FINANCING AGRICULTURE

Largest Circulated Farm Journal

OCTOBER-DECEMBER 1994

Annual Subscription Rs. 50

GOVERNMENT REGULATIONS FOR BIOTECHNOLOGY INDUSTRY ●

FINANCIAL SECTOR REFORMS AND RURAL CREDIT ●

VERMICULTURE BIO-TECHNOLOGY ●

AGRO-CLIMATIC REGIONAL PLANNING APPROACH ●

ORGANISATIONAL DYNAMICS FOR RURAL DEVELOPMENT ●

QUARTERLY JOURNAL OF AGRICULTURAL FINANCE CORPORATION LTD.

'Financing Agriculture' is published every quarter in January-March, April-June, July-September, and October-December. Views expressed by the authors do not necessarily reflect those of the Agricultural Finance Corporation Ltd. No permission is necessary to reproduce contents except for the copyright text.

ANNUAL SUBSCRIPTION

India, Pakistan, Sri Lanka, Nepal and Bangladesh. Rs. 50. Other Countries (By Air Mail) $35. Single Copy Rs. 15

VOL. XXVI No. 4 OCTOBER - DECEMBER 1994

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GOVERNMENT REGULATIONS, LICENSING AND APPROVALS FOR THE BIOTECHNOLOGY INDUSTRY

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The term "Biotechnology" means different things to different people. Many scientists consider only the new biological techniques of recombinant DNA (r-DNA) that found commercial applications in early eighties and onwards, as biotechnology. In India however the term is used on a much broader sense. Indeed, the term is used by us (1) to include the application of scientific and engineering principles to :

(a) the processing of materials by biological agents living or non-living, natural or modified;

(b) the processing of biological materials to isolate active principles or concentrates;

(c) the transformation of living bodies into genetically different bodies not currently known to be existing in nature; and

(d) the identification/authentification of living bodies or substances secreted therefrom.

Biotechnology is technique based. The processes requiring the use of r-DNA techniques, hybridoma technology, immunological methods, cell culture methods and finally separation, purification as well as assay methods of biological materials are included in this area. To us biotechnology has more "technology" component in it; indeed it is considered to be the enabling means of achieving higher productivity or manufacture of newer products or use of novel methods for known products by deploying microbes, plants, animals, different cell lines or enzymes in the production processes. An illustrative list of biotechnology industries as is understood in India is placed at Table-I (2).

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* Views expressed in the Article are personal and do not necessarily express the views of the organisation to which the author belongs.

TABLE-I

(Illustrative list of Biotechnology Industries)

A. Agriculture, Horticulture, Flowering Plants and Forestry

— Hybrid high yielding seeds and synthetic seeds

— Tissue culture propagation of plant materials

— Transgenic Plants

— Diagnostic kits or probes for plant diseases

— Mushroom including spawns

— Cut flowers grown in controlled environment.

B. Animal Husbandry and Aquatic Life Forms

— Products and processes based on embryo transfer technology and artificial insemination

— Fish spawning inducing agents (GnRH, Chorionic Gonadotropin, Pituitary extracts etc.)

— Animal hormones (FSH, LH, LHRH, Prolactin, TSH, Somatotropin, Somatostatin, etc.)

— Development of transgenic life forms (transgenic fishes, animals, microbes etc.)

— Development of specialised feed and other supplements for ruminants, poultry animals as well as aquatic life forms.

C. Biofertilizers

— Biofertilizers using natural or modified micro-organisms like Rhizobium, Azotobacter, Blue-green algae etc.

— Composted fertilizers produced by tretment of biological wastes using micro-organisms or by vermiculture.

— Various plant growth hormones and plant growth promoters.

D. Biopesticides/Insecticides

— Biopesticides and insecticides using various natural or modified micro-organisms (dead or alive) e.g. Bt, Bs, NPV, GV, Trichograma, etc.

— Secondary metabolites produced by fermentation using desired micro-organisms.

— Plant based active principles eg. Neem extracts etc.

E. Products and Processes by use of Micro-Organisms/Cell lines (other than drugs)

— Large molecules such as enzymes, proteins, carbohydrates, fats and oils etc;

— Primary and secondary metabolites including enzymes having industrial use, other than drugs; and

— Different recombinant DNA products produced by recombinant microbes, cell lines, life forms, etc.

F. Drugs and Pharmaceuticals

— Drugs and pharmaceuticals by use of micro-organisms e.g. antibiotics, vitamins, microbial transformations, etc.

— Products produced by use of r-DNA technology, e.g. insulin, interferons, erythropoietin, interlukins, growth hormones, recombinant vaccines, G-CSF, GM-CSF, streptokinase, urokinase, t-PA, Blood factors, epidermal growth factor, calcitonin, etc. produced by rDNA technology.

— Enzymes, amino acids, vaccines, monoclonal antibodies, thrombolytic agents, coagulants, anti-coagulants, etc.

— Diagnostics including nucleic acid probes.

G. Miscellaneous items

Oligonucleotides; restriction enzymes; gels/ modified polymers required for bio-processes; special devices used in biotechnology etc.

In some of the areas listed in Table-I, the Indian developments are significant; these include the production of certain cell cultured vaccines, immuno-diagnostics and a few primary metabolites (alcohol, citric acid, lactic acid etc.) and certain secondary metabolites (like antibiotics) produced by fermentation. In certain areas, expertise is getting further perfected and industries are coming up; these are areas of whole blood processing, production of hybrid high yielding seeds, micropropagation of ornamentals and horticultural plants, production of certain industrial enzymes and organic acids.

However local expertise is not yet significant in many frontier areas such as recombinant products, specialised enzymes, amino acids etc., and several products in such areas are currently being imported and used.

The following Table-II indicates the current consumption and the anticipated demand of different categories of products during 1992, 1995 and 2000 A.D. as estimated by us (1).

TABLE-II

Consumption and future demand of biotech products in India*

(Unit : Rs. In Million)

Product category	Consumption 1992	Estimated demand 1995	2000 AD
Human and animal Health	13750	19590	35320
Agriculture*	680	1540	3850
Industrial products	4290	5700	15000
Other biotech Products	20	300	1300
Total	**18740**	**27130**	**55470**
(in U.S. million $)	825	904	1849

(* Excludes processed food industry and fisheries)

The demand of biotech products is increasing fast. As the demand is increasing and as the volume of local consumption is significant, the scope of trade as well as new investment in most of the above areas is considered enormous. Currently the scope of free trade and industrial approvals have been significantly broadened and liberalised by the Government of India. This has meant elimination of unnecessary procedural controls and emergence into relaxation and liberalisation by the removal of quantitative plant capacity restrictions, reduction of tariff barriers,

rationalization of customs duties and introduction of liberal import policies.

The economic reforms are initiated to improve the industrial structure to attract foreign investment, improve industrial productivity, raise the standards of the quality of local products and to increase the market share including the export market so as to maximize the long term generation of wealth and improve the reserves of foreign exchange of the country on a sustainable basis.

The recent reforms in Industrial licensing policy and the revised procedures that have been announced by the Govt. from the beginning of 1991 and subsequently, is now being discussed with reference to their relevance to **Biotechnology Industries.**

Industrial Licensing Policy (3-9)

Industrial undertakings are classified according to investments in plant and machinery or total assets as described in Table-III.

TABLE-III

(Classification of Industrial Undertakings)

Investment Limits	Category of Industrial Undertakings
1. Total Investment Up to Rs. 5 lakhs	Tiny Undertaking
2. No limit on total investment but	
(a) Investment in Plant and Machinery up to Rs. 60 lakhs	Small Scale Unit
(b) Investment in Plant & Machinery upto Rs. 75 lakhs and unit undertakes to export atleast 30% of its annual production (from 3rd year onwards)	Small Scale Unit
(c) Investment in Plant & Machinery upto Rs. 75 lakhs and unit supplies upto 50% of its production to one or more other industrial undertakings	Ancillary Unit
(d) Investment in Plant & Machinery more than Rs. 60 lakhs for (a) above and above Rs. 75 lakhs for (b) and (c) above.	Large Scale Unit

Industrial licensing is governed by the Industries (Development and Regulation) Act, 1951. The Industrial Policy Resolution of 1956 identified certain categories of products for development through the **Public Sector,** certain others through **Private Sector** with or without state participation and finally another category of products for preferential investment initiatives coming from the **Private Sector** (4). In India, the management of economy and industry is vested upon the Central Government which promulgates from time to time the policies of planning, control of industrial capacities, regulation of locations of industrial undertakings and approval of foreign collaborations. In continuation of this process, with the objective of developing a globally competitive industrial sector, the Central Govt. from the Ministry of Industry substantially modified the previous licensing policy in 1991 and onwards (5-7). The essence of these modifications alongwith our clarifications are furnished below:

(i) All the articles to be manufactured are being described in accordance with a **New Classification System** called the **Indian Trade Classification System.** The new system of classification is based on the **Harmonised Commodity Description and Coding System** which classifies every article with a broad serial number and a specific product code number alongwith the name of the product/article. The Coding System is published by the Ministry of Commerce, Govt. of India Directorate General of Commercial Intelligence and Statistics, Calcutta.

New articles proposed to be manufactured which are not classified according to the new system should normally be outside the scope of Industrial Licensing until and unless they are classified and added to the new classification system.

(ii) Industrial Licensing has been abolished for all industries including MRTP and FERA companies, except those specified below irrespective of levels of investment. The specified industries, which will continue to be subjected to **COMPULSORY LICENSING** have special attributes related to social and economic justice, security, safety, over-riding environmental issues, products of hazardous nature or articles of elasticity consumption.

The broad heading of the articles/industries placed under compulsory licensing which could include biotechnology industries is as follows:

A. Coal and lignite
B. Distillation and brewing of alcohol drinks
C. Animal fats and oils
D. Raw hides and skins, leather, chamois leather and patent leather
E. Tanned and dressed furskins
F. Drugs and Pharmaceuticals (according to Drug Policy)

For the authentic description of each article alongwith product code number as per the new classification under the above broad heading of **COMPULSORY LICENSING,** the Indian Trade Classification, Harmonised System may be consulted.

The six broad heads as indicated above could have articles or industries falling in the area of biotechnology. Thus microbial benefication of coal or lignite for the removal of sulfur; use of genetically improved yeast strains for brewing; use of enzymes/microbes for efficient isolation or improvement in the quality of fats and oils; microbial or enzymatic treatment methods for the production of better varieties of skins and leather; and finally production of different kinds of bulk and formulated drugs using microbial strains, genetic engineering, hybridoma technology, immunology, liposomal technology etc. are examples. Setting up of such biotechnology industries would need compulsory industrial licensing.

(iii) Industries reserved for the small scale sector will continue to be reserved for the sector.

(iv) Areas where security and strategic concerns predominate, will continue to be reserved for **Public Sector.** The industries under the following broad heading of this sector could have biotechnology based industries.

A. Coal and lignite
B. Mineral oils
C. Mining of iron ore, manganese ore, chrome ore, gypsum, sulfur, gold, diamond, copper, lead, zinc, tin, molybdenum and wolfram.
D. Minerals specified in the Schedule to the Atomic Energy (Control of Production and Use) Order, 1953.

(v) In projects other than those described earlier, where imported capital goods are required, automatic clearance for all sectors of the industry including the biotechnology sector would be accorded if :

(a) Foreign exchange availability is ensured through foreign equity.

(b) If the CIF Value of imported capital goods required is less than 25% of the total value (net of taxes) of plant and equipment, upto a maximum value of Rs. 2 crores.

(c) In other cases, import of capital goods will require the clearance from the Secretarial for Industrial Approvals (SIA) in the Deptt. of Industrial Development, Ministry of Industry, New Delhi.

(vi) In locating industries other than cities of more than 1 million population, there will be no requirement of obtaining industrial approval from the Central Government except for industries subject to compulsory licensing as described earlier. The list of cities with population of one million and above as per the provisional results of the 1991 census is at Table-IV.

TABLE-IV

(List of cities with population of 10 lakhs and above according to provisional results of 1991 Census)

Cities	Population in lakhs
Greater Bombay	125.7
Calcutta	109.2
Delhi	83.8
Madras	53.6
Hyderabad	42.8
Bangalore	40.9
Ahmedabad	32.8
Pune	24.9
Kanpur	21.1
Nagpur	16.6
Lucknow	16.4
Surat	15.2
Jaipur	15.1
Kochi	11.4
Coimbatore	11.4
Vadodara	11.2
Indore	11.0
Patna	11.0
Madurai	10.9
Bhopal	10.6
Visakhapatnam	10.5
Varanasi	10.3
Ludhiana	10.1

In respect of these cities, industries other than those of non-polluting nature will be located outside 25 Kms. of the periphery except in priorly designated industrial areas. Non-polluting industries could, however, be located anywhere and no locational restrictions for these exist.

(vii) The exemption from licensing will apply to all substantial expansions of existing units. Existing units will also be permitted to manufacture any new article without additional investment if the article is not otherwise subjected to compulsory licensing.

(viii) Several agricultural activities such as production of hybrid high-yielding seeds, plantlets developed through plant tissue-culture, biofertilisers and biopesticides have been classified as industrial activities.

In consequence of the new industrial policy, all the earlier registration schemes (like the D.G.T.D. registration, delicensed registration and exempted industries registration etc.) have been abolished. At present for the setting up of new projects (or expansion of existing undertaking) not covered by compulsory licensing, the only requirement from the entrepreneurs will be to file a Memorandum in the prescribed form in 10 copies to the SIA in the Ministry of Industry alongwith a crossed demand draft for Rs. 1000 in favour of the Pay and Accounts Officer, Deptt. of Industrial Development, Ministry of Industry. The Industrial undertaking shall file another Memorandum in the prescribed form with the SIA at the time of commencement of commercial production; no payment is to be made during filling this Memorandum.

Foreign Collaboration and Foreign Investments

(i) The broad heading of the priority industries identified by the Govt. which have relevance to the setting up of biotechnology industries is furnished below:

1. Drugs and Pharmaceuticals according to Drug Policy
2. Photosynthesis Improvers
3. Genetically modified free living symbiotic nitrogen fixing organisms
4. Pheromones
5. Bioinsecticides
6. Soya products including texture proteins; protein isolates, protein concentrates, refined soyabean oil and specialised products of soyabean
7. Certified high-yielding hybrid seeds and synthetic seeds
8. Certified high-yielding plantlets developed through plant tissue culture.
9. All food processing industries other than milk-food, malted foods and flower, but excluding the items reserved for the small scale sector.

(ii) Automatic permission will be given by the Govt. to the Foreign Technology Agreements in the above areas if the Agreements involve a lumpsum payment of Rs. one crore, 5% royalty for domestic sales and 8% for exports, subject to the limitation of total payments of 8% of the sales over a 10 year period from the commencement of production. The prescribed royalty rates are net of taxes and will be calculated according to the standard procedures. All the Foreign Collaboration Approval Agreements issued by the Government normally have certain standard conditions attached to such approvals.

In respect of all biotechnology industries other than those indicated above, permission will also be accorded subject to the same guidelines as above if no free foreign exchange is required for any payments. All other proposals will need specific approval under the general procedure.

(iii) The import of raw materials, intermediates and components as well as payment of knowhow fees and royalties will be governed by the general policy applicable to other domestic units. The payment of dividends will be monitored through the Reserve Bank of India so as to ensure that outflows on account of dividend payments are balanced by export earnings over a period of time.

(iv) Foreign technicians could be hired henceforth without prior permission from the Government, irrespective of whether the hiring is under an approved collaboration agreement or not.

(v) Government of India has decided to provide approval for direct foreign investments upto 51% foreign equity in high priority industries in order to invite foreign investments. Such clearance will be available if foreign equity covers the foreign exchange requirements for the imported capital goods. Foreign equity holding upto 51%

will be allowed for trading companies also which are primarily engaged in export activities.

(vi) Applications for approvals will have to be filled in the prescribed form in 10 copies with the Enterpreneurial Assistance Unit of the SIA in the Department of Industrial Development, Udyog Bhavan, New Delhi. The applicants shall state the description of the article to be manufactured in accordance with the India Trade Clarification System. The payment terms are to comply with the conditions indicated in the previous paras. On receipt of the applications, the SIA will communicate the approval after confirming that the item is covered within the priority industries identified by the Government. No other scrutiny of the application will be done. A copy of the approval will be sent by the SIA to the Reserve Bank of India (RBI).

(vii) After the SIA approval, the entrepreneurs may approach the RBI and furnish such other information as may be prescribed by the RBI from time to time. RBI usually seeks the attestation of the requirements of Capital Goods from the Administrative Ministries (DBT for Biotechnology Industries) before processing the applications. The RBI will then issue the necessary permission for foreign equity investment, and instruct all the other authorities like the Chief Controller of Imports and Exports for the issue of the relevant import licenses for Capital Goods, Raw materials, Components etc. There will be no requirement or necessity of indigenous clearance for the Capital Goods.

Small Scale Units, Ancillary Units and Tiny Enterprises

Small scale and ancillary undertakings are exempted from licensing for all articles of manufacture except those which acquire compulsory licensing. In addition, they are also exempted from Industrial licensing for the article of manufacture exclusively reserved for small/ancillary sector. Small scale/ancillary units are exempt from locational conditions subject to the provisions of any Central or State environmental law or Land use law and regulations. Investment limit in respect of tiny enterprises is Rupees five lakhs irrespective of the location of the unit.

In order to strengthen the tiny sector it has been decided to recognize all industry-related services and business enterprises irrespective of their location as small scale industries. Their investment ceiling would correspond to those of tiny enterprises.

While the small sector (other than tiny enterprises) would be mainly entitled to one-time benefits (like preference in land allocation/power connection, access to facilities for skill/technology upgradation), the tiny enterprises would also be eligible for additional support on a continuing basis, including easier access to institutional finances, priority in Government purchase programme and relaxation from certain provisions of labour laws. It has been decided to allow equity participation by other industrial undertakings in Small Scale Industries, not exceeding 24 percent of the total share holding. This will provide access to the capital market and technological upgradation.

Export Oriented Units and Units in Export Processing Zone

All units including those dealing with Biotechnology products are eligible to set up Export Oriented Units (EOU) Scheme or Export Processing Zones (EPZ) Scheme. Such Units are eligible to import **free of duty** their requirement of capital goods including captive power plants, raw materials and components, prototypes, office equipment and consumables for office use, material handling equipment etc. An EOU/EPZ unit may also source the capital goods from a domestic leasing company if a firm contract is entered into. In such a case the domestic leasing company will be eligible to import the capital goods free of duty and supply kit to the EOU/EPZ unit on such terms and conditions as may be mutually agreed upon. The capital goods shall remain as a part of the capital assets of the EOU/EPZ unit till the export obligation is discharged. The EOU/EPZ units are required to achieve minimum Value Addition as has been specified from time to time for different sectors of the industry by the Government (8). For example, for setting up of plant tissue culture activities, the Value Addition norm is 60%. The entire production of EOU/EPZ units shall have to be exported except rejections upto 5% or such percentage as may be fixed by the Board of Approvals of the Ministry of Commerce, Government of India. The rejections may be sold in the Domestic Tariff Area (DTA). Such units may be permitted to sell upto 25% of the production in value in DTA when the use of indigenous inputs is more than 30% in value terms. For Biotechnology units the minimum FOB value of export during 5 years period shall be Rs. 10 crores. The projects satisfying certain conditions as specified by the Ministry of Industry (9) are given automatic approval by the Development Commissioner of the EPZ concerned. In case of EOUs, however, such approvals are available from the SIA of the Ministry of Industry on submitting applications in prescribed forms.

Modifications in Drug Policy, 1986

The Government of India had announced the Drug Policy in September, 1994 which was designated as "Modification in Drug Policy, 1986." The policy, interalia, deals with the issues related to biotechnology, and the essence of this policy is as under:

i. Para 22.1 — LICENSING, states that bulk drugs produced by the use of recombinant DNA technology and bulk drugs requiring in-vivo use of nucleic acids as the active principles would require an industrial license for production. Further, licensing shall be abolished for all formulations except in cases of specific cell/ tissue targetted formulations.

ii. Para 22.7.2 — SPAN OF CONTROL, states that genetically engineered drugs produced by recombinant DNA technologies and specific cell/tissue targetted drug formulations will not be under price control for five years from the date of manufacture in India.

iii. Industrial licensing of all bulk drugs other than those indicated in para (i) is abolished except production of Vitamin B1, Vitamin B2, Folic acid, Tetracycline and Oxytetracycline which shall continue to be reserved for production by public sector units. Vitamin B2 is manufactured internationally by some units by fermentation and both tetracycline and oxytetracycline are produced by microbial fermentation, and are biotech products.

iv. Para 22.5 — FOREIGN TECHNOLOGY AGREEMENTS, states that automatic approval for foreign technology agreements shall be given in case of all bulk drugs, their intermediates and formulations except those produced by the use of recombinant DNA technology, for which the existing procedure will continue.

v. Foreign investments upto 51% would be permitted in case of all bulk drugs, their intermediates and formulations, and these provisions would attract biotech drugs also. Further, investments, above 51% would be considered on a case-by-case basis in areas where investment is otherwise not forthcoming, particularly in the manufacture of bulk drugs produced by the use of recombinant DNA technology as well as specific cell/tissue targetted formulations.

The 1994 drug policy is very much stimulating for promoting investments in new biotech areas.

Concluding remarks

The modified licensing policies have substantially been simplified. Foreign investment upto 51% in equity is almost automatic and in deserving cases, further foreign investments have also been allowed based on case by case analysis. Several agricultural activities have been classified as industrial activities and many others are going to be included in future; these have resulted in entrepreneurs' obtaining bank finance easily and in teaming up with foreign collaborators for the supply of technologies. The locational policies have also been simplified. These reform policies had built within it, several far reaching strategic implications. There is also an increase in the public awareness of the benefits of biotechnological products and processes in health, agriculture, industrial products and environmental management. The Government is also facilitating the development of indigenous technologies by setting up demonstration units, promoting industry-institutional tie-ups and quickening the process of approvals at various stages. All these factors are already showing up in terms of newer and more proposals being cleared for investments in biotech industrial sector.

Investment in India including foreign investments have been profitable and returns on such investments compare well with those in other countries. Once collaborations are approved, all the deserving remittances are parts of the approved packages. The earlier Govt. approval procedures have been substantially simplified and for several project packages approvals are automatic as discussed.

In the light of the current liberalised licensing policy and having regard to the fact that India has developed a large pool of trained manpower and has a potentially large market of biotechnology products, it is felt that industrialists would take maximum advantage of the situation for industrialising the country using appropriate technologies either developed in the country or imported from abroad.

There is no price control on recombinant DNA products for a period of 5 years from the start of manufacture. The demand of these products is also on the rise as these are used in life threatening

situations as well as in conditions where life can be prolonged by their use e.g., reombinant insulin will help patients maintain better quality of life than without it; patients with kidney problems could be maintained better by use of erythropoietin. Cancer patients have hope for prolonging their longeivity by use of interferons, G-CSF, GM-CSF, etc. and these therapies are specific in specific situations. It is therefore foreseen that every effort would be made by the society to bring in these products in Indian market, and the liberalised licensing policy will go a long way in promoting induction of such technologies into the country.

Acknowledgements

The efforts of Shri Arvind Thapliyal, JTA, of the Department of Biotechnology in carefully typing the manuscript is gratefully acknowledged.

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