Maharashtra Biotechnology Policy 2001 Preamble:

1. The State of Maharashtra has always played a leadership role in the national economic and social renaissance. It has looked at advances in science and technology as great opportunities for bringing about economic transformation and social change. One great opportunity in this new century, rightly termed as the 'Century of Knowledge', is the emergence of knowledge-based industries. Information Technology (IT) was just a forerunner among these industries and Maharashtra responded rapidly and became a leading State in IT. Another emerging opportunity on the horizon is Biotechnology.
2. Biotechnology deals with living systems, including plants, animals and microbes. Biotechnology derives its strength by harnessing biological processes that sustain life. It incorporates any technique, which uses living organisms, parts of organisms and enzymes, proteins, etc., which are either naturally occurring or are derived from such living systems. Such techniques can be used to make or modify the products, improve plant or animal productivity or develop microorganisms for special use. Emerging Biotechnology uses recombinant DNA, cell fusion, embryo manipulation, etc.
3. Biotechnology has the potential to transform the lives of the people in the State by impacting hugely on agriculture, animal husbandry, health, environmental protection, material transformation, etc. Further, Maharashtra has the potential to become a leader in Biotechnology, not only in the country but also in the entire world. It is to realize this potential that the State is announcing this Biotechnology Policy 2001.

4. **Exciting biofuture:**
   Thanks to our increasingly deeper understanding of the intricate biochemical interactions at the cellular and molecular levels, there are new paradigms in health care. We have moved from 'preventive' medicine (vaccines) and 'curative' medicine (antibiotics) to 'predictive and corrective' medicine, thanks to the unravelling of the mystery of the human genome. We can now identify not only the genes that cause a disease but also correct the defects through gene therapy. Recent breakthroughs in stem cell research have, for the first time, given the hope that we may be able to regenerate diseased organs, thus paving the way for 'regenerative' medicine.

5. Agriculture contributes in a major way to our Gross National Product (GNP). The maximum impact of Biotechnology will be felt in this sector. The Green Revolution transformed the country from one perennially beset with food shortages and resultant hunger to one where the silos are overflowing. In future, however, the State will face the problem of producing 'more from less', that is, more food from less arable land, less water per capita, less polluting energy sources, etc. New Biotechnology holds the promise of finding a solution to this problem through creation of high-yielding and disease and drought resistant crops.
6. Thanks to the white revolution, we achieved the proud distinction of being the highest producer of milk in the world. That quite often makes us forget that as much as 80 percent of this milk comes from small and even marginal farmers, who own a single head of cattle. The individual yields are also nowhere near the world average. This situation is to be radically changed by selective breeding of high-yielding animals, which would profit not only the producers but also the consumers of milk. Biotechnology thus has the promise of making the White Revolution sparkling white.
7. Bio-fuels will provide new sources of energy. Biopesticides will provide ecologically safe pest treatments. Bio-fertilizers will provide safer and ecologically friendly fertilizers. Bioremediation, rather than chemical treatment, can now convert hazardous wastes into useful products. Bioinformatics, with confluence of information technology and biotechnology, for the first time is opening up exciting new opportunities of unparalleled dimensions. Indeed, the future in the 21st century is 'bio-future' all the way, and Maharashtra wants to be a participant in building this 'bio-future'.

Advantage Maharashtra:

8. The State derives its confidence that it will be a leader in Biotechnology based on its diverse strengths. These strengths include its superior human resource, the excellence of its private and public institutions, the superb infrastructure, and a conducive business environment as well as the inherent strength of its industry. Equally important is the progressive and proactive government which is prepared to go that 'extra mile' to make things happen. This confidence is not merely based on its potential, but on its proven performance.

9. The Sahyadri range running along the entire western perimeter of the State is adorned with an extremely rich flora. There are many plants with medicinal properties and essential oils. Many are also of value to other industries like the detergent or tanning industries. Proper and comprehensive documentation of this bio-diversity would lead to its conservation and to adding value to it. This diverse and resplendent flora would prove to be a gold mine for the Biotechnology industry.
10. Look at these facts. Maharashtra produces around one-fifth of national industrial output and accounts for 30% of exports (including in knowledge-based industries such as electronics and IT products, drugs and pharma, etc.). It has 22% of the new Company registrations. It accounts for 30% of the patents filed from India. It is one of the most urbanised States, with a per capita income that is 1.5 times the national average. It has registered 7% growth per annum in the last decade. The investor confidence is the highest for Maharashtra with $ 12 billion in terms of Foreign Direct Investment approvals and proposed industrial investment of Rupees 220,000 crore, both in the last ten years, the highest in the country. Its success rate of implementation of projects is also the highest among major States.
11. Mumbai is the financial capital of India. It is the hub of the country's financial services sector. The Reserve Bank of India and the State Bank of India, NABARD, SEBI, etc., are headquartered in Mumbai. The country's oldest and biggest stock exchange, the Bombay Stock Exchange, is in Mumbai. Technology financing mechanisms and institutions in Maharashtra are some of the strongest in India. The presence of venture capital companies such as ICICI, Rabo Bank, etc. provides the much needed support in technology financing and development.
12. This overall confidence in the strength of the State gets easily reflected and translated into a 'biotech advantage'. The biotech foundations in Maharashtra go back a long way. The Haffkine Institute, established in 1899, is the oldest biotech institution in Maharashtra. In 1954, Pune created a landmark in Biotechnology by becoming the first city in India to have an industry producing Penicillin, the Hindustan Antibiotics Ltd. The plant was then the largest producer of Penicillin in the whole of Asia. The vaccines produced by Serum Institute of India Ltd, the foremost and the largest manufacturer of vaccines, sera and biologicals in India, reach every one out of four children in the world! The Venkateshwara Hatcheries group is the largest producer of poultry vaccines in India
13. Maharashtra has the strength to make it the 'most preferred destination' for the pharmaceutical industry, and to attract and accelerate investment in Drugs and Pharmaceuticals. Maharashtra already contributes about 40% of the total turn over. It has 4,100 registered pharmaceutical manufacturers out of the total of 20,053 in India. Most international companies have shown their preference for Maharashtra. These include, among others, GlaxoSmithKline, Novartis, Pfizer, Johnson & Johnson, Abbott, Aventis, Knoll, and many others.
14. Major Indian companies such as Wockhardt, CIPLA, LUPIN, Nicholas Piramal, etc. do not only have their presence in Maharashtra, but they are also marching forward in the most challenging and frontline areas of Biotechnology. Wockhardt is already entering biopharmaceuticals. Whereas Lupin and Nicholas Piramal are moving in a major way in innovative drug research, the latter have made major forays in pharmacogenomics. Reliance Life Sciences have made forays into stem cell research and have already been recognized as one of the key suppliers of cell lines by the U.S. Government.
15. Agro-Biotechnology has strengthened its roots in the State through one of the largest seed producing companies, MAHYCO, which supplies hybrid seeds to farmers throughout the country. Currently, it is engaged in conducting field trials of transgenic seeds in collaboration with a multinational company. The State's Agriculture Universities have made considerable headway in the field. The development of molecular techniques has been initiated. Various research projects are in progress, and subject of Biotechnology forms a part of the curriculum at all levels of study in the Agriculture Universities. Components of Biotechnology in the form of tissue culture, bio-fertilisers and bio-pesticides have already gained popularity in the State. As many as 21 tissue culture laboratories have been set up in the Maharashtra.
16. The State has an excellent intellectual infrastructure. Through nearly 1000 institutions, it produces around 163,000 trained technical personnel each year. The State has already set up specialised parks for different sections including IT. The bio-industrial enterprises cannot sustain themselves unless they are backed up by a highly trained and skilled human resource. Some of the best Centres of excellence in India that are present in Maharashtra do precisely that. These include the Bhabha Atomic Research Centre, Indian Institute of Technology, Tata Institute of Fundamental Research, University Department of Chemical Technology, and the Cancer Research Institute, all at Mumbai.

They also include several life science and Biotechnology based departments of the University of Pune, National Centre for Cell Science, National Institute of Virology, National Chemical Laboratory, National Aids Research Institute, Agharkar Research Institute, Bharati Vidyapeeth's Institute of Environment Education & Research and the Rajiv Gandhi Institute of Information Technology & Biotechnology, the Vasant Dada Sugar Institute, all at Pune, as also the National Environmental Engineering Research Institute at Nagpur. The Animal Diseases Investigations Laboratory, Pune involved in diagnosis and research of animal diseases, especially in four States of the Western region of the country, has been recognised as reference laboratory by Government of India. New forward-looking initiatives in providing specialized education in Biotechnology, such as by the Vidya Pratisthan's School in Biotechnology, have already begun to emerge. A number of defence research establishments in the State have been engaged in conducting cutting edge research in Biomedicals, Bioinformatics and Biotechnology.

17. This existing intellectual infrastructure is dynamic and responding to new challenges by creating new institutions. As an example, an Advanced Centre for Treatment, Research and Education in Cancer (ACTREC) in Navi Mumbai has two wings: one on basic research, which has been formed by complete shifting of the present Cancer Research Institute (CRI) and also another institution, a Clinical Research Centre. The exciting research agenda includes gene and antisense therapy, immunotherapy, and stem cell transplantation. Modern biomedical research requires a chain of hospitals and clinics which could establish clinical research organizations. Some of the best hospitals in India are located in Maharashtra, giving that extra support and impetus.
18. Maharashtra State is the major sugar producer in India and it has the largest sugar belt. It also happens to be a major contributor to agricultural wealth in the country.
19. Adding to these existing advantages is also the potential for future growth due to Maharashtra's natural attributes. The natural availability of coastline 720 kilo metres in length, which is very productive and rich in biodiversity, is yet another strength for important marine Biotechnology ventures in the State. The existing well-knit infrastructure of the State Government could be effectively explored not only for fisheries, aquaculture and marine plant Biotechnology, but could also be exploited to harvest the marine microbes for diverse purposes, from new drug development to solving the environmental problems of urban India. Fisheries and aquaculture would also form an important industry for developing the newer food products and other derivatives.
20. Maharashtra has now emerged as a leading horticultural State in the country. Different types of soils, diverse agro-climatic conditions, adequate technical manpower, well-developed communication facilities, increasing use of drip irrigation, green houses, use of cold chain facilities and vibrant farmer organizations offer wide opportunities for growing different horticultural crops in the State. The results are there for all to see. Maharashtra produces 28% of banana, 28% of cashew, 64% of mandarin orange, 38% of sweet orange and over 72% of the grapes in India and also, of course, the world famous Alphonso mangoes! Chicoo production is unique to the coastal region of the State. Overall, the State contributes 18% of the total fruit production in India. Although floriculture in the State is of a very recent origin, after the entry of the private sector for business in cut flowers, Maharashtra accounts for one-third of the business in India
21. Maharashtra has a large area that falls in the rain shadow region. However, even in the face of natural obstacles such as water shortage and wastelands, the State has accomplished a dramatic increase in horticultural production. This is indicative of the core competence of the State's farmers and their determination to make sizeable contributions to the national exchequer.

Objectives:

22. To develop the Biotechnology industry in the State in order to:
    - Provide to the farmers of the State better, high-yielding, drought and pest-resistant crops suited to the agro-climatic conditions of the State;
    - Help develop affordable and more cost-effective drugs and devices to counter diseases common to India and to tropical and sub-tropical areas, and to reduce the disease burden;
    - Develop cheaper and effective technologies to purify water sources and to deal with industrial effluents and urban wastes, etc.;
    - Improve the livestock in the State in order to increase the earning capacity in rural areas;
    - Improve the marine stock to improve the productivity of the fishing industry;

- Enhance the value and utility of medicinal plants and traditional systems of medicine by developing new products with global potential;
- Develop and promote utilization of animal diagnostics and vaccines for preventing losses and increasing realization from livestock and poultry;
- Augment feed and fodder availability and processing;
- Improve the overall nutritional security in the State;
- Improve the quality of life through better health and better environment.

23. To lead the biotechnology industry in the State to a growth path from where it can become globally competitive, the following steps would be taken:
    - Providing the appropriate policy framework which will smoothen its path;
    - Providing adequate infrastructure, especially in the form of Biotechnology Parks;
    - Providing an appropriate package of incentives;
    - Developing a world-class higher education and research base to serve the needs of a growing Biotechnology industry and for creating high quality employment in the State;
    - Creating supporting institutions for the Biotechnology industry for the development of human resource as well as for the applications of Biotechnology;
    - Simplifying the application of labour and other laws and procedures to accelerate the development and growth of the biotechnology industry;
    - Facilitating new ventures and innovations.

Strategic Initiatives:

Institutional Mechanisms:

24. The State realises that it requires a robust implementation strategy to fructify its vision to be a leading Biotech State. Therefore, the State Government will take tangible and firm steps to realize the ambitious goals. Towards this, two apex institutions will be created. The first will be the Maharashtra Biotechnology Board, and the second will be the Maharashtra Biotechnology Commission. These will be backed up by a Biotechnology Development Fund.
25. The Chief Minister of Maharashtra would preside over the Maharashtra Biotechnology Board. It will have as its members, among others, eminent leaders in science and technology and also industry.
26. The Board would ensure proper and timely implementation of this Policy, which is essentially meant to see that the social and economic benefits of the Biotechnology Revolution will be available to every citizen of the state. It will act in a manner so that the Biotechnology industry in the State will retain its competitive edge at all times. Towards this, it will liaise with the Central Government to remove all the impediments that come in the way of the growth of Biotechnology in India.
27. With a public-private partnership, the Government will set up a special Biotechnology Development Fund with an initial corpus of Rs. 50 Crores. This Fund will receive annually a specially earmarked contribution of 1% from the annual Plan funds from different departments of the State Government, who are likely to be the beneficiaries of the Biotechnology Revolution. The Fund can be further augmented by grants and donations from overseas for financing different ventures.
28. The Board will be supported by the Maharashtra Biotechnology Commission, which will be the key implementation body. It will have an eminent scientist as its Chairman, with knowledgeable professionals from academia, industry, as well as the concerned government officials as its members.
29. The Commission will be responsible for effective utilization of the Biotechnology Development Fund. The Commission will act as a think tank and key advisor to the Maharashtra Biotechnology Board on diverse policy related issues. It will identify areas where the investments by the State in biotech interventions in a proactive manner will lead to large economic and social benefits for the State. It will promote research in the emerging and nascent technology areas by inviting proposals from different institutions and industrial enterprises. It will assess and then approve the proposals for financial grants from the Fund. It will also be responsible for the management of the Resource Centre and Business Facilitation Centre to be located at the Pune Biotechnology Park. The Commission will also review diverse aspects of biosafety approvals for genetic engineering interventions and coordination of activities at the State level. The Commission will help the State in creating greater public awareness about issues arising from new Biotechnology, which impinge on diverse aspects of culture, morality, ethics, economics, etc.

State as an Enabler and a Facilitator:

30. The State specifically intends to facilitate for the farmers the provision of high yielding and drought and pest resistant varieties of crops that are genetically modified to thrive in the prevalent agro-climatic conditions. Crops where such biotechnological interventions can yield beneficial results will be identified. Taluka-level seed farms, farms of the Agricultural Universities and lands in the Maharashtra Industrial Development Corporation (MIDC) areas will be made available to Biotechnology units so that field trials and seed multiplication of approved varieties can be undertaken. It will be ensured that all laws of the land and regulations will be followed so that a 'responsible Biotechnology' will be promoted in the State.
31. Biotechnology companies located in the State will be permitted to acquire and own agricultural lands in excess of the current ceiling limits provided they are being specifically utilized for experimentation and field trials, which are a logical part of the research and development chain.
32. The State has a vast public health machinery and therefore invaluable data at its command. It will share these data with the Biotechnology companies in a transparent and ethical manner. The public health machinery of the State will also actively collaborate with Biotechnology companies in clinical research by following internationally accepted norms.
33. Maharashtra's Food and Drug Administration (FDA) is one of the most progressive and competent in the country. The FDA will play a facilitating role in the growth and development of pharmaceutical and food processing Biotechnology industry. Several vaccine-producing units are in the State-controlled public sector. These will serve as valuable allies to the Biotechnology industry. Similar measures will be taken for the livestock and fishery industries also.
34. Proper treatment of urban wastes and industrial effluents is of crucial importance to the State, with its concern for the maintenance of the region's ecology. Municipal bodies and organizations such as CIDCO, MHADA, MJP and MIDC, which presently deal with these problems, will take up joint projects with Biotechnology companies for developing effective technologies for converting wastes into useful products and to purify water, thereby aiding its conservation. The existing infrastructure and data available with these undertakings will be made available to the Biotechnology companies for experimentation and trials.
35. In pursuance of its new Industrial Policy 2001, the State has declared its intention to amend certain provisions of the Industrial Disputes Act and the Contract Labour Act, subject to the approval of the Central Government (since these are Central laws) and the Legislature. The amendments would apply to Biotechnology units covered under these Acts. Moreover, in the case of Biotechnology units within the purview of the Shops and Establishments Act, restrictions on shift working, working hours and employment of women would be relaxed, as has been done in respect of Information Technology units.

Financial Incentives:

36. Government will make the industrial power tariff applicable to all Biotechnology industries engaged in the production of high-end products. This benefit will be applicable to both new and old companies. Additionally, agricultural Biotechnology companies will be given power at agricultural rates. All Biotechnological industries will be exempted from statutory power cuts.
37. Biotechnology units will be exempted from paying electricity duty. Captive power generation will be permitted to Biotechnology units throughout the State. Public bodies or their joint ventures will be permitted to establish 'Independent Power Producers' for the dedicated provision of power to Biotechnology Parks promoted by them.
38. Sales tax/value added tax on Biotechnology products would be decided as per recommendations of the empowered committee at the national level. A methodology to define Biotechnology products would be evolved. Definition of Biotechnology products would be decided by the Central Government or it would be finalised in consultation with the Task Force appointed by the State Government.
39. Biotechnology units throughout the State will be eligible for all the benefits available to industrial units located in 'D' areas of the State under the New Package Scheme of Incentives, 2001, except in the D+ and 'No Industry District' areas, where such units will be eligible for benefits in the D+ and 'No Industry District' areas. These include capital subsidy for small-scale Biotechnology units, and refund of octroi and similar levies.
40. New Biotechnology units, and expansions of existing units, will be exempted from payment of Stamp Duty and Registration fees in C, D, D+ and No Industry Zones in terms of Package Scheme of

Incentives, 2001 of the State. In other areas, such exemption will be extended to units in Biotechnology Parks promoted by public bodies. In private Parks, such Stamp Duty and Registration fees would be waived to the extent of 50%. In addition, only 10% of the admissible Stamp Duty would be payable on property transactions resulting from amalgamation of Biotechnology companies.

41. Twice the admissible Floor Space Index would be admissible for Biotechnology units in Parks promoted by MIDC and other public bodies, and at other designated locations.
42. Information Technology and Biotechnology are fuelled by continuous generation and advancement of new knowledge. Therefore, the locations of all such undertakings will be treated as 'Knowledge Processing Zones' and will be given special privileges. For example, Information Technology undertakings have already been enjoying certain privileges in view of their special status. The Government recognises that the role of bioinformatics centres, which symbolize the confluence of Biotechnology and Information Technology, is crucial to the development and sustenance of the Biotechnology industry. Therefore, all such centres will also be treated on par with Information Technology units, and all the incentives applicable to Information Technology units will be extended to these centres.
43. The Government will encourage setting up world class "Centres of Excellence", which will cover all aspects of cutting edge research and development in emerging areas of life sciences and technology. To facilitate this, the Government will offer land at concessional rates to Centres of Excellence in the area of Biotechnology. Specific norms will be laid down to define such Centres, and each prospective Centre will be subjected to scrutiny and approval on an individual basis.

Incentives for Promoting Biotechnology Parks:

44. The State Government will promote setting up of Biotechnology Parks, Research and Development Centres and pilot plant facilities for undertaking contract research by putting equity stakes in such projects. The Government equity would be in kind, such as in the form of land allotted for the projects.
45. Units engaged in agricultural Biotechnology ventures will be designated as agricultural industries with extension of all the incentives, exemptions and benefits accruing to that industry. Further, MIDC will allot land to such industrial units in areas under its jurisdiction at industrial rates.

Infrastructural Support:

46. The Government is aware of the important role of a supportive infrastructure in the growth and development of any industry. It will, therefore, lay great emphasis on the quality of infrastructure that is made available to the industry.
47. Unlike other industries, Biotechnology industries are crucially dependent on highly skilled personnel at all levels of their operations. The centres supplying such manpower at present will therefore have to be strengthened and diversified. Biotechnology Parks will be set up at Pune (pharma Biotechnology), Shendre/Jalna and Akola (agricultural Biotechnology).
48. Among other routine facilities common to any Technology Park, these Parks will offer -
    - GMP facilities in conformity with US FDA norms;
    - Business Facilitation Centres (BFC), which will offer services to the clients of the Park so that a hassle-free environment is created in the Park. The services to be provided to the clients through BFC will comprise:
      i. A cell for facilitating rapid regulatory and customs clearances and interface with Government bodies;
      ii. Handholding services to entrepreneurs in getting power connection, telephone connection, etc.;
      iii. Technology transfer and access services;
      iv. Commercialization services;
      v. Networking with research institutions;
      vi. Mentoring and information and support on intellectual property protection, etc.
      The BFC will also maintain databases on Biotechnology and also deal with quarantine issues. Initially, it is planned to have experts in regulatory affairs, Biotechnology, and marketing. There will be adequate supporting staff to assist these experts. Also, the BFC will be equipped with all the necessary facilities to provide secretarial services, communication services, etc.
    - Connectivity with academic and research institutions for providing the necessary human resource development base.

- Physical infrastructure such as quality power, telecommunication, connectivity, adequate bandwidth, reliable water supply etc.
- Land for building residential complexes for scientists and Biotechnology professionals, complete with schooling and recreational facilities.

49. The Government will create a Biotechnology Resource Centre, a reference centre for certification of products after testing them intensively, and an experimental animal facility that will meet all the ethical, legal and safety standards. Land will be made available for these purposes. The State Government may undertake civil construction work for these facilities depending on contributions from the industry or from charitable institutions. The State will actively seek participation in the setting up and running of these special facilities from NRI and academic and other organizations overseas.
50. The Biotechnology Parks and the Resource Centre will evolve new patterns of collaboration between research scientists, industry personnel, extension workers, farming community and the consumers for wider dissemination and better understanding of the costs and benefits of Biotechnology.

Taking BT to the People:

51. Acceptance of Biotechnology-mediated products by the consumers would be of paramount importance to the continued flourishing of the Biotechnology industry. The State Agricultural Universities have demonstrated their mettle in such non-formal education of consumers as well as farmers through their extension programmes. The Educational Media Research Centre (EMRC) of the Pune University is also well equipped to carry out such programmes. These organizations will be encouraged to take up specific projects for wider dissemination of Biotechnology
52. The State will also emphasize the importance it attaches to Biotechnology by observing a State Biotechnology Day on 14th November, the birth anniversary of Jawaharlal Nehru, who embodied independent India's commitment to science and technology. The purpose of this Day will be to carry the message that Biotechnology can be a key 'life care tool' of the twenty first century to the public at large by improving food, health, environment, etc. in a major way. The Biotechnology Commission will work out details of each year's programme.

Intellectual Property Rights:

53. The Government realizes that one of the foremost concerns amongst the industry as well as the research community would be one revolving around protection of intellectual property rights. The Government will, therefore, launch programmes to create awareness about IPR among the users as well as society in general. The latter component would be tackled through a special manpower-training programme to be developed at the University of Pune, which has already pioneered the forays into IPR by setting up the first CSIR Chair in IPR. In addition, a special course will be introduced at the postgraduate level in the HRD programmes so as to cover various aspects of IPR. It will also be necessary to revise and create new curricula for the law faculty in order to incorporate Patent Law and International IPR related law courses This will be accorded high priority.

Back to the future:

54. While it is true that there has been a distinct, even dramatic improvement in the living standards of a large section of the population, many other basic needs of the people remain to be adequately met. Maharashtra has the inherent potential and the necessary will not only to solve these problems satisfactorily but also to leapfrog into an era of economic prosperity. The State is confident that setting up this bold and visionary Biotechnology Policy will set the mood and tone for taking Maharashtra on the path of sustainable development which ensures for its citizens the very best of food, nutrition, health, environmental and livelihood security.