbial cultures for industrial enzymes production, bio-fertilizers, bio-pesticides, etc. if they require. State and Central Govt R&D institutions and Agriculture universities will be the life science resource centers for cutting edge R&D or innovation centers for companies in biotechnology sector.

An e-platform will be created for facilitating all industrial clearances in 31 working days. This platform shall integrate requisite pre/post commencement services and clearances provided by multiple agencies/departments through the investment lifecycle.

E. UTTARAKHAND BIOTECHNOLOGY COMMITTEE (UKBC)

The incentives and initiatives for the biotechnology sector envisaged by the Uttarakhand Govt. for the industrial development and employment generation can be effective only through a coordinated and concerted effort. Thus in order to realize the potential of biotechnology sector, State Govt. will set up an UKBC to facilitate administration and management of these plans. The committee will be headed by Chief Secretary to the Government and have the members representing following domains:

- Scientific Community (2)
- Business Community (2)
- Academia (2)
- Biotechnology Association (2)
- GoUK Officials (Industries, Pollution Control Board, Agriculture etc.)

Convener of UKBC will be Secretary, Industries, GoUK.

