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COUNTRY NEWS

Australia

New Legislation

The New South Wales government in Australia is planning to introduce legislation to cover biological control of weeds and pests. It would be the first government in the world to bring in such rules. (Source: European Chemical News, 18 March 1985)

Belgium

Biotechnology in Belgium

Belgium has a strong chemical industry, and outstanding strengths in its universities and research institutes in the biomedical sector (e.g. the Institute for Cellular and Molecular Pathology) and in plant genetics (University of Ghent), as well as in other areas (e.g. bacteriology in various institutions). The international pharmaceutical companies are also attracted by the high quality environment provided by the research teams in the various universities of the country.

At the level of the regional authorities, Wallonie, Flanders and Brussels are seeking to attract foreign investment in high technology sectors such as biotechnology; Wallonie and Flanders have each created two R and D companies. Hybritech (the US leader in hybridoma technology and marketing) has established a plant at Liège; Biogen (the Swiss and U.S.-based group owned by Monsanto, International Nickel, Schering-Plough and Grand Metropolitan Hotels) has established a subsidiary at Ghent (Biogent). At the level of the national authorities, the IRSIA - a national industrial research association - is coordinating R and D projects on biotechnology topics, and its Biotechnology Committee comprises 32 companies from various industrial sectors and university laboratories specialising in monoclonal antibodies, fermentation, immunology and genetic engineering. (Extracted from Industrial Biotechnology Wales, February 1985)

Canada

Wellcome in Canadian biotechnology venture

In a joint venture with the Terry Fox Medical Research Foundation, a Canadian charity, The Wellcome Foundation is to establish a Biomedical Research Centre in Vancouver, British Columbia. Claimed to be a unique concept, the centre will combine laboratory facilities with on-the-spot in- and out-patient facilities, an arrangement which the company expects will allow ideas to move "quickly and efficiently forward from basic research in clinical application".

To be based on the campus of the University of Columbia, the centre's initial thrust is to be towards biologically active proteins, with "emphasis on new substances now emerging on a production scale from biotechnology, such as lymphokines, interferons and monoclonal antibodies", according to Bill Castell, managing director of Wellcome Biotechnology.

The British Columbian Provincial Government has helped finance the project through its Development Corporation. (Extracted from Manufacturing Chemist, May 1985)

ChinaChinese set a virus to catch a virus

Virologists at Beijing University claim to have cured two-thirds of mice who would otherwise have died of Japanese viral encephalitis. They did it by infecting them with another, related virus called M14.

C.H. Huang, one of the researchers, told the International Congress for Infectious Diseases that M14 reduced the amount of macrophage-inhibiting factor, which blocks natural non-specific immunity. The Chinese do not know yet whether this effect will save a human with encephalitis. They plan first to try M14 in T-cell leukemia, another disease in which macrophage inhibition plays an important role.

M14 may eventually have its most important effects on encephalitis while the disease is still being carried by the mosquito. Huang said the encephalitis virus "disappears" from various organs of mosquitos which are infected with M14. Encephalitis is not cleared from the entire insect, but in several cases Huang says it disappeared from the salivary glands, which transmit the disease to humans.

What seems to happen is that the two viruses compete for binding sites in cells. M14 wins. The phenomenon is not new to science and several virologists in Cairo described the finding as "reinventing the wheel".

Huang has high hopes for his "new concept" of therapy with non-pathogenic viruses, however. He wants to block the transmission of dangerous viruses by the mass infection of wild mosquitos with M14 in places where the diseases are endemic. This could lead to the eventual eradication of encephalitis and perhaps another, more important viral disease spread by mosquitos, yellow fever. (Source: New Scientist, 30 May 1985)

DenmarkBiotechnology in Denmark

Biotechnology is very strong in Denmark, whose economy is based on agriculture (24 per cent of output), food processing (34 per cent) and chemical industry (10 per cent). Everyone has heard of the Carlsberg brewery, with its traditional skills in brewing, which have supported the creation of an international research centre with outstanding competence in plant genetics and cell biology. Everyone has also heard of Novo, which dominates the world market in industrial enzymes. Novo practised biotechnology before the word was invented, and is now arguably the world's leading company in the field.

In 1978, the Danish Technical Research Council, under the chairmanship of Prof. O.B. Jorgensen, of the Technical University, took the first initiative in the field and supported projects in genetic engineering scale-up problems (with particular reference to genetic stability), product recovery (with special reference to selective recovery of intracellular products) and on protein synthesis. More recently, a Ministry of Industry "initiative group" recommended against creating a new institute specially for biotechnology because the subject was of such widespread interest that it needed to be practised widely. (Extracted from Industrial Biotechnology Wales, February 1985)

European Economic CommunityEuropean biotechnology

Agriculture and food processing, forestry, health care, pharmaceuticals and major sectors of the chemical industry are among the areas of activity which may be radically altered by the recent breakthrough in biological science, and their technological applications. Biotechnology is of fundamental importance to every society, and to many businesses. In the United States, over 200 new companies have been created, and several billion dollars invested in biotechnology, over the past 10 years; giant multinationals are reorienting their strategies towards the applied life sciences, and spending massively on research. In Japan, the expenditure is more modest, but the coordinating role of MITI's

"Bio-industry Office" brings together all the major groups in a concerted assault on the commanding heights of this, the other "microtechnology". The dynamo of change is the breathtaking pace of scientific progress, and Europe is strong in all the key areas - molecular and cellular biology, microbiology, process engineering and fermentation science. But will the Old World, with its fragmented markets and complex political machinery, manage to hold its place in the race to commercialization?

The European Community cannot be passive, faced with the massive challenge of the new opportunities, and the sharp competitive threat from the other industrialised countries. The means exist within the Community - the human skills, the financial resources, the potential scale of the home market. These need mobilisation by a concerted effort, involving decision-makers both in private industry and the public sector; in small and large firms; at national Ministries, and in the Community institutions.

The studies and the experience are available, on which to build a Community effort. The Commission has argued since the mid-70s for a collaborative R and D programme in the key areas of genetic engineering and enzymology. The futures group FAST (Forecasting and Assessment in Science and Technology) argued for a comprehensive Community strategy for biotechnology - of what use the advanced research, if firms are being driven out of the Community because of the price of agricultural raw materials? Meanwhile, the development of biotechnology in the countries of Europe proceeds slowly and sporadically; constrained by history to gradual innovation and institutional change, condemned by future competition if it fails to move more quickly enough.

Biotechnology is a "knowledge based business", and therefore R and D capability is central. That capability has to achieve "critical mass", by developing centres in Europe with the equipment, the people (above all the broad interdisciplinary teams), the intellectual stimulus and density in "brains per square metre". The best young researchers in each area must be able to find and move to centres of world class within the Community. By all means, with transatlantic collaboration and exchange - but a two-way shuttle, not a one-way brain-drain.

To stimulate the development of these advanced technologies, at a precompetitive level under-pinning applications capability, the Community first launched a programme oriented towards the transfer of the scientific breakthroughs into European agriculture:

A Multi-annual (1982-86), 15 million ECU, cost-sharing Research and Training Programme

This programme, started in April 1982, now includes 104 research contracts, covering periods between 24 and 40 months, and involving Commission co-finance averaging 40,000 ECU per year per laboratory. The six areas, all oriented to agriculture and the food industry, comprise:

- development of advanced bioreactors for agriculture and the food industry;
- improved production of materials for stock breeding and for agriculture and the food industry through application of biomolecular engineering techniques;
- improvement of plant products;
- development of methods for the identification and transfer of new genetic information in plants;
- improvement of the symbiotic relations between cultivated plants and soil micro-organisms;
- development of methods for cell selection and regeneration in other plants.

Wider in its scope, the training programme covers all aspects of biomolecular engineering, including methods of risk assessment in biotechnology.

The need for a wider concept of strategy is reflected in the Commission's new proposals for a five-year, Biotechnology Action Programme (1985-89), of which Research forms only the first of six points.

1. Research and Training - prolonging the activities of the outstandingly successful first R and D programme, and enlarging its scope to a broader range of topics in basic biotechnology; ranging from such frontiers as "protein engineering", to work on the development of better health diagnostic tools, and better methods of toxicological testing for new drugs. A "Contextual Measures" sub-programme aims to strengthen the research infrastructure for biotechnology, in data banks, information services, and banks of genetic materials (cells, microorganisms, etc.).
2. Concertation Action - for monitoring coordination, and the essential communication functions, between Commission services, between biotechnology policy makers at Community and national levels, between the various scientific disciplines and economic sectors, through informal networks spanning the internal national frontiers of the Community.
3. Access to Raw Materials - sugar, starch or some such organic and digestible energy source is fundamental to all the fermentation industries of biotechnology; but it must be available at a competitive price, if Europe's biotechnology firms are to thrive. Proposals for the necessary changes of agricultural régimes have been put to Council. The development, through biotechnology, of high-added-value and non-food uses for agricultural materials is of strategic importance for the future of Europe's agriculture.
4. Regulatory Régimes - the long-standing effort towards the creation of a true Common Market acquire a new urgency from the needs of biotechnology, which include the need for a clear, responsible and uniform regulatory environment. In pharmaceutical products, foodstuffs, feedstuffs, chemicals and other areas, the need is the same: to derive the economies of scale and consequent benefits of a market of 300 million people.
5. Protection of Intellectual Property - the law of patents, and the conventions for the protection of plant varieties, find some of their basic concepts brought into question by the radical innovations of biotechnology. Thus the existing proliferation of different national systems, both within the Community and world-wide, is further complicated by technical uncertainties at the interface between science and jurisprudence. Industry - particularly within Europe - chafes at its impediments, and at the more advantageous conditions in the USA and Japan; while jurists at national, European and OECD level wrestle with the slow processes of legislative innovation and the modification of international conventions. The Commission's working group on patenting in biotechnology is battling to assert in this complex domain the urgent and growing need for a Community approach.
6. Demonstration Projects - and other forms of closer collaboration with industry, are seen as essential to the Community's long-term strategy.

Action and proposals on this plan have been intensifying through 1984, the new five-year research Programme being timed to start in early 1985, to run at roughly 15 million ECU per year to 1989.

The Commission's plan attempts to address the strategic challenge, but the resources are modest, the constraints on implementation, many and complex.

The role of the European Community

The strength and diversity of European capabilities in biotechnology include all application areas in industry, agriculture, health care and environmental or resource management, and all the relevant areas of fundamental science and advanced technology. Of no single European country could this be said. Industrialists need to recover the heavy R and D costs and capital investments by the economies of scale achieved only at European and world level. Students and researchers need access to worldclass centres where the key resources and accumulated multi-disciplinary expertise are available; such access, for collaboration, service and training, is no less necessary for those concerned with applications.

To create in biotechnology this "espace européen", continuing Community initiatives are needed in several policy areas: in research, in agriculture, in regulations, in industrial policy. These policy initiatives have to be based on a concerted approach, not only within the Commission services, but between the Community institutions and national administrations,

and in association with those groupings or institutions which command the key scientific, industrial and agricultural strengths. (Extracted from Industrial Biotechnology Wales, February 1985)

Clean incentive

The European Commission has invited applicants for its biotechnology and "clean" technology programmes. The biotech programme runs from 1985-89 and covers training and basic research proposals. On clean technology, the EEC will put up 30 per cent of the investment costs for development of processes which produce less waste or use less resources. (Source: European Chemical News, 20 May 1985)

Federal Republic of Germany

Biotechnology in the FRG

Germany was amongst the first to give official recognition to the importance of the field, when in 1974 the Ministry for Research and Technology (BMFT) took up the suggestions of a DECHEMA report (the German Chemical Equipment Manufacturers' Association). This association has remained an active promoter of biotechnology, both in Germany and at the European level: being a founder association and secretariat of the European Federation of Biotechnology (founded in 1978, and now comprising 49 scientific societies, from 18 European countries). The German research effort is focussed on major centres at Braunschweig and Jülich, as well as at many other public or private institutions, such as the Technical University of Berlin.

Hoechst, the world leader in pharmaceutical (particularly antibiotic) production, has also pioneered production of single-cell protein for human consumption (with BMFT cofinance). Boehringer Mannheim is a leader in the new biochemicals - restriction enzymes and oligonucleotides - used in genetic engineering. Boehringer Ingelheim produces speciality chemicals by fermentation (citric acid). Bayer, number two in pharmaceuticals world-wide, applies enzymology to the production of semi-synthetic penicillins. Schering uses microbial transformations in producing steroid hormones. Degussa produces amino acids (for animal nutrition) using immobilised biocatalysts. There are some twenty other significantly active companies, although these are usually established firms rather than venture capital activities on the U.S. model. (Extracted from Industrial Biotechnology Wales, February 1985)

Bacteria eat up sewage

Although much of the environmental damage is recognised nowadays, the causes are often still a mystery to scientists, especially in the case of massive damage to forests, even though much information has been gathered on the subject. The figures are alarming: almost half of German forests are already damaged, while the scientists are still disputing how and to what extent air pollution, the condition of the ground, climatic fluctuations or pests are to blame for it.

Recently the bark beetle, also called the "engraver", has developed into a veritable plague. These greedy creatures prefer to attack ailing trees. Bark beetles signal to other members of the species by means of a particular scent where they have found food, and it is possible to synthesise this odiferous substance. The success is sensational: in the Federal State of Hesse alone over one hundred million of these beetles went into the scented traps set for them.

In the area of water conservation, great progress has been achieved in recent years, not least owing to the research work of the chemical industry since the regulations for protecting the environment have been drastically tightened.

A pioneer in the development of new methods of water purification is Hoechst AG, which has invested some 330 million marks in clean water in the last four years. The Frankfurt chemical giant is first and foremost backing the development of so-called large-scale bio-reactors, the third generation of biological purification plants developed by Hoechst. This largest chemical group in the Federal Republic of Germany spends about five per cent of its total turnover on environmental protection, equal to 18 per cent of its overall investments.

The bio-reactor method has been copied from nature, whereby bacteria feed on organic substances, convert them into cellular materials or oxidise them to produce energy. The organically dirty sewage is literally thrown down for the bacteria to eat. In order to give these minute organisms ideal working conditions either oxygen or granulated active charcoal is added, since for their work the bacteria need air. Active charcoal also helps to detoxicate particularly obnoxious sewage. In this way over 95 per cent of organic impurities can be removed. Dangerous alkaline and acid solutions and heavy metals are filtered out of the sewage before it is piped into the bio-reactors. The tower-like plants have the added advantage that there are neither objectionable smells nor any noise during the process. Although the bio-reactors constitute the essential item in purifying very dirty effluent, they alone are not enough. Part of the Hoechst AG's "Purification Programme" is also a so-called "Demercurising Plant", which removes mercury from the effluent of potassium chloride electrolysis. Since its introduction, the mercury passed into the River Main, which is already polluted to some extent, has decreased considerably. (Extracted from Scala, No. 5, 1985)

France

French biotechnology

The country of Louis Pasteur seemed to be falling behind in biotechnology until a strongly renewed government interest was signalled in 1979-80 with the publication of strategic analysis and reports, by Gros, Jacob and Roger ("Sciences de la Vie et Société"), de Rosnay ("Bio-Industrie"), and subsequently Pelissolo ("La Biotechnologie, Demain?"). The Pelissolo recommendations for the creation of a "Mission Biotechnologie" were accepted, leading to the launch of the national "Programme Mobilisateur" now being implemented. This focuses national efforts in biotechnology on four 'poles' in particular: Toulouse, Compiègne (long known for its enzyme engineering and bio-process technology), Pasteur Institute (a private foundation, 50 per cent financed by government, with capabilities in genetic engineering, hybridoma technology, virology and immunology), and ParisGrigon (the newly rebuilt centre of fermentation technology in INRA, the National Institute for Agricultural Research). A particular objective of these centres is to improve the transfer of knowledge into industry. The strong molecular biology at the University of Strasbourg should also be mentioned.

In addition to the many multi-nationals with strong bases in France, major French companies using biotechnology in fine chemicals and pharmaceuticals include Rhone-Poulenc (antibodies, and world leader in production of vitamin B12), with its subsidiaries Institut Mérieux (for vaccines) and Genetica (for genetic engineering); and Roussel-Uclaf (a subsidiary of Hoechst) for antibodies and steroids. But the largest commitment to biotechnology comes from the oil company Elf Aquitaine. In human biologicals, it has acquired Sanofi, Clin Midy, Choay and Institut Pasteur Production. Elf Bioindustries and Elf Bioresearch are developing biotechnology in the food and agricultural sectors. There are research-minded companies in the dairy industry (Bel-Industries, BSN-Gervais-Danone, Entremont), and in starch conversion, Roquette Frères are world leaders in sorbitol production. In animal feeds, amino acids are produced by Orsan, Eurolysine (associated with Ajinomoto) and Rhone-Poulenc.

Of new biotechnology companies set up, Genetica has been mentioned; and Transgène, in genetic engineering, benefits from its proximity to the University of Strasbourg. (Extracted from Industrial Biotechnology Wales, February 1985)

Biomechanics and biomaterials training and research in Marseille

The successful treatment of a wide range of traumatic injuries, such as are encountered by military personnel, requires a close integration of surgery with a knowledge of the properties and characteristics of an ever-growing list of natural and synthetic materials. The Faculty of Medicine of the University of Aix-Marseille, France, has designed a teaching and research programme aimed at providing orthopaedic surgeons and others with a broad and comprehensive diploma built around biomechanics and biomaterials. This programme which trains 10 to 40 students per year, is led by Professor Agrege D. Poitout; it is the first of its kind in France, embracing the technological application of materials in medicine and cooperative work between hospitals, research laboratories, and industry.

France currently implants annually a total of 50,000 hip prostheses; 5,000 knee prostheses; 15,000 cardiac valves; 15,000 vascular prostheses; and 20,000 cardiac pacemakers. Many of the materials were actually developed for nonmedical uses in, for example, the aeronautics industry, the electronics industry, or agriculture. While the functional aspects of implanted materials can usually be predicted with a certain degree of accuracy, estimation of the biological performance still needs much research in order to be considered reliable in many cases. The progress which has been made in recent years in the study of the interface between materials and living tissues has enabled the development of implants which are far more reliable and effective. However, the biocompatibility of the materials used is still not completely satisfactory, and this would seem to justify an intensification of research and collaboration between designers (engineers) and users (clinicians).

The course of study in the Poitou's programme is designed to be of interest to medical students who are preparing for orthopaedic, cardiovascular, neurological, or general surgery; general anatomy; and dentistry. Some students who are in physical and biomedical sciences may also enter the course.

Through close cooperation with manufacturers and researchers, the course aims to provide students with in-depth knowledge of new materials and new technologies to enable them to take their place at the forefront of current practice and to orient their research in terms of industrial needs. In a like manner, manufacturers will acquire a better understanding of practical problems, enabling them to solve them more satisfactorily and to provide materials that are better adapted to the needs of the clinician. (Source: European Science News, 39-6 (1985))

Greece

Biotechnology in Greece

In Greece, the Ministry of Coordination, in consultation with the Ministries of Science and Technology, Education and Agriculture, is currently developing plans to stimulate awareness, education and application of biotechnology, in the context of the 1983-88 five-year plan for economic and social development. This includes a programme for scientific and technological development, and an element of which concerns "key technologies", containing three themes:

- (a) microelectronics and informatics
- (b) biotechnology
- (c) technologies relating to marine exploitation.

This choice reflects top-level political decisions, and ambitious plans are now being implemented to create the necessary foundations.

Biotechnology and life sciences research are being vigorously promoted at the new Institute for Molecular Biology and Biotechnology in Heraklion, Crete; as well as at several other universities (Athens, Patras, Thessalonika) and at research centres such as the National Hellenic Research Foundation, the Cancer Research Centre (Salonika), and NRC Demokritos (Athens).

Professor Stavropoulos, associated with the science-based biotechnology company Vioryl (food additives, preservatives, flavourings, plant nutrients), is working with the government planners to identify new industrial opportunities in biotechnology. There has been created a national company, "Bio-Hellas", which will work in close association with the research centres mentioned. (Extracted from Industrial Biotechnology Wales, February 1985)

India

India sets five-year-plan

India has earmarked \$400 million for biotechnology over the next five years, sealed a long-delayed science agreement with the U.S.A. and sought a joint bio-collaboration with the Soviet Union.

The Gandhi-Reagan Science and Technology Initiative (GRSTI) agreement lays particular focus on applied biology, genetic engineering and plant biotechnology. While GRSTI is broad in its scientific scope, it emphasizes Indo-U.S. cooperation in developing recombinant vaccines and pharmaceuticals for measles, cholera, typhoid, malaria, non-A/non-B hepatitis, human and animal rabies and leprosy - with particular attention to preclinical leprosy diagnosis - and development of a male contraceptive vaccine.

Coordinating the five-year bio-plan is India's National Biotechnology Board (NBB). Created in 1982, it has initiated postgraduate biotechnology programmes in six Indian universities, and aims to open five more by year's end. NBB will set up embryo-transfer and animal-breeding centres, gene banks, genomic libraries, and biotechnology manufacturing units.

Meanwhile, India is about to sign an agreement for collaboration in biotechnology with the Soviet Union. Later this year the two nations will identify four to six areas of mutual Indian-Soviet interest, including biomass conversion and macromolecular interactions. (Extracted from McGraw-Hill's Biotechnology Newswatch, 6 May 1985)

Biotechnology in India

India is now posed to become the first developing country in this part of the world to make use of biotechnology to solve many problems being faced in medicine, agriculture and industry.

In recent years, biotechnology has emerged as an important discipline which can be broadly defined as the development of biological forms and systems for obtaining maximum benefits to man and other forms of life while maintaining an optimum ecological balance.

The recent epoch-making discoveries which have led to the development of techniques of genetic engineering, cell-cell fusion amongst plants and animals and micro-organisms and manipulation of enzyme and metabolic pathways have opened up new possibilities for the cost-effective production of fuel from renewable resources, cloning and mass fertilization of crops, better yielding varieties of plants, cheaper products, better methods for early diagnosis of diseases, selective methods of pest control and stabilisation of waste water.

Several basic disciplines of science like biochemistry, physics, mathematics, chemistry and engineering have an interface with biotechnology. The grounding and advances in basic research in Indian universities and institutes over several decades have made possible the emergence of biotechnology as an interdisciplinary thrust area of research with a potential future.

Genetic engineering: Work on genetic engineering has been taken up at a number of institutions. In the capital, various institutions are active in the field. Studies are being carried out on transfer of "nif" genes into plant cells at the School of Environmental Sciences, Jawaharlal Nehru University. Construction of M-Laprae DNA library and cloning of DNA and coding the hormones, HCG and human placental lactogen is in progress at the National Institute of Immunology.

At the Indian Agricultural Research Institute an active group is working on characterisation of translation and transcription process in *E. coli* during cell division and gene expression in plant tissues. At the Indian Institute of Technology, Delhi, stress is given on conversion of cellulose to alcohol and this is the major facility for detailed studies on all aspects of fermentation. At the CSIR Centre for Biochemicals, a support facility has been created to ensure that restriction enzymes and other strategically important materials are readily available.

Two of the major institutions in Bombay active in the field of genetic engineering are the Tata Institute of Fundamental Research and the Bhabha Atomic Research Centre. The Department of Zoology at the Poona University and the Department of Biochemistry at the National Chemical Laboratory house two important groups working in the field of genetic engineering at Pune.

Several groups are active in the Indian Institute of Science, Bangalore, working in diverse areas like gene expression in Rinderpest virus, Histone gene expression in rice

embryos, structure and expression of genes regulating silk, fibroin synthesis in Bombyx mori, regulation of nitrogen fixation etc. Work on molecular cloning and sequencing of genes, coding for restriction and anti-restriction proteins in E. coli and Shigella dysenteriae as well as cloning of biocide gene from Bacillus sphaericus and B. Thuringiensis is pursued at the Madurai Kamaraj University, Madurai, the Osmania University and the Centre for Cellular & Molecular Biology, Hyderabad, the Indian Institute of Chemical Biology, the Bose Institute and the Saha Institute of Nuclear Physics are leading Institutions in Calcutta where several groups work on application of genetic engineering techniques, studies of biological nitrogen fixation and insertion of genes of applied importance to bacteria.

At Banares work on studies on cloning of genes of the bacteriophage in E. coli is being pursued at the Institute of Medical Sciences. Other centres of the activity include the Central Drug Research Institute, Lucknow and the Aligarh Muslim University, Aligarh.

Fermentation technology: The Biochemical Engineering Research Centre at IIT, Delhi, has several research groups working on different aspects of fermentation technology starting from strain improvement using mutagens/genetic engineering right up to pilot plant fermentations with computer controls. The Department of Microbiology at the MS University, Baroda, the Indian Institute of Science, Bangalore, the National Chemical Laboratory, Pune, the Jadavpur University, Calcutta, the National Sugar Institute and the Harcourt Butler Technology Institute, Kanpur, the Regional Research Laboratories at Jammu and Jorhat, the Central Food Technology Research Institute at Mysore, the Department of Microbiology, the Punjab University, Chandigarh, are some of the other important centres where basic studies on fermentation technology are carried on.

Among industries, work on fermentation technology is being actively conducted at the Hindustan Antibiotics Ltd., Pimpri, Pune, Anil Starch Products Limited, Ahmedabad, Bharat Serums and Vaccines, Thana, Cadilla Laboratories Pvt. Ltd., Ahmedabad, Hindustan Lever, Bombay and Hoechst Pharmaceuticals, Bombay.

Enzyme engineering: Major centres in India where work on immobilisation of enzymes is going on include Hindustan Antibiotics Ltd., Pimpri, the Biochemical Engineering Research Centre, IIT Delhi, National Chemical Laboratory, Pune, the Jadavpur University, Calcutta, the Indian Institute of Science, Bangalore, IIT Kanpur and the Indian Institute of Chemical Biology. The work being done covers immobilised enzymes for use in medicine, industrial fermentation, food processing and waste water treatment.

Tissue culture: A large number of establishments are active in the field of plant tissue culture. These include National Botanical Research Institute, Lucknow, National Chemical Laboratory, Pune, Regional Research Laboratory, Jammu, Department of Botany, University of Delhi, Calicut University, Calicut, MK University, Madurai, Indian Institute of Science, Bangalore, Central Arid Zone Research, Institute Jodhpur, Bose Institute, Calcutta, Rajasthan University, Jaipur, Department of Botany, MS University of Baroda, BARC Bombay, JNU, New Delhi and IARI, New Delhi.

Work in various areas including clonal propagation and protoplast fusion and regeneration of fruit and forest trees, plantation crops like sugarcane, papaya, banana, cardamom etc. for applied use, as also basic studies in subjects like cell diversification, immobilisation of plant cells, submerged tissue culture, etc. is being pursued in these institutions. Recently the Central Plantation Crops Research Institute, Kasaragod has successfully propagated coconut plantlets in test tube.

In addition, work on different aspects related to biotechnology including immunology, photosynthesis, diagnostics, vaccine production by improved methods is being done in a number of laboratories spread throughout the country.

The National Biotechnology Board (NBTB), was set up to promote and oversee research in this field. It has completed the working plans for implementing various decisions on major issues namely, integrated short term training courses for manpower development; formulation of long term plan with time schedule; finalisation of NBTB fellowships, visiting scientist programme; formulation of proposals for creation of infrastructural facilities; safety regulations to be followed for DNA research in India, supply of radio-labelled chemicals and restriction enzymes required for genetic engineering; and preparation of feasibility reports for setting up biotechnology based manufacturing units.

One of the charters of NBTB is to identify priority areas in biotechnology and prepare programmes in these areas for carrying out research and development work, for generating know-how required for the application of biotechnology in areas of national relevance such as health (human and animal) and family planning, food and agriculture, industry, energy, chemicals, environment etc. and survey the work done by various agencies in the area of biotechnology. In this connection a long-term plan has been formulated. It was suggested that the sectoral long term plan should be discussed with member agencies and a time schedule drawn up.

The Board was entrusted to set up and provide centralised assistance for procurement of materials required for genetic engineering from abroad and to initiate follow-up action for production of these materials. In view of the urgency, the department initiated a coordinated, multi-institutional programme on production of restriction enzymes which are essential for genetic engineering research. Management and monitoring of the project is being done by NBTB. In the first phase of the project, production of five enzymes has been completed. As an interim measure, NBTB arranged for bulk import and distribution of restriction enzymes with the help of the Centre for Biochemicals at the VP Chest Institute, Delhi. The Board is also arranging the centralised import of radio-labelled nucleotides through the Bhabha Atomic Research Centre, Bombay.

Simultaneously, effort is being made for the production of radio-labelled nucleotides by BARC. The CSIR has agreed to provide laboratory space and other facilities in the Centre for Cellular and Molecular Biology Campus, Hyderabad.

NBTB has formulated an integrated plan for conducting short term training courses. Training programme in plant tissue and cell culture; methods and application; workshop-cum-seminar on enzyme engineering; training programme on recombinant DNA techniques in genetic engineering and workshop course on "gene cloning and allied techniques" under genetic engineering programme. Fellowships were also given by NBTB to scientists for short or long term training within the country and abroad. It has been decided to send some scientists abroad in different sectors for training in advanced techniques to expose them to the recent developments wherever infrastructural facilities and expertise are not existing within the country. NBTB will award 30 junior and 12 junior overseas fellowships of 1-2 years duration and 5 senior overseas fellowships of 3 months duration.

Realising the hazard involved in recombinant DNA research, the Board desired to evolve safety regulations. The task was entrusted to a special committee, which on the basis of guidelines followed in other countries viz. the US National Institute of Health, formulated guidelines relevant to Indian conditions which were subsequently approved by the Board.

Research and development effort in the field of biotechnology would become crippled for lack of certain essential infrastructural support facilities. The authenticity of microbial culture, animal cell lines, plant cell lines primate and small animals used in the production of biotechnological product/metabolite is an essential prerequisite for a successful industrial production of the product concerned. Such a rigorous demand can only be met by proper preservation, maintenance, consistency and monitoring of the desirable pool which becomes, therefore, paramount. The need for such centralised facilities having collections of these is, thus acute. Noting that any organised effort in this direction is yet to take place the following proposals have been formulated in consultation with the experts:

(a) Germplasm banks for microorganisms, protozoa and other parasites, plant and animal tissues and cell lines and viruses; (b) Experimental facilities using non-human primates and specialised small laboratory animals; (c) Pilot plant and other bioengineering scale up facilities for process development and optimisation and for producing sufficient quantities of new products for field trials; (d) Procurement/manufacture of enzyme, reagents and labelled isotopes essential for R&D work in bioengineering and related fields; and (e) A network of information disseminating system to provide up-to-date S&T information to the scientists working in the frontier area of modern biotechnology.

An International Centre for Genetic Engineering and Biotechnology is being set up at the Jawaharlal Nehru University, Delhi with the help of the United Nations Industrial Development Organisation (UNIDO). It will take up research and development work in agriculture, human and animal health, industrial technology for pharmaceuticals and other products.

If and when advances in biotechnology are achieved, it would benefit not only India but the world as a whole. As a result of the stimulus of the green revolution, developing countries are aware of potentials for improving crop yields and are maintaining indigenous agricultural stations capable of acting as centres for technology transfer. (Source: The Hindu, 27 February 1985)

Italy

Italian biotechnology

A new centre for biotechnology research and development is being founded at Pomezia, 45 km south of Rome, by Menarini SaS, the Florence-based pharmaceutical company. Dr. Alberto Aleotti, president of Menarini, says the company is investing 28,000 million lire in the new biotechnology centre.

The first goal of the centre will be the manufacture of TPA (tissue plasminogen activator) and its derivatives for human pharmaceutical purposes, using recombinant DNA technology developed by Creative Biomolecules, a California corporation founded in 1982 by Roberto Crea and Charles M. Cohen.

The agreement between Menarini and Creative Biomolecules is aimed at the production of an economic drug for the international market. The Pomezia team will include researchers from Italy, the United States and Britain. The first TPA for chemical and biological evaluation is expected in the summer.

Inaugurating the Menarini centre (and the toxicology research facility on the same site), Italian minister of research Luigi Granelli pointed to several encouraging signs of development in Italian biotechnology by way of international co-operation. The International Genetic Engineering Centre of the United Nations Industrial Development Organization, to be based at Trieste, is one of these. But Granelli added that developments in this field in Europe as a whole are still not a sufficient counter to developments in Japan and the United States, perhaps because governments see their interests as stronger than supra national ventures.

Italian biotechnology is in part held back by the lack of venture capital, with the result that most of the companies involved are either well established in some related field such as pharmaceuticals or are public enterprises. The companies with declared interests include Farmitalia-Carlo Erba (Montedison group, now under the umbrella of Erbamont), Lepetit and Serono. Sorin Biomedica (wholly owned by Fiat), Farmitalia and various companies of the ENI group have declared an interest in protein chemistry; Sclavo, an ENI company, plans to produce beta-interferon. Biotechnology in agriculture is quite advanced at ENEA, the public corporation for nuclear and alternative sources of energy, and Assoreni (ENI group) has interests in agricultural biotechnology.

University researchers have been drawn into biotechnology in various ways. Thus the multinational Roche facility at Milan has an agreement with the Pharmacology Institute of the University of Milan, headed by Professor Rodolfo Paoletti, for applications to molecular neurobiology. The Italian Society for Biotechnology (SIB) has signed a convention with IASM, the public sponsor of development in the south of Italy, and with FINAM, a financial holding for agriculture, to set up a centre for biotechnology transfer in the south.

The first objective of the centre will be to evaluate the degree of innovation in small and medium-size industries so that by the end of 1985 agricultural experiments on a pilot-plant scale may be started. (Source: Nature, Vol. 314, 14 March 1985)

The Netherlands

Dutch biotechnology

The Netherlands is outstandingly strong in biotechnology, in industrial companies, academic departments, and a light but well-organised structure for national coordination.

It has an excellent tradition of microbiology, biochemistry and process engineering, and

retains a leading international position in effluent treatment, developed in response to the needs of the food industries.

The company Gist-Brocades is Europe's major producer of penicillin, with corresponding expertise in fermentation technology. It is also one of the world's major producers of enzymes, and is carrying out intensive study on their production, isolation and application, on laboratory and commercial scale. Related research is under way to the universities of Delft and Wageningen. In the food industry, Dutch breweries and dairy plants are sophisticated and internationally competitive.

Academic strengths in biotechnology include the universities of Amsterdam (microbial physiology), Leiden (genetics), Groningen (protein crystallography, molecular dynamics), Wageningen (which along with the various research institutes there, covers a wide range of agricultural sciences) and Delft (where the Technical University has a close association with industrial fermentation). (Extracted from Industrial Biotechnology Wales, February 1985)

Genentech and Cetus talk to Dutch

U.S. biotech concerns, Genentech and Cetus, are negotiating with the Dutch Government Industrial Projects Company, MIP, an investment promotion body to set up subsidiaries in the Netherlands. The two companies say their eventual settlement in Holland will be conditional upon government financial support.

Genentech had earlier considered establishing a research centre for its "genemachine" venture with Hewlett Packard in the Netherlands in 1983, but finally chose Benders of Austria, a Boeringer Ingelheim subsidiary. If government support is adequate, production facilities to build machines to synthesise genetic material may be located in the Netherlands.

Cetus is interested in working jointly with Leiden University on genetic manipulation of plant cells. Leiden University recently joined biotech ventures with Centocor and Molecular Genetics of the USA. (Source: Manufacturing Chemist, April 1985)

Switzerland

Fixed binding sites

Fixed binding sites exist to hold DNA to a protein scaffold, according to Dr. U. Laemmli of the University of Geneva. A loop of DNA may represent a single gene or a set of adjacent genes that are coordinately expressed. A major protein in the scaffold is an enzyme called topoisomerase II. The enzyme is used in untangling DNA. The attachment sites may be sites where topoisomerase II binds DNA. The function of the attachment sites is uncertain. (Extracted from Science News, 23 February 1985)

Basel Institute for Immunology

The Basel Institute for Immunology (BII) conducts basic research with full academic freedom, even though it has been and still is supported entirely by F. Hoffmann-Laroche AG, a family-owned Swiss pharmaceutical company. The work of this institute helps indicate the Swiss pharmaceutical industry's commitment to basic research.

BII was founded in 1968 and began operation in 1971 with Dr. Niels Jerne as its first director. (Jerne shared the Nobel Prize in Medicine and Physiology with Drs. Milstein and Kohler for the concept and development of the methods for monoclonal antibody production.) Dr. Fritz Melchers is the present director of the BII. There is a board of directors which is responsible for the operation of BII and for ensuring its independence. BII also has a board of advisors which has an international representation. Most of the members of the board of advisors are former Nobel Prize winners, making this a very high-powered group.

In addition to the above-named boards, the institute also has a board of consultants. This board consists of scientists working in other Swiss laboratories. It acts in a capacity similar to the board of advisors and encourages cooperation among immunologists in Switzerland.

About one-third of the projects have been cooperative work with scientists from Austria, Canada, Denmark, Finland, France, West Germany, Great Britain, The Netherlands, Sweden, Switzerland, and the U.S. The research projects encompass the following topics: gene structure; DNA cloning and transfection; structure and function of immunoglobulin; structure and synthesis of surface antigens; repertoires of T and B cells; biochemical studies on activated lymphocytes; activation of lymphocytes by lectins and antibodies; lymphokines; hemopoietic factors; differentiation *in vitro* and *in vivo*; cell surface of lymphocytes; formal genetics; lymphocyte migration; idiotypes; T cell lines and hybridomas; helper T-cells and T-B collaboration; autoimmunity; and development of new methods for immunological studies.

Research at BII has led to the development of new reagents and techniques. Monoclonal antibodies with interesting specificities have been generated. These include large libraries of gamma light chain-producing antibodies from mitogen-stimulated spleen cells of kappa light-chain-suppressed mice, and of antibodies from mitogen-stimulated as well as ovalbumin-primed spleen cells in which rheumatoid autoantibodies could be found. Conditions for serum-free cultures of chicken lymphocytes were improved. Antibodies secreted by a B cell clone in semisolid agar can be detected, and single cells can be probed *in situ* for the expression of specific messenger RNA (mRNA), for example, B lymphocytes for the expression of Ig-specific mRNA. A mouse fibroblast line has been established in culture that offers an alternative to L cells and NIH 3T3 fibroblasts for DNA transfection experiments. Methods for DNA transfection have been further refined. For the first time, a complete epitope-binding, biologically active Ig molecule was produced by gene-transfer techniques. With present methods for modifying genes, research is being carried out to construct new Ig genes, such as a variable region of heavy chains linked to a constant region of light chains. New alleles of genetic markers were found, and new haplotypes and recombinants were bred. Two-dimensional gel electrophoresis is being used to analyze the phenotype of cells. A fully automated oligonucleotide synthesizer has been built at the institute's workshop. It uses the chemistry of oligonucleotide synthesis developed at the Roche Research Department to prepare probes for gene isolation and modification.

BII offers an ideal environment for a research scientist. Since the institute is entirely funded by the Hoffman-LaRoche Company, the scientific staff does not have to apply to the Swiss Government or to any other sources for research funds.

The main criterion for a research project is that it be innovative, without the requirement of any direct application to a potential product for Hoffmann-LaRoche. Thus, the independence of the scientific staff is equivalent to that at any university. Many of the scientists at the institute also teach at the University of Basel and train graduate students as well as post-doctoral fellows. Since most of the staff positions are on a temporary basis of 3 to 5 years - in some cases, 8 years - there is a continuing influx of new ideas and projects. In addition, the international composition of the staff is conducive to the generation of new concepts and to collaboration with scientists from other countries. The organization of the institute, in that there are no departments or sections and no chairmen, facilitates collaboration rather than competition among the scientific staff. They are also permitted to publish freely the results of their research. The excellence of the research has led to international recognition of the institute as an organization devoted to research of the highest quality. (Source: European Science News, 39-6 (1985))

The Friedrich Miescher Institute, Basel

The institute was established in 1970 as an independent foundation by Ciba-Geigy Limited. The aims of the institute are: (1) to engage in basic research, originally in the fields of biochemistry and medicine and, more recently, in plant science; and (2) to provide an international centre for research, study, and training for young scientists. This institute is entirely funded by Ciba-Geigy, but the staff scientists carry out research without constraints by Ciba-Geigy. Thus this institute has the same independence in research projects as the Basel Institute of Immunology and the Roche Institute of Molecular Biology in the U.S., the latter two being entirely funded by the Hoffmann-LaRoche Company. The director of the Friedrich Miescher Institute is Dr. Edward Reich.

The institute was originally housed at the Biozentrum, University of Basel, but is now in new and larger quarters in the Rosental complex of Ciba-Geigy. These quarters are well

equipped with supporting facilities required for modern research in the life sciences. Current work at the institute spans a wide range of subject matter in cell and molecular biology of eukaryotic organisms. The institute maintains a programme of internal research seminars and journal clubs, seminars, and lectures by a constant stream of visitors from Europe and overseas, as well as meetings on special topics of interest. The staff scientists as well as research fellows comprise an international group representing, in addition to Swiss nationals, other European countries as well as Japan and the U.S. Some of the staff scientists as well as research fellows have temporary appointments for periods from 2 to 5 years, similar to the situation at the Basel Institute of Immunology. This turnover allows for an influx of new ideas and approaches to research projects.

A board of trustees is responsible for overseeing the long-term activities of the institute. It is helped in its assessment of the institute's work by an independent scientific advisory board that consists of an international group of distinguished scientists.

A large number of diverse research projects are carried out at the institute: gene expression in yeast; plant development; culture and genetic modification of cereal protoplasts; regulation of storage proteins in corn seeds; biochemical genetics of cultured plant cells; studies on cauliflower mosaic virus; gene expression in plants; neuronal microdifferentiation; desensitization of β -adrenergic receptors; glia-derived modulations of neurite outgrowth in neuronal cells; human oncogenes; human interferon; mechanisms of DNA repair; hormonal regulation of gene expression; regulation of tumour functions by hormones; structure, function, and hormonal regulation of specific eukaryotic genes; regulation of protein synthesis and S6 phosphorylation; molecular aspects of protein phosphorylation; structure and function of plasma proteases; hemopoietic cell differentiation and transformation; biochemistry of fibrinolysis; translational control mechanisms and clinical immunology; regulatory events of the cell cycle. (Source: European Science News, 39-6 (1985))

United Kingdom

Britain planning biotech research

The British Government is planning to establish a joint biotechnology research programme involving industry, public and private sector research bodies and universities, according to Geoffrey Pattie, industry minister responsible for biotechnology.

Five U.K. food and chemical groups - Unilever, ICI, Shell, Rank Hovis McDougall and Cadbury-Schweppes - have already discussed the proposal with the minister. So have three Government research councils and Agricultural Genetics Co.

Under discussion is a joint R&D programme of £5-10m a year over five years, with the Government contributing a large part of the cost. The object would be to carry out basic research to enable food and agro-chemical companies to exploit new areas such as genetic engineering.

Participating companies would form partnerships with universities, polytechnics and research council laboratories. Study groups set up to investigate three separate areas - food science, plant science and animal sciences - are due to report to the Government in June. The programme could be launched later this year.

Of the European Community countries, the United Kingdom has the strongest research base in biotechnology, with world class centres in many of the key disciplines. The institutes of the Medical Research Council (e.g. Molecular Biology, Cambridge), and of the Agricultural and Food Research Council (e.g. The John Innes Institute, Norwich) complement strong university departments; and another public institute of special importance of biotechnology is the Centre for Applied Microbiology and Research at Porton Down, strong in fermentation science, and home of a recently founded centre for animal cell lines.

Industrial biotechnology in the U.K. is represented by leading chemical firms, as in ICI's "Pruteen" plant for single-cell protein combining a major innovation in engineering (the air-lift continuous fermenter) with a major innovation in nutrition. In fermentation for pharmaceuticals, Glaxo and Beechams are well known, and G.D. Searle and Wellcome are also

noted for their capability in genetic engineering. In agro-food, Unilever's success in cloning cells of the oil-palm is a breakthrough in applied genetics of major practical benefit; Rank Hovis McDougall's mycoprotein is another promising food innovation.

The U.K. also has many smaller, venture-capital companies, with special skills or application areas, or providing ancillary services and supplies to the larger firms. Celltech, launched by government co-finance with industry, is strong in animal cell culture and in the production of monoclonal antibodies (for diagnostic or analytical applications), as is to be expected in view of its original links with the institutes of the Medical Research Council; a similar link with the agricultural institutes provides access to the knowledge base for Agricultural Genetics Co. Ltd. (Source: Industrial Biotechnology Wales, February 1985 and European Chemical News, 29 April 1985)

U.K. Biotechnology

One of the most unusual arrangements yet for turning public investment in research into industrial channels, Porton International, announced an arrangement with the British Government that gives it the right of first refusal on biotechnology innovations at the Centre for Applied Microbiology and Research (CAMR).

The new arrangement is the outcome of several years of negotiation. Porton International already has agreements with CAMR for the exploitation of two of its proprietary developments, asparaginase (used in cancer chemotherapy) and a vaccine for herpes simplex virus (based on developments at the University of Birmingham as well as at CAMR).

In a joint statement, the company and the Public Health Laboratory Services Board said that the new arrangement will run for thirteen years from 1 April, and that the arrangement might be continued thereafter. A spokesman for Porton International said that developments not taken up by the company would remain the property of CAMR, and might be offered to other companies. But he suggested that such happenings would be few and far between.

The management of the laboratory will remain the independent responsibility of the director, Dr. Peter Sutton, the Public Health Laboratory Service and ultimately the Department of Health and Social Services. But the existence of the new agreement is likely to divert the scientific interests of many members of the laboratory into directions that may be profitably exploited.

Porton International Ltd. is for the time being a holding company, with a number of subsidiaries (such as LH Fermentation) active in fields related to biotechnology. The recent development appears to have been financed by capital contributions from a number of financial institutions, including the pensions funds of several public companies and a number of insurance companies. (Extracted from Nature, Vol. 314, 18 April 1985)

British thalassaemia

Britain seems to have its own form of α -thalassaemia, a genetic disorder that disrupts the synthesis of α -globin chains, which form part of the oxygen-carrying haemoglobin in the blood. Researchers at the John Radcliffe Hospital in Oxford have diagnosed the rare genetic defect in eight people with no known foreign ancestry (British Medical Journal, Vol. 290, p. 1303).

Normal individuals have two α -genes on each of the relevant paired chromosomes (number 16). People with only one functional α -gene ($--/\alpha$) suffer from a moderately severe anaemia, whereas people with no α -genes die early on. The discovery of the heterozygote condition ($--/\alpha$, which causes no illness) in British people is interesting because researchers have long thought that only people of Mediterranean or Southeast Asian origins showed deletions of both α -genes on one chromosome. The study has implications for genetic counselling: we now know that a child of either British-Mediterranean or British-Southeast Asian parents could suffer from the lethal ($--/--$) form of α -thalassaemia. (Source: New Scientist, 16 May 1985)

United States of AmericaU.S. biotechnology policy

Most technologically developed countries have a well defined science policy, in which biotechnology is targeted for support as a national goal. The United Kingdom, France, West Germany, the Soviet Union, and, even more vigorously, Japan have national efforts involving government support of industrial-academic collaborations, financial support of private companies, legislative support, and rapid modification of scientific guidelines.

In contrast, the United States' policy appears to be in some turmoil. The Environmental Protection Agency has not been given any specific authority in this area, but has loosely interpreted the Toxic Substances Control Act and the Federal Insecticide, Fungicide, and Rodenticide Act to encompass DNA as a potentially hazardous chemical. The Departments of Defense, Commerce, and State debate the extent of restrictions on exporting biotechnology to other countries. Lawsuits filed in U.S. courts challenge a host of biotechnology issues ranging from deliberate release of microorganisms, to patent questions (particularly those involving universities and industry), to the rights of patients to share in profits of biotechnology created from their body tissues. In all of these areas, industrial participation in formulating national policy has been largely restricted, if not nonexistent. Many initiatives need to be addressed in terms of a comprehensive national science policy in biotechnology: supporting basic research; targeting in areas like bioprocessing, plant molecular biology and biochemistry; improving intellectual property law; regulating technology transfer rather than products; modifying import-export regulations, to name a few.

The National Institutes of Health (NIH) originally established guidelines for recombinant DNA research under the Recombinant DNA Advisory Committee (RAC). Both academia and industry have adhered to the guidelines and have sought RAC approval as necessary. This single scientific oversight system of review and recommendation is considered by nearly all to have functioned in an exemplary fashion. The gamut of controversial issues and experimental proposals has been brought forward, accepted for discussion, and acted upon in the light of current knowledge - all with dispatch. These issues include deliberate release to the environment and human gene therapy, and will probably include the issue of "convertibility" for military uses. With the exception of hybridoma technology, the major recent discoveries leading to modern biotechnology have been made in the United States. These include methods for manipulating, reading, cutting, and splicing DNA chains. Seen in this light, the disarray of U.S. policy seems surprising.

In the last half of this decade, the United States will clearly compete with coordinated efforts in biotechnology from most of the industrialized countries. The U.S. Office of Science and Technology Policy (OSTP) has published a Proposal for a Coordinated Framework for Regulation of Biotechnology, (Federal Register, 49: 50856, December 31, 1984). The Proposal recommends establishing separate rDNA Advisory Committees within the Food and Drug Administration (FDA), EPA, Department of Agriculture (USDA), NIH, and National Science Foundation (NSF). The FDA, EPA, and USDA have provided position statements, included in the Proposal, but NIH and NSF provided none. The statements from the FDA and USDA acknowledge that they have no need for additional authority for regulation and will deal with biotechnology on a case-by-case basis. There are inconsistencies in the FDA statement. The agency says on one hand that it intends to regulate products "based on a rational and scientific evaluation of products and not on a priori assumptions about certain processes," yet it says that animal and food additive products must be subject to approval "even if the active substance is shown to be identical to that in approved products produced by conventional methods." In contrast, the USDA policy statement notes that agriculture and Forestry products developed by biotechnology will not differ fundamentally from conventional products.

The OSTP proposal provides for a second or different review process for biotechnology products by establishing a Biotechnology Science Board (BSB). This creates a two-tiered system in which submissions are made to the appropriate authority, which forwards them to BSB, which may send the proposal back with recommendations or send them on to yet another authority for further consideration. Products of biotechnology are not inherently different from "conventional" products. (Extracted from Bio/Technology, Vol. 3, May 1985)

USSR

Two-stage bio-oxidation used to purify postfermentation mash

At the Kropotkin Chemical Plant a method has been introduced for biological purification of afteryeast mash (PDB) which, in addition to lowering pollutant content of PDB, makes it possible to recover an additional amount of biomass. Under the conditions at the Kropotkin plant, the method is the most suitable and effective, since the plant processes vegetation waste from agriculture mixed with molasses slops into feed yeast, and along with augmenting output, this causes significant increase in pollutant content of PDB passing into the general discharge channel of the plant. Unutilized nutrients remain in PDB (carbohydrates, organic acids, nitrogen and phosphorus salts, trace elements) which have high parameters for chemical and biological oxygen demand.

The biooxidation process takes place in two stages in yeast-growing fermenters as follows: the nutrient substrate delivered for first-stage biooxidation (in 600 m³ tank) consist of mash that has risen and mash from the bottom separators of the basic production fermenters. Partially purified PDB is discharged from the bottom separator of the vat and directed as nutrient medium to the second-stage biooxidizer (1,300 m³ tank). Purified PDB is discharged into general discharge channel of the plant. The cultivated biomass is recovered from the top separators of the fermenters, mixed in a flotation unit with the general flow of yeast suspension and delivered for separation and drying.

The yeast-like fungus, *Trichosporon cutaneum*, serves as the main culture for biological purification of PDB. Pure culture of the fungus is added once a week to each biooxidizer; however, there is mostly the basic production yeast culture in the first-stage bio-oxidizer, whereas in the second-stage one there is prevalence of the fungus.

Aeration of the biooxidation process is effected on the level of yeast fermentation at a temperature of 39-40°C; medium pH is controlled with sulfuric acid; the concentration of biomass in the fermenters is kept at 15-17 g/l; PDB remains in the first- and second-stage fermenters for 2.7 and 7.0 h, respectively.

Thus, introduction of technology for two-stage biooxidation of afteryeast mash made it possible to lower contamination by 40-45% according to chemical oxygen minimum and by 50-55% according to biochemical oxygen demand, as well as to produce an additional 2,662 kg per day of commercial yeast. The economic effectiveness of obtaining additional biomass constituted 212,300 rubles/year. (Extracted from Microbiologicheskaya Promyshlennost'. Ekspres-Infomatsiya, No. 5, 1984)