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ASSISTANCE IN FORMULATING A NATIONAL SECTORAL PLAN ON BIOTECHNOLOGY

SI/PHI/90/804/11-51

REPUBLIC OF THE PHILIPPINES

Technical report: Implementation plan on biotechnology in health and veterinary section*

Prepared for the Government of the Republic of the Philippines by the United Nations Industrial Development Organization, acting as executing agency for the United Nations Development Programme

Based on the work of Dr. J. Fari, expert in biotechnology

Backstopping Officer: Mayra Sanchez

Chemical Industries Branch

United Nations Industrial Development Organization

Vienna

* This document has not been edited.
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table of Contents</td>
<td>2</td>
</tr>
<tr>
<td>List of Abbreviation</td>
<td>4</td>
</tr>
<tr>
<td>Abstract</td>
<td>6</td>
</tr>
<tr>
<td>Introduction</td>
<td>7</td>
</tr>
<tr>
<td>I. BIOTECHNOLOGY</td>
<td></td>
</tr>
<tr>
<td>A. Development of biotechnology in general</td>
<td>8</td>
</tr>
<tr>
<td>B. Development of PCASTRD biotechnology program</td>
<td>9</td>
</tr>
<tr>
<td>Biotechnology Action Plan</td>
<td>10</td>
</tr>
<tr>
<td>Biotechnology Implementation Plan</td>
<td>12</td>
</tr>
<tr>
<td>Biotechnology mega-projects</td>
<td>13</td>
</tr>
<tr>
<td>Pilot plant scale penicillin production</td>
<td>13</td>
</tr>
<tr>
<td>Diagnostics and vaccines</td>
<td>17</td>
</tr>
<tr>
<td>Coconut Tissue Culture</td>
<td>18</td>
</tr>
<tr>
<td>Tailored fats from coconut oils</td>
<td>19</td>
</tr>
<tr>
<td>Application of biotechnology in urban wastes</td>
<td>19</td>
</tr>
<tr>
<td>Application of biotechnology in reforestation</td>
<td>20</td>
</tr>
<tr>
<td>C. Development of PCHRD biotechnology program</td>
<td>21</td>
</tr>
<tr>
<td>The PCHRD program thrusts</td>
<td>21</td>
</tr>
<tr>
<td>Human Diagnostics and Vaccines (HD&amp;V) program</td>
<td>21</td>
</tr>
<tr>
<td>II. VISITS-DISCUSSIONS</td>
<td></td>
</tr>
<tr>
<td>A. Research Laboratories</td>
<td>22</td>
</tr>
<tr>
<td>Bureau of Research and Laboratories, BRL-DOH</td>
<td>22</td>
</tr>
<tr>
<td>Industrial Technology Development Institute, ITDI-DOST</td>
<td>23</td>
</tr>
<tr>
<td>BIOTECH. UPLB</td>
<td>24</td>
</tr>
<tr>
<td>Bureau of Animal Industry, BAI-DA</td>
<td>25</td>
</tr>
<tr>
<td>Animal Disease Diagnostic Laboratory, CVM-UPLB</td>
<td>25</td>
</tr>
<tr>
<td>B. Production facilities</td>
<td>25</td>
</tr>
<tr>
<td>Biologicals Production Service</td>
<td>25</td>
</tr>
<tr>
<td>The Laboratory Services Devision</td>
<td>28</td>
</tr>
<tr>
<td>C. National Kidney Institute</td>
<td>28</td>
</tr>
<tr>
<td>D. United Laboratories Inc.</td>
<td>29</td>
</tr>
<tr>
<td>Recommendation</td>
<td>30</td>
</tr>
<tr>
<td>Biotechnology Implementation Plan</td>
<td>30</td>
</tr>
<tr>
<td>Penicillin fermentation</td>
<td>31</td>
</tr>
</tbody>
</table>
Annexes

1. Job description
2. PCASTRD's letter to Dr. J. Fari
3. Tentative schedule of expert
4. Senior counterpart staff - list of people met
5. Biotech for 6 mega projects
6. Biotech on the go
7. Biotechnology Action Plan
8. Biotechnology Implementation Plan
9. STCC Technical Panel on Biotechnology
10. Pilot Plant Production of Penicillin
11. Top 30 hospitals in Metro Manila
12. HD&V Biotechnology Network PCASTRD
14. Biotechnology Megaprojects, Human Vaccines and Diagnostics
15. Biotechnology Lectures
16. Medical Biotechnology Package
17. EPS general. specific recommendation
18. The Laboratory Services Division
19. BSO Comments on the report
# List of Abbreviation

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMBAP</td>
<td>Advanced Medical Biotechnology Action Program</td>
</tr>
<tr>
<td>BAI</td>
<td>Bureau of Animal Industry</td>
</tr>
<tr>
<td>BAP</td>
<td>Biotechnology Action Plan</td>
</tr>
<tr>
<td>BIOTECH</td>
<td>National Institutes of Biotechnology and Applied Microbiology</td>
</tr>
<tr>
<td>BPS</td>
<td>Biologicals Production Service</td>
</tr>
<tr>
<td>BRD</td>
<td>Bureau of Research Department</td>
</tr>
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<td>BRL</td>
<td>Bureau of Research Laboratories</td>
</tr>
<tr>
<td>BTP</td>
<td>Biotechnology Technical Panel</td>
</tr>
<tr>
<td>CM</td>
<td>College of Medicine</td>
</tr>
<tr>
<td>CRC</td>
<td>Center of Research and Communication</td>
</tr>
<tr>
<td>DENR</td>
<td>Department of Environment and Natural Resources</td>
</tr>
<tr>
<td>DOA</td>
<td>Department of Agriculture</td>
</tr>
<tr>
<td>DOH</td>
<td>Department of Health</td>
</tr>
<tr>
<td>DOST</td>
<td>Department of Science and Technology</td>
</tr>
<tr>
<td>ERDB</td>
<td>Environmental Research and Development Bureau</td>
</tr>
<tr>
<td>FASAS</td>
<td>Federation of Asian Scientific Academies and Societies</td>
</tr>
<tr>
<td>FEU</td>
<td>Far Eastern University</td>
</tr>
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<td>FMB</td>
<td>Forest Management Bureau</td>
</tr>
<tr>
<td>FNRI</td>
<td>Food and Nutrition Research Institute</td>
</tr>
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<td>HD&amp;V</td>
<td>Human Diagnostics &amp; Vaccines</td>
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<tr>
<td>IBS</td>
<td>Institute of Biological Sciences</td>
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<tr>
<td>IC</td>
<td>Institute of Chemistry</td>
</tr>
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<td>ICPP</td>
<td>Integrated Coconut Processing Plant</td>
</tr>
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<td>IPB</td>
<td>Institute of Plant Breeding</td>
</tr>
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<td>LSD</td>
<td>Laboratory Services Division</td>
</tr>
<tr>
<td>MBP</td>
<td>Molecular and Biotechnology Program</td>
</tr>
<tr>
<td>MMA</td>
<td>Metro Manila Authority</td>
</tr>
<tr>
<td>NAST</td>
<td>National Academy of Science and Technology</td>
</tr>
<tr>
<td>NCPC</td>
<td>National Crop Protection Center</td>
</tr>
<tr>
<td>NKI</td>
<td>National Kidney Institute</td>
</tr>
<tr>
<td>NSRI</td>
<td>National Science Research Institute</td>
</tr>
<tr>
<td>PCA</td>
<td>Philippine Coconut Authority</td>
</tr>
<tr>
<td>PCARRD</td>
<td>Philippine Council for Agriculture, Forestry and Natural Resources Research and Development</td>
</tr>
<tr>
<td>PCASTRD</td>
<td>Philippine Council for Advanced Science and Technology Research and Development</td>
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<tr>
<td>Acronym</td>
<td>Full Name</td>
</tr>
<tr>
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<td>-----------</td>
</tr>
<tr>
<td>PCC</td>
<td>Poison Control Committee</td>
</tr>
<tr>
<td>PCIC</td>
<td>Poison Control and Information Center</td>
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<tr>
<td>PCISN</td>
<td>Poison Control and Information Service Network</td>
</tr>
<tr>
<td>PCHRD</td>
<td>Philippine Council for Health Research and Development</td>
</tr>
<tr>
<td>PCRDF</td>
<td>Philippine Coconut Research and Development Foundation</td>
</tr>
<tr>
<td>PGH</td>
<td>Philippine General Hospital</td>
</tr>
<tr>
<td>RITM</td>
<td>Research Institute for Tropical Medicine</td>
</tr>
<tr>
<td>STCC</td>
<td>Science and Technology Coordinating Council</td>
</tr>
<tr>
<td>UNILAB</td>
<td>United Laboratories, Inc.</td>
</tr>
<tr>
<td>UP</td>
<td>University of the Philippines</td>
</tr>
<tr>
<td>UPD</td>
<td>University of the Philippines, Diliman</td>
</tr>
<tr>
<td>UPLB</td>
<td>University of the Philippines, Los Banos</td>
</tr>
<tr>
<td>UST</td>
<td>University of Santo Thomas</td>
</tr>
</tbody>
</table>
Abstract

The title and number of the project:
SUPPORT to PCASTRD
SI/PHI/90/804/11-51

The objective and duration of the activity in question:
To provide advice and assistance to the Philippine Council for Advanced Science and Technology Research and Development (PCASTRD) in formulating the national action and implementation plan on biotechnology to be presented to the Science and Technology Coordinating Council (STCC).

The mission was between 18-31 January 1991.

The main conclusions:

1. Though some years ago the initial work has been established the development in the field of biotechnology just now is being organized in the Philippines.
2. The level of knowledge and training of experts to start with is satisfactory for the beginning but they are spread in many institutes.
3. The instrumentation in general is adequate for the moderate start, but coordination is necessary in its use.
4. The proposed projects for vaccines and diagnostic kits with biotechnology developments are carefully screened.
5. The Implementation Plan does not contain information regarding the production program of the expected results.
6. The Alabang BPS is not in the condition to be able to start production of modern vaccines.
7. There is no information in respect of production possibilities of diagnostic kits.
8. Penicillin production:
   - The present laboratory conditions do not support the wish to buy industrial strain. First proper microbiological laboratory is to be established.
   - The pilot plant size fermentation unit should be multipurpose.
Introduction

This report is written by Dr. J. Fari, expert in biotechnology based on discussions with experts and visiting laboratories, institutions and factories during his field mission in Manila in the Philippines between 18-31 January 1991.

Recently, the new results obtained worldwide in the different areas of biotechnology opened substantial interest in the Philippines too, in particular among the scientists. Lately even on government level this interest took shape in different programmes.

The objective of this mission specified in the job description emphasized two priority areas as vaccines and diagnostics for human and animal health-care in the National Action and Implementation Plans on Biotechnology of the Philippines. (Annex 1.) The receiving government agency, the PCASTRD wished to broaden the task to the whole range of their program. (Annex 2.) In the thick schedule visits were organized to different universities and research institutions in Manila and in Los Banos, to the National Kidney Institute and to the United Laboratories Inc. The programme included the NAST Mega Project Presentation and gave opportunity to inform experts in two lectures about the biotechnology in general and the production and use of Monoclonal Antibodies. The programme included also visit to Alabang BF3 unit and to the LSD of Bureau of Animal Industry. The visit to Los Banos comprised the University, the BIOTECH center and the Livestock Research Division of PCARRD. (Annex 3.)

The organized schedule gave quite an opportunity to meet scientists dealing with different programmes in the vaccines and diagnostics development areas, to visit their laboratories, to discuss problems. So it was opportunity also to study the places for actual vaccines production. Unfortunately production of diagnostics in commercial scale was nowhere to see. (Annex 4.)
I. BIOTECHNOLOGY

Biology → Molecular biology → Biotechnique → Biotechnology

A. Development of biotechnology in general

It is important that we understand the content of biotechnology according internationally accepted terms. There are processes and technologies in our everyday life with use of "Special ingredients" to transform certain "substrates" to "new products". It is enough to refer to the baking of bread, to process milk to different products, to beer fermentation, to vine production, etc. Some definition refer to these ancient processes as "old biotechnology" with different enzymes.

In the last thirty years there were amazing developments in different fields of science. With new instruments, with the electronics we could have deeper insight in the living cells and even further into molecular details of many functions of them. Watson-Crick established the DNA structure. This opened the new development with the genetic engineering toward the "new biotechnology". Parallel with it the cell fusion in the immunology led us to the hybridoma-cells and with this technique to the antibodies. Application of use of recombinant DNA and cell fusion techniques are the two basic pillars of the modern biotechnology.

In the industrial states in the last twenty years the development sped up. Hundreds and thousands of scientists are working on the most different projects. The main aim is to find proper application of the new knowledge in the practical field like health, industry, agriculture, etc.

The astonishing results supported a general enthusiasm: the biotechnology is omnipotent. It is fact that with the new knowledge and techniques offered by the biotechnology in the coming years great changes will come practically in all level of the life. At the same time we have also to accept the fact that the biotechnology has real limitations and its real potential will
develop only maybe in the coming decades. One important comment also is to be taken into consideration: the old and new biotechnology cannot be separated and the new techniques should be used -like feedback- to help the developments of the old ones.

We have to refer to another, today generally accepted fact, too: the development of biotechnology runs parallel and proportional with the development of other sciences. This complex process is very expensive. Results are not immediate and in many cases fail to come about. The support of biotechnology is to be planned with great care and caution, coordinating the progress, because in lack of these it will appear as unjustified expense. The supporting authorities usually expect quick, spectacular and even economically attractive return of investment. Failure of these could lead to disappointment and withdrawal of support. This is an important aspect in countries where the government directly takes up the interest in the biotechnology.

The last fact what we have to consider is that the results of biotechnology can improve processes already established and on long term basis. It is general opinion that substantial transformation of economy could be expected after 20-30 years of development, according Swedish estimation after a century.

This real short summary which refers only to very basic interconnections today is internationally accepted. From practical considerations -it seems- this assumption is to be used as assessing principle by the estimation of current status of the biotechnology in the Philippines.

B. Development of PCASTRD biotechnology program

This agency has rendered very competent preparation for the development of biotechnology and screening the program on different level of experts from 11th January 1990 till 7th December 1990 according the detailed minutes of 16 meetings.
After the Workshop Meeting on Biotechnology on 11 January 1990, and the two meetings on 9th March and 26th March dealing with possibilities of development of biotechnology on 8th May —meeting with participation of Sec. Ceferino Follisco—they have fixed the frames, some organizational structure, certain coordination and made decisions in respect of financing and defined the necessary further preparations.

In this four meetings PCASTRD made all the basic steps to establish the development of biotechnology in the Philippines. The involved experts, their professional respect, the support of institutes and universities made the necessary impact to receive the approval of DOST.

Following that the preparation continued in 12 STCC Technical Panel Meetings on Biotechnology. On 9th November the Implementation Plan and its mega-projects were discussed and on 15th November 1990 the final form of Implementation Plan has been approved.

The ST Post—the DOST official publication—already in its December 1990 issue announced the Implementation Plan and the Six Mega-Projects. The same issue gave details about the development possibilities of agriculture by biotechnology discussed in a Regional Seminar—Workshop on Biotechnology meeting. In his keynote address Sec. Ceferino Follisco gave special emphasis to the importance of biotechnology. (Annexes 5, 6)

Biotechnology Action Plan

In general it is moderate and good program to assess the available pool of scientists, the government institutions. The field of activity for the future impact of biotechnology is also reasonable. There should be no doubt about the vast potential of biotechnology sector in the Philippines. Regarding the constraints the BAP refers with special importance to the "lack of qualified R&D manpower". There are at the present time 58 PhD's and 151 MS distributed among 20 institutions. (Annex 7.)

It should have been given some reference to the fact that the biotechnology in the Philippines is just in the very initial phase
of development. Maybe the present pool of trained experts is really not a constraint at the moment. More serious hindering fact is that the level of sophistication of research techniques (in the sense of application methods and instrumentation) has not quite reached the level of sophistication associated with modern techniques of genetic manipulations. The use of cell fusion as a technique has been employed in only a number of projects." To distribute the available pool of experts into 20 institutions is also to be reconsidered.

Despite the referred constraints this action plan seemingly starts with the assumption that biotechnology is already established in the Philippines and the results will come automatically. If financial calculations according local practice are not integral part of such planning, still we feel that some time-schedule should have been given and the objectives in more concrete forms. Cost of instruments, chemicals, wages should have been calculated. As regarding the obtainable results and their proposed use also should have been specified.

There is a very important point also: in what form should the obtained results be available? In the form of a scientific paper? In the form of a detailed description or prototype? How should the transfer of results be organized? In most of the cases the transfer is more complicated than the development work. There is no reflection of the need of necessary infrastructure what is for application of the obtained results of biotechnology development.

There is mentioning that the scientific sector has maintained a rural and need-oriented R&D program. This is too general. Unless the biotechnology is coordinated to the demand and available industrial and agricultural infrastructure where the results automatically could be transferred to with financial conditions according market value and substantial financial feed-back, the further development will stop. Presently the government is cooperative with the assumption that the biotechnology is a very useful investment with quick return, but after a couple of years they would like to see the results of R&D efforts. In long term planning system it is evident.
Biotechnology Implementation Plan

This plan formulate the objectives and targets in the frame of overall strategy for harnessing biotechnology for national development and identified the emphasized projects with detailed specification. The implementation plan is a result of numerous consultations and shall be very useful in coordinating the most different, individual details of the program. (Annexes 8.9)

The implementation plan reflects in describing its objectives the simplified, optimistic spirit of Biotechnology Action Plan.

The selected and specified mega-projects are the focus points where the application of new processes and techniques of biotechnology can promote the development. It seems that all the six projects are well selected. In the specification of individual programmes there are details regarding objectives, timing and listing up the participant agencies, budget allocations.

We can find only very general references in the program goal descriptions. We miss the detailed data regarding the present infrastructure of different places involved: instruments, equipment, training of people, work previously accomplished, results achieved in the given projects, etc.

The individual projects proposed by different institutions are not referred at all. They are given well detailed in separate program, but seemingly the final screening has not yet been accomplished. There is not fixed the exact content of individual propositions in the sense that in what form the results should be available. The Implementation Plan should have a section in this respect to give the government proper advice what to expect and what results should be calculated for transfer towards actual use in industry or agriculture or elsewhere.

It would be very helpful to know which DOST Service Institutes will be responsible for the transfer. For training experts SEI, for application TAPI services could be used.
The total budget for the six mega-projects prescribes 131.6 m.P. Hopefully the budget list is not the priority list. Seemingly some projects are not supported properly i.e. coconut tissue culture with 3.6 m.P. only.

Biotechnology mega-projects

Pilot plant scale penicillin production

For proper evaluation of the project (Annex 10.) we have to consider the following facts:

1. The Government of the Philippines initiated the "Philippine Pharmaceutical Industry Development Study" with the development objective as "the establishment and development of a pharmaceutical industry in the Philippines to achieve self-reliance in selected strategic pharmaceutical items." In the government program with emphasized priority in the industrial section the fermentation in general, in the biotechnology section the genetic engineering and industrial biotechnology are in the focus.

2. Regarding this megaproject the UNIDO Technical report DP/PHI/87/19 contains detailed estimation for a fermentation pilot-plant for antibiotics. (p.654)


With reference to the above facts the mega-project is well justified. The formulation of the program goal is somewhat different from the spirit of objectives proposed by UNIDO experts. The objectives of the project are research oriented: cell growth condition, optimum product recovery, data for scaling up, toxicological evaluation should not be the aimed program at this stage. Such a pilot plant fermentation unit should not be used "for production and purification of penicillin". Only the last
point fits the demand: to develop manpower i.e. to train experts in different fields necessary for the complex task of industrial fermentation. The emphasis is on the industrial attribute.

There is one another aspect. The project is specified only for penicillin fermentation with the assumption that this unit will introduce the eventual industrial scale fermentation of penicillin. Three comments:

-The pilot plant fermentation unit should be multipurpose. It is evident that the fermenters and auxiliary equipments are apt for every type of sterile fermentation. The difference is in the broth processing technologies.

-The penicillin fermentation is the most sophisticated technology with the modern "multiple feed batch" pattern. Any sterile fermentation could be used as initial program for training people, to develop the complex knowledge, the team of experts, etc.

-Parallel with the establishing of pilot plant fermentation unit additional program is necessary to include other sections too: instrumentation control, engineering in general, maintenance, etc.

We can accept that the duration of the project is proposed for five (5) years. Some considerations indicate that the P 25 M financial requirement will not cover the expenses of such a complex program what is necessary. In the minutes of the 15th November 1990 of the Biotechnology Panel Meeting there is the information that the above budget has been fixed. It seems to be essential to review the cost calculations or the content of program. The minutes of the same panel (7th December 1990) gave the information that STCC already agreed to purchase the proposed industrial strain for Penicillin Production Megaproject by joining PanLab (Penicillin Club) whose membership fee is USD 500,000 and the annual fee is USD 70,000.

Regarding buying strain we have to share some information: PanLab Company is expert only in developing strains for high yield penicillin production, it is fact. But they develop the strains only in shakers scale. These strains are not proved in industrial level, even not in pilot plant size. The high yield strains are
extremely sensitive: the least change in the process conditions, feeding, etc. could destroy the expected high yield. PanLab strains are for the peak producers.

Regarding PanLab fees: to enter the club means USD 950,000 expense (you have to accept the five (5) years membership condition). This way of buying strain might be worth for consideration for the industrial production. Till then the pilot plant size fermentation unit should use in training operations a more simple and less expensive penicillin producing or other strain.

Now the question is: when and what type of penicillin producing strain will be necessary for the pilot plant fermentation unit and how much expense is justified for it?

We have to accept the fact that presently no strain is available for training in the Philippines. This fact is revealed at personal discussion and visit in UPLB Biotech. Presently small shaker-size experiments are conducted only. The level of their strain is "guessed" to be 1000 U/ml., but even this activity is not correct in lack of method, instruments and experience. The used strain is unidentified.

There are not available acceptable conditions to maintain a better strain. First step should be to establish the microbiological background for it and train people. We refer to the UNIDO technical report again. There are very good suggestions offered in this respect too.

The 30,000 U/ml activity penicillin strain suggestion was made in the Vienna Ad-Hoc panel meeting on 27th October 1988 with the condition that the pilot plant size fermentation unit will be installed according the proposed concept and some strain with such activity should be available for further study. But this suggestion does suppose that this is for a later period when the complex is developed and trained people with infrastructure, with practice could start working towards the final goal: industrial fermentation.
For initial training in the strain maintaining laboratory is less active, less sensitive strain could serve very well the need. 15-20,000 U/ml activity strain is substantially less expensive and available from other sources than PanLab, even with training conditions.

The work for installation a pilot plant size multipurpose fermentation unit could be organized parallel with it. What we miss very much that there is no detailed feasibility study available in regard the expenses of the establishing of the pilot plant fermentation unit but the UNIDO Technical report. It is to be emphasized that the relevant parts of the report are very good and the spirit and assumption of it is adaptable, but an actual and detailed study with present conditions is necessary for the final decision.

They are the considerations which suggest that this megaproject is to be rediscussed and rescheduled in terms of time, content and expenses.

Finally there is still one unclear point. We do not know about the present situation of the ITDI-proposal concerning a fermentation pilot plant for antibiotics submitted to UNIDO in 1987. Independent from our comments and suggestions UPLB-BIOTECH is the only acceptable place for setting a pilot plant scale multipurpose fermentation unit.

There is still something worth for consideration what refers for the UNIDO Technical report DP/PHI/87/19 in respect of economical calculations for penicillin fermentation (See p. 698-699). The study refers as import prices for Penicillin V 41 USD/kg and for Penicillin G 35 USD/kg. Today the world market prices are respectively 35 USD and 25 USD. As time goes on the feasibility is changing. It seems worth for PCASTRD and PCHRD to consider the continuous monitoring of the economic aspects in case the government of the Philippines is planning to start the penicillin industrial production project.
Diagnostics and vaccines

This is well composed program. The goals are defined and serve the actual need. The sub-programmes are cut to the real use and demand. There are proper institutes for the development.

At this point we can object the lack of assessment regarding the present use (types, systems, quantities, distribution among hospitals, instruments for application, etc.). According informations substantial import is there. Local foreign companies, like Abbot, Merck, etc. are marketing different vaccines and diagnostic kits. The United Laboratories Inc. proved to be an extremely well organized company with vast potential and plans in this field too. It is impressive the list of top hospitals. (Annex 11) In Metro Manila the health-care should use substantial quantity of vaccines and diagnostics presently. It seems to us that this actual use should be assessed and classified: what type of products are in use, what part of them are to be replaced, what is the proportion of the products locally made, what are imported. Pragmatically those products are to be produced first for what is demand, for what local conditions are available and what are easier to produce even if they are not high tech products with the help of biotechnology.

The same way we can ask the question: where plan the authorities the production of new vaccines and diagnostic kits? We have to see at the beginning of such substential development all the impacts and enduser aspects too.

In the budget section the allocation seems not to be proportional. The human sector is low, it is 40 % only of the amount of the animal section.

The project applications of this section are given in separate papers. (Annex 12) We feel that the projects are selected mainly according scientific interest of scientists. There is no question that these are justified, but we have to express the concern: who is going to promote the development and production of vaccines and diagnostic kits what are not interconnected with the advanced use of biotechnology?
Coconut Tissue Culture

This section is really no part of the Job Description which emphasizes the priority of health-care. But integral part of the field where biotechnology in the Philippines can exercise great help if properly introduced and coordinated. In the NAST meeting in this respect three conclusions were clear for an independent observer:

-the vast importance of coconut planting material
- export of coconut products is substantial part of the Philippine hard currency earning
- there are 300 million coconut trees on the islands. due to hurricanes great damages are continuous
  the age of coconut trees is about 60 years. they are in declining phase in nut production
- presently they calculate 90 million trees shortage
- price of one seedling is about 300 P.
- the research-work is not coordinated. results are not exchanged.
  only a couple of scientists work in this field
- the budget allocation with 3.5 mP is extremly unproportional

It is fact that the micropropagation of coconut is not yet solved. Presently this field is far away from the basic knowledge and techniques and production technology but the importance for Philippines should dictate special understanding and attention. (Annex 13) Palm Tissue Culture (US Development of Agriculture, Agric. Res. Service ARS-5 January 1988)

This is well defined field for biotechnology research and the results immediately could be transferred for the actual use. In some countries e.g. in Netherlands and Hungary automated systems are used for micropropagation for mass production of seedlings. Such complex project could be formulated for Philippines for coconut clonal propagation selecting the high yielding and elite cultivars and virus free hybrids.
Tailored fats from coconut oils

This program is quite reasonable both in content and its description. The auxiliary enzymes i.e lipases are available with microbes.

The program-goal is moderate accordingly. Regarding utilisation of coconut oil different ideas clash: to use it for diesel-engines or to convert as much coconut oil to synthetic products as possible. Both ideas are extreme: for diesel engines still the mineral oil would be cheaper on word market. As for total chemical conversion huge investment is necessary. For present need the aimed program is acceptable.

The projects are proportional and cover the whole area: lipase-production by microbial methods, controlling the processes, purification of raw-enzymes and ultimatly the use of lipase for synthesis of tailored fats from the coconut oil. In two smaller chapter they intend to study the nutritional aspects and actual use of the tailored fats in food.

Still we have to make a comment in respect of microbial lipase production. It is a token assumption that lipase will be available. According L. Hepnes this type of use of lipase is only in the experimental stage. The established consumption of lipase is for the cheese industry. (L.Hepner and Associates Ltd: Industrial enzimes by 1990 p.3:65)

In this program too one can ask feasibility questions: what is the proposed capacity, potential of similar products in the food market, what should be the economy of the project, price structure, expenses of establishing such production in industrial-scale, etc. How to commercialize the eventual new technique?

Application of biotechnology in urban wastes

It is just one well defined project and we can call it as a test program. Definition of goal is good and cut to the necessary
limit for the first year. The waste disposal for big cities is very serious problem. It is clever approach just to try one section i.e. the wet market. As the conversion of such wastes to biogas-methan is not questionable. For such projects the engineering part with suitable machines and mechanisms will be the essential part to face to and very expensive due to huge quantities. There is only one comment: during dry season the biodegradation is very fast compared to the rainy season.

Applications of biotechnology in reforestation

This program is very pragmatic: how to speed up germination with microorganisms and to produce seedlings by tissue-culture technique. One can discuss a bit the efforts for fertilizer substitution but it is definitely important to look for disease control either by the proposed approach i.e. using antagonistic microorganisms or maybe to develop disease-resistant or virus-free seedlings.

We can say that timewise the program is very short. The more correct time-frame should be 15-20 years. The tree type seedlings are to be seasoned for the field transfer. Greenhouses, nurseries shall be necessary. All this is long process, unless this program is limited only for an initial test period. Anyway there is no mentioning about it. For long term thinking and planning the reforestation program should be worked-up in details with need, with timing and financing. Such a program involves tens of millions of seedlings. It is an enormous project. But in spite of all these for Philippines this type of project should be very important. The analysis of international practice or development work is missing. How do they try to start reforestation in other countries in tropical areas, how do they do this type of development in the rainforest zones?

From environmental control aspects the project is an example-value. Much more cooperation is necessary to start at all. Maybe international cooperation could be involved.
The PCHRD program thrusts:

The present number of population of the Philippines is very near to 60 million people. The annual population growth is 2.7%. According to the Population Commission in 1987 there were 57 million people in the country. In 1992 this number will reach 62 million people. In 2000 it will reach 75 million.

The health-care for such a high population demands great attention and concentration of the sources available. Accordingly the National Health Research and Development Plan identified three major research and development thrusts, namely:

biotechnological R&D
pharmaceutical R&D
health services R&D

The present research and development activity includes mostly clinical studies. A total of 19 separate institutions are involved in biotechnology related programs. The general impression is that the level of accomplishment could be assessed as being in the initial phase. In the field of immunology the research is limited by the availability of facilities and reagents. Mostly that is the reason that the work on monoclonal antibodies has a good start but the application of this work is not yet worked out. Similar is the situation in the field of recombinant DNA techniques. The program in the field of animal cell culture is on very low level. The products are available by this technique could be very important soon. In the field of plant cell and tissue culture the UPLB BIOTECH made progress by producing shikonin.

Human Diagnostics and Vaccines (HD&V) program

For the Biotechnology Implementation Plan the PCASTRD prepared the network of coordination of health-care institutes
participating in the biotechnology R&D field. (Annex...) This was the very useful support to select the important priority projects of vaccines and diagnostics. Ultimately this program was incorporated to the Implementation Plan. (Annex 14.)

II. VISITS-DISCUSIONS

PCASTRD organized a two weeks program between 18th and 31st January 1991. During this period there were 22 opportunities to visit institutes, universities and meet scientists and experts. (Annex 3) It is not exaggerated to say that the pool of people involved in the development of biotechnology is full of interest and goodwill to help the programs.

Some of the places are simple with moderate instrumentation, but the majority is in the possession of the basic need to start working. Quite many places are very well furnished with instruments and necessary equipments. In a number of places we can just ask where are the results? It is an observation that neither personal nor institutional coordination is not yet established and the personal cooperation seems to be missing. This is very typical when instruments are available only after long skirmishing. The available instrumentation and infrastructure assets could be much better used with organized cooperation.

A. Research laboratories

Bureau of Research and Laboratories
BRL-DOH

This institute can be one of the centers where the biotechnological developments in the field of vaccines and diagnostic kits could be concentrated. They have different laboratories with acceptable instruments and well trained staff. For further training they organize special lectures in the field of biotechnology. (Annex 15) Some photos are available showing their activity-tables.
There is something to observe: they are keen to start to develop different clinical chemical kits of conventional type. They use presently imported kits from leading manufacturers, like Bio-Merieux, Merck, Sterling, Abbott. Such kits are e.g. triglycerides, transaminase OT-GT, albumin, cholesterol, etc. It is their decision to start developing and producing similar kits or simple other type of diagnostics. With this background BRL should be a new center for the production of diagnostics being developed in the frame of BIP. (Annex 16.)

Industrial Technology Development Institute
ITDI-DOST

This institute is a complex system of services. It includes laboratories for standards-testing, fuel-energy, electronics, etc. Two divisions are to be referred to in the line of biotechnology.

Food processing
Microbiology and Genetic Division

This two divisions are interconnected in the sense that the latter included in their development program projects like production of glucose isomerase, glucoamilase, α-amilase, etc. The MGD is very much determined to proceed also in the fermentation line: the production of antifungal antibiotics and antibiotics in general from agro-industrial wastes. This division forwarded in 1987 an application to UNIDO for a grant to set up a pilot plant fermentation unit for penicillin fermentation. This is parallel with UPLB and BIOTECH.

The visit in the premises of ITDI has shown that some divisions are very well even extremely well furnished with instruments in good buildings and laboratories. The MGD has been shifted recently to the central compound and accommodated in premises hardly adequate. The present conditions are not supporting the idea that the MGD will be able to make good program in lack of proper facilities.

In the vicinity of ITDI is the Coconut Processing Training Center what is very attractive. The building-system is ultramodern
and the machinery installed is superb. One can wonder seeing the phantastc collection of different instruments who and for what work will use them? This set of instruments seems to be quite enough for a big international research center with dozens of senior researchers. The actual performance seems to be very poor. The proposed scheme of activity refers the most sophisticated complex-use of coconut. If the aim is to train experts in advance for a national program in this field one can wonder what could the trained pool of experts do in the interim period till such an industrial complex established? It seems that this marvellous training center is too early and out of the real need.

In contrast to it the present MGD accomodation is absolutely improper.

BIOTECH
UPLB

Though this institute is strongly oriented towards agriculture in the well equipped laboratories we can find advanced work in molecular biology and genetic engineering. It has already a pilot plant fermentation facility modestly equipped with one each of 30, 100, 130, 200 and 1000 liter fermenters from grant-aid funds of Japan for producing Bacillus thuringiensis to control malaria by killing the larvae. This small unit is furnished also with different processing equipmements.

The building is specious enough to accomodate the proposed penicillin fermentation pilot plant too with some improvement of the infrastructure. Ample of place is available even for construction of a new adjoining building for the antibiotic fermentation pilot plant.

To promote the penicillin fermentation development one cannot resist to ask why do they not use the existing fermentation facilities which are quite proper for steril fermentation work with the present conditions? It was impossible to realise if they still use the existing pilot plant for B. thuringiensis fermentation. The general outlook indicated that no work was going on in this line. Something is sure the small unit is inadequate
for industrial scale B. thuringiensis production.

It could easily be installed a microbiological laboratory for strain development and use the existing pilot plant for its support. Later an independent antibiotic fermentation pilot plant in separate building could be the best support for an eventual penicillin industrial fermentation project.

Bureau of Animal Industry
BAI-DA

Animal Disease Diagnostic Laboratory
CVM UPLB

Their project proposal outlines are incorporated into the Biotechnology Implementation Plan. The concepts of those project proposals indicate that both institutes are very much aware of the importance and the need to develop and produce vaccines and diagnostic kits for the use of animal industry. In some respect the proposed projects are more pragmatic for the actual use and for the present need as we can feel in the field of human health-care. Both of the institutes are ready to receive and realise the new results of biotechnology developments in their respective fields.

B. Production facilities

Biologicals Production Service

The BPS is very important unit because it is the only institute to produce vaccines for human health-care. This is the place where the expected new vaccines resulted from biotechnological support would be produced. This report concentrates to exterior aspects only due to the very short time available for inspection.
Buildings-compound

The production of quality vaccines to support the EPI and other vaccines for prevention of dangerous diseases is accomplished in very old buildings using very inadequate facilities and equipments with processes practically outdated, controlled poorly within a 110 hectare lot in Alabang 25 kilometers from Manila. The general appearance is not attractive despite the great efforts of management to scope with the problems. The contrast is even bigger if we consider that the most modern facilities of Japanese supported RITM are on the same compound.

Production-activity

This performance is hardly could be compared with the recommendation values of UNIDO Model Programme UC/GLO/84/120 p.17. One fact is evident that the personnal of "BPS managed to go beyond what was clearly far from its human and material resource capacity" as undersecretary Mr. R.M. Gamboa commented. Their efforts deserve more than appretiation.

Infrastructure

The present conditions are not at all acceptable. Majority of the buildings are in very poor conditions. As appearance except the main office building and BCG Laboratory building it looks like very unproper for production of vaccines. The insulation of building against rain is not acceptable. Wall-plastering, painting are heavily demaged. The benches are not proper for the requirements of this type of work, so are the floors. Electric wiring is uncoverd with ducts. Ventillation is improper. Seemingly the drain system is not matching the sanitary requirements.

Equipments, instruments

Majority of installed such units are very old and used up. Autoclaves are not to acceptable standars. Some units are absolutely outdated. One can have a feeling that the available budget is not enough even to maintain the installed machinery and
Quality of products

In spite of the efforts of the Quality Control Division we have to accept that quality of BPS products presently could not be compared to international standards.

UNIDO visit

In 1989 a UNIDO panel of experts visited BPS. The objective of this visit was—according the BPS management—"to have a first hand information—and to give recommendations whether BPS should continue to exist or cease operations". This question is very well supported by the facts found in January 1991. (Annex 17/1-17/2)

"The chief of the UNIDO office in the Philippines pledged USD 300,000 as assistance to BPS. Other members of the panel also promised to link BPS with prestigious laboratories abroad, to promote technical cooperation".

The management of BPS is aware of the follow up reg. UNIDO/Vienna efforts to build up with Canadian Connaught Laboratories the promised technical assistance. As further informations say the process stopped because of the new discussions with Japanese government. DOH is keeping the very unfortunate situation still pending, hopefully not as long as the production conditions would be as bad that the operations in Alabang BPS should be stopped.

Proposition

UNIDO/Vienna maybe could review the situation with the Philippine government regarding the promised USD 300,000 support. BPS needs badly the improvement of infrastructure. This is with that special aspect that Alabang BPS will not be in the position to start producing new modern vaccines what are now under development according the Biotechnological Implementation Plan.
The Laboratory Services Division

According the direction of Bureau Animal Industry the LBS is responsible for the prevention and eradication of dangerous animal diseases in the Philippines. The LSD has very wide program of activity. Among others it is responsible for providing laboratory diagnosis of animal diseases and development and production of vaccines against them. (Annex 18.)

The priority diseases specified by BAI are presently:

1. Footh-and-Mouth Disease
2. Rabies
3. Hemorrhagic septicemia
4. Hog cholera
5. Newcastle Disease
6. Anthrax/Blackleg

The LBS with its Regional Laboratories is very well organized government agency for the animal industry. It is proper without doubt for producing the new vaccines and diagnostic kits specified in the Biotechnological Implementation Plan. They use already the modern bacterial vaccine production technology in B.Braun fermenters. They have the most modern fermenters with instrument-control in the Philippines.

C. National Kidney Institute

The main task of the institute is to provide dialysis for kidney patients, to function as an urological clinic. The institute is superbly built and and constructed. It is furnished with laboratories and instruments of high standars. The place is extremely well run with professional precision.

The reason we can include this institute as one of high interest for biotechnological development is that their
cooperation with other research institutes of different universities is already well established. One other aspect they are open for joint research programs offering their excellent facilities for use by other researchers.

D.United Laboratories Inc.

Basically this private company is for formulation of drugs and additional feed-products. It is so well managed that it was real pleasure to visit the premises, laboratories. The quality control is specially carefully planned and used. The management expressed their interest in the field of vaccines and diagnostic kits. It was given the information that e.g. the Hepatitis B vaccine is already available with them and they plan the marketing of it.

For the visiting experts it seems that some kind of cooperation in the field of marketing vaccines and diagnostics could be well justified with this very good company. Specially because they expressed their interest for the subject. They have all the facilities even for stability tests and formulation and packing design matters.
Recommendation

Biotechnology Implementation Plan

1./ In the course of preparatory work the numerous propositions already have been screened and grouped. The program included in the BIP is still spread into many institutes. For sake of coordination it seems advisable to select 2-3 institutes of excellence and support them with special attention. They should later be the leading centers in the biotechnology development work.

2./ In the present research and development work practically only scientists and research fellows of academic or clinical institutions are involved. Experts also working in the application field should be included. This arrangement could support the final phase of development, i.e. the implementation of research projects in the practice.

3./ The present budget allocated for supporting the biotechnology research and development is divided among participant institutes. The support is basically moderate. Some projects should be better supported, e.g. the coconut tissue culture specially, but also the vaccines and diagnostics for human health-care.

4./ In the present BIP only state institutes are involved. It could be useful to invite experts of private companies to exploit all the national resources and to avoid parallel work.

5./ It advisable to consider already in the present period of research and development how would it be the most realistic way of the practical application of eventual results, which institute will be responsible for the actual production of the new products. The expenses involved should be calculated.

6./ With special attention is to be reviewed the present
production facilities of vaccines in the Alabang BPS and decision is to be made for the reconstruction of this institute to make it acceptable at all for the production of vaccines.

Penicillin fermentation

1./ The first step should be towards the later industrial penicillin fermentation the establishment of proper microbiological laboratory for maintaining the strains.

2./ For training purposes relatively simple stable penicillin strain could be used. The proposed way to get strains through PanLab is very expensive. 15-20.000 U/ml strain is adequate for initial work in laboratory and pilot plant size fermentation operation. This type of strain is available from other sources and much cheaper.

3./ It is an unacceptable consideration that the pilot plant fermentation unit should be responsible to provide high yield industrial strain for the actual industrial penicillin production through PanLab. For the industrial production foreign technology will be necessary and that should provide the strain with maintenance instructions.

4./ The UPLB-BIOTECH facility is the best site to install the pilot plant fermentation unit. For final expense estimation detailed feasibility calculations are necessary with building construction, installation, piping, instrumentation, etc.

5./ As the preparation for the industrial fermentation production the auxiliary services are to be taken seriously. Accordingly training programs should be organized for maintenance, instrumentation and general engineering.
Annexes:

1. Job Description
2. PCASTRD’s letter to dr.J.Fari
3. Tentative schedule of expert
4. Senior counterpart staff - list of people met
7. Biotechnology Action Plan
8. Biotechnology Implementation Plan
9. STCC Technical Panel on Biotechnology
10. Pilot Plant Production of Penicillin
11. Top 30 hospitals in Metro Manila
12. HD&V Biotechnology Network PCASTRD
14. Biotechnology Megaprojects Human Vaccines and Diagnostics (For Final Approval)
15. Biotechnology Lectures
16. Medical Biotechnology Package
17. BPS general recommendations. specific recommendations
18. The Laboratory Services Division
JOB DESCRIPTION

Post title
Health/Veterinary Biotechnologist

Duration
2 weeks

Date required
October 1990

Duty station
Manila, Philippines

Purpose of project
To provide advice and assistance to the Philippine Council for Advanced Science and Technology Research and Development (PCASTRD) in formulating the national action and implementation plan on biotechnology to be presented to the Science and Technology Coordinating Council (STCC).

Duties

1. Preparation of an activity plan in consultation with PCASTRD and STCC

2. Assessment of prevailing conditions in the health/veterinary biotechnology sector covering:
   - enterprises in operation
   - approved/planned/under approval/under consideration projects
   - tariff structure pertaining to the product groups
   - incentives and regulatory policies
   - material flows by sources of supply
   - domestic and international market demand
   - local research and development capacity
   - linkages with other sectors

3. Recommendations on:
   - areas of concentration and related programmes projects
   - policy and promotion strategies
   - role of various Government agencies.
Qualifications: Biotechnologist/Microbiologist, medical doctor with extensive experience in the field of biotechnology

Language: English

Background information: PCASTRD is acting as secretariat to the three (3) leading edges mentioned above. Presently, the STCC Technical Panel on Biotechnology, is in the process of formulating a well-coordinated, integrated Action Plan (for presentation in November 1990), and Implementation Plan (for presentation in December 1990) on Biotechnology. Since this sector encompasses a broad area for research and development (i.e. agriculture, aquaculture, health, industrial and environmental), the panel has identified the need for two consultants (to cover agricultural biotechnology and health/veterinary aspects) with an external objective view and an understanding of the international situation when it comes to biotechnology. The consultants will, eventually, given the Philippine situation on biotechnology, be able to pinpoint the gaps in biotechnology areas that the Philippines can excel in based on the demands of the international market. It is the general consensus that, given the limited resources available (manpower, institutions and funding for projects), the Philippines may have to concentrate on a few selected high priority areas that the consultants will help identify.

The National Sectoral Plan will consist of (1) an Action Plan to be presented to the STCC in November 1990, and (2) an Implementation Plan to be presented in December 1990.

Upon approval of the STCC, these plans will be the basis for all the activities in the area of biotechnology in the country knowing the limitations posed by the present situation (limited manpower and financial resources), the plan will seek to maximize the country’s efforts in attaining the developmental goal of becoming an NIC by the year 2000.

The need for identifying the "niches" in biotechnology that the country can excel in, in terms of economic returns (export-oriented, import-savings) again surfaces. With the relatively short lead time available for the formulation, review and assessment of the plans, the sector is in urgent need of technical assistance from UNIDO which has a broad resource base of available international consultants in the area of S & T.

The beneficiaries of the project will include all the sectors with programs that are biotechnology-based. Initially, these are the government institutions, universities (state and private) and private industries engaged in activities related to biotechnology mentioned in the background of this proposal.

All these proposed activities are in line with the 1987-1992 Medium-term Philippine Development Plan which states that S & T resources shall be harnessed fully to help achieve the objectives of economic recovery and create conditions for sustained economic growth.
January 17, 1990

DR. JANUS FARl
UNIDO Consultant /
Director Biotecnnoiological Operations 
for Industry
Protein and Biotecnnoiological Division
National Committee for Technical Development
1056 Budapest
Vaci utca 81
Hungary

Dear Dr. Fari:

Greetings! We would like to take this opportunity to welcome you to the Philippines. We are glad that you can come to participate in the review and assessment of the National Action and implementation Plans on Biotecnnoology.

Enclosed are the past activities of the STCC Technical Panel on Biotecnnoology (minutes of their meetings) and the National Action and Implementation Plans on Biotecnnoology which were presented to the STCC last August 15, 1990 and November 21, 1990, respectively, for your perusal. Also included is a listing of STCC technical panel members.

Thank you.

very truly yours.

[Signature]

DR. SUSANA E. CHUA
Chief SRS. ATD
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*Note: Times and dates are placeholders for demonstration purposes.*
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Biotech for 6 mega projects

Plans are underway for the Department of Science and Technology (DOST) to implement the use of biotechnology on six mega projects by 1991-1995.

This was announced by Science Secretary Ceferino L. Follosco in a keynote address delivered before the participants to the regional Seminar-Workshop on Biotechnology held December 4-5 at the Philippine Village Hotel.

The six mega projects that would implement the use of biotechnology are penicillin production, diagnostics and vaccines, coconut tissue culture, coconut tailored fats, urban waste and reforestation.

The use of biotechnology on antibiotics especially penicillin, Follosco explained, would help us produce penicillin locally and hopefully initiate the development of local pharmaceutical industry.

He added that DOST shall explore the possibility of developing techniques which could produce human and animal vaccines as well as diagnostic methods for important human, animal and plant diseases. This would involve the development of monoclonal antibodies-based diagnostic kits.

Follosco cited that the biotech plan would help revitalize the local coconut industry which used to be one of the country's primary source of foreign exchange. This would be undertaken through diversification of products derived from coconut oil.

There are two on-going projects along this area, he said. These projects deal on the production of lipases and lipase-catalyzed
synthesis of tailored fats. Another program on coconut tissue culture also addresses the problem of lack of planting materials with high yielding properties, elite cultivars and hybrids.

Follosco also disclosed DOST plan to undertake a three-year project on waste management which would convert wet market waste to biogas and biofertilizer. This will be undertaken in collaboration with research institutions such as the Natural Science Research Institute and Biotech at the University of the Philippines, Los Banos, Laguna (UPLB) and other concerned government agencies.

Finally, he added, biotechnology will also be applied to help accelerate efforts on reforestation. Along this line, DOST will engage in projects on tissue culture and other micropropagation techniques for disterocaps and other forest tree species. (RSL)
The recently concluded Regional Seminar-Workshop on Biotechnology organized by DOST-NAST, FASAS, and UP left a minewealth of scientific papers that deal with biotech. We would like to highlight here a few of them.

"Industrialization of Agriculture" by Dr. Augustine SH Ong presented the most recent advances in plant and animal biotechnology and the possible environmental impacts. Issues related intellectual property rights were also raised specially in relation to affordability of patenting by small farmers.

Among the most interesting recent developments are as follow:

(1) Development of crop plants producing novel foods, naturally decaffeinated coffee, low cholesterol oats, etc.

(2) "Tailor-made" ornamental plants

(3) Transgenic plants capable of producing mammalian antibodies

(4) Improved wool production in sheep

(5) Cloned growth hormone for increased milk production

In connection with the environment, there are minuses and plusses. For example, one can think of producing more efficient microbes for waste treatment. On the other hand, concern has been expressed over the safety of plants where recombinant materials have been introduced for animal and human consumption.

Dr. Ernesto del Rosario's paper discussed several biotechnologies which can be used to increase production of food as basis for industrial processes using plant biomass - liqui-cellulose bioconversion, product of both chemicals (ethanol
and methane), enzymes for agricultural crop processing, bioinsecticides and microbial inoculant and protoplast fusion in recombinant DNA technologies.

We would like to quote here also the resolutions and recommendations made during Workshop 2 which were

(1) There is a need to prioritize efforts in biotechnology. Efforts should be directed towards answering industry and market needs.

(2) Stable, long-term policies are needed. Policies should not be fad-oriented. Efforts towards a particular goal should be sustained despite changes in situation and administration.

(3) Diversification is important. All possible products should be explored. For example, from the coconut can be obtained not only coconut oil but glycerin and methyl esters as well.

(4) Businesses and industries should be encouraged to develop and utilize biotechnology. This may be done by offering incentives for movement in this direction.

(5) Education and information drive are needed for technology transfer to occur and for farmers and communities to adapt the new techniques of biotechnology.

Other scientific papers presented during the seminarworkshop were:

(1) "Biotechnology for Agriculture: Food Production to Cash Crop Production" by Dr. Corazon T. Aragon

(2) "Biotechnology for Agriculture" by Dr. Augustine SH Ong

(3) "Biotechnology for Agriculture: Environmental Impact of Agriculture" by Dr. Percy E. Sajise

(4) "Biotechnology for Agriculture: Substitution Process" by Dr. Nagesh Kumar

(5) "Biotechnology for Agriculture: Reversal of Marginalization of
Farmers and Loss of their Influence" by Mr. Pat Roy Mooney

(6) "Access to Information. Materials and Patenting in Biotechnology" by Dr. Wilfredo Clemente
BIOTECHNOLOGY ACTION PLAN

Dr. William Padolina
Chairman, STCC Sectoral Technical Panel on Biotechnology
(As of 07 August 1990)

I. CURRENT SITUATION

Biotechnology is the application of engineering and scientific principles to the processing of materials by biological agents to provide goods and services. In the Philippines, the major commercial applications of biotechnology are in the production of beer, beverage ethanol, and monosodium glutamate (MSG). Other applications are in small enterprises which produce traditional fermented food products.

Several institutions are involved in R & D activities in this area but work is concentrated in government institutions. Currently engaged in such activities are the following:

A. Government research institutions

1. Industrial Technology Development Institute
2. Philippine Nuclear Research Institute
3. Department of Health
   a. National Kidney Institute
   b. Malaria Eradication Service
   c. Schistosomiasis-Control and Research Service
   d. Research Institute for Tropical Medicine
   e. Epidemiology Research and Training Service
4. SEAFDEC
5. PHILRICE
6. Philippine Coconut Authority (PCA)
7. Department of Agriculture - Bureau of Animal Industry
8. Department of Agriculture - Bureau of Plant Industry - Davao Experiment Station
9. Department of Environment and Natural Resources - Ecosystems Research and Development Bureau
10. Sugar Regulatory Administration - La Granja Experiment Station (SRA-LGES)
B. Universities

1. University of the Philippines System

   a. National Institutes of Biotechnology and Applied Microbiology, Los Banos (BITECH)
   b. Natural Science Research Institute (Diliman)
   c. College of Medicine, Manila
   d. Institute of Biological Sciences, Los Banos
   e. Institute of Chemistry, Los Banos
   f. College of Veterinary Medicine, Los Banos
   g. College of Pharmacy, Manila
   h. College of Public Health, Manila
   i. Marine Science Institute, Diliman
   j. College of Home Economics, Diliman
   k. Institute of Plant Breeding, Los Banos
   l. Molecular Biology and Biotechnology Program, College of Science, Diliman
   m. Institute of Food Science and Technology, Los Banos
   n. Department of Forest Biological Sciences, Los Banos
   o. National Crop Protection Center, Los Banos
   p. Department of Horticulture, Los Banos
   q. Department of Entomology, Los Banos
   r. Department of Plant Pathology, Los Banos
   s. Museum of Natural History, Los Banos
   t. College of Fisheries, UP Visayas

2. Central Luzon State University
3. University of Sto. Tomas
4. De La Salle University
5. Silliman University
6. Philippine Women's University
7. Ateneo de Manila University
8. Visayas State College of Agriculture (VISCA)

C. Industries

1. United Laboratories Incorporated
2. San Miguel Corporation
3. Zymtech Corporation
4. Pilipinas Kao

There is a general lack of commitment to research and consequently, the dependence of the research community on external grants.

Nevertheless, the scientific sector has maintained a rural-and need-oriented R & D Program. The broadening field of Biotechnology is being utilized to solve problems concerning
health and the environment and to supply the needs of agriculture
and industry.

In health, research is presently subdivided into Drugs, Vaccines and Diagnostics. Drug research is focused on the pro-
duction and utilization of plant materials that are indigenous
under the umbrella of the herbal medicine program. The program
has thus far accomplished the production of galenical preparation
in pilot plants. Simultaneously, research on antibiotics and
toxic plants are on-going.

In the areas of vaccines and diagnostics, researches include
studies on schistosomiasis and malaria; biochemical
characterization and disease pattern caused by microsporidia; and
development of diagnostics against infectious human and animal
diseases and parasitic diseases.

Applications in the fields of agriculture and industry
concern the production of biofuels, microbial enzymes such as
amylase, cellulase, protease and rennet-like enzymes and others;
organic acids, bioinsecticides, microbial-based fertilizers,
microbial polysaccharides, and plant tissue culture.

However the level of sophistication of research techniques
currently employed in the development of various biotechnologies
has not quite reached the level of sophistication associated with
modern techniques of genetic manipulations. The use of cell
fusion as a technique has been employed in only a number of
projects namely: improving cellulose degradation; increasing
alcohol yields; improving animal vaccine production; and for
producing monoclonal antibodies for plant viral diagnosis. This
reflects the limited number of personnel trained in new biology
techniques, and the lack of funds to finance new projects.

R & D efforts/activities in Biotechnology have been diffused and lacked focus. There has been no mechanism to coordinate the activities of the different institutions.

The following table lists the distribution among leading institutions of the existing manpower undertaking researches in the biotechnology areas mentioned.

<table>
<thead>
<tr>
<th>Table 1. EXISTING MANPOWER INVOLVED IN LEADING INSTITUTIONS UNDERTAKING BIOTECHNOLOGY R &amp; D</th>
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<tbody>
<tr>
<td>Institution</td>
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<tr>
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<tr>
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<tr>
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<td>---------------------------------</td>
</tr>
<tr>
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</tr>
<tr>
<td>United Laboratories</td>
</tr>
<tr>
<td>San Miguel Corp.</td>
</tr>
<tr>
<td>TOTAL</td>
</tr>
</tbody>
</table>

* Total number of MD and PhD holders
II. CONSTRAINTS AND POTENTIALS OF THE SECTOR

One of the major constraints being experienced by this sector is the lack of qualified R & D manpower. Inspite of its relatively larger high level manpower pool among the emerging technology sectors, there are at the present time only 58 PhD's and 151 MS distributed among 20 institutions undertaking R & D in the various Biotechnology areas (see Table 1). The problem of limited pool of qualified manpower undertaking R & D in biotechnology is compounded by inadequate laboratory facilities.

Despite its serious handicaps, the prospects for growth in this sector are numerous. Among the potentials worth mentioning are the following:

A. Applications of R & D in genetic engineering, tissue culture, biochemistry and physiology, enzymology (see Figure 1).

B. Biotechnology can be implemented at different levels of sophistication. The low level of sophistication includes biogas facilities in farms and homes while the high level includes fermentation plants for pharmaceuticals.

C. The Philippines has a vast array of raw materials such as agro-industrial byproducts, urban waste and mineral resources that can serve as substrates for biological transformations.

D. Biotechnology can offer alternative production routes that are environmentally sound. Some examples are biopesticides, biofertilizers, microbially mediated waste treatment processes, superior crop varieties and trees that can survive adverse conditions.
Figure 1. Applications of biotechnology R&D
(Laboratory of the Government Chemist, 1986)
III. OBJECTIVES AND TARGETS

The sector has agreed to set forth the following objectives and targets:

A. Provide R&D support towards the establishment of bioindustries. Included are pharmaceuticals, food, diagnostics and vaccines, new products from coconut and sugar.

B. Develop and/or adapt new techniques for self-sufficiency in food, especially in livestock and in the production of some antibiotics.

C. Augment and upgrade the existing pool of experts on biotechnology. This will include producing at least additional 30 PhD’s and 60 MS's in biotechnology.

D. Strengthen research institutions.

E. Adapt appropriate biotechnological methods to protect and maintain the integrity of the environment.

IV. RESEARCH PROGRAM THRUST:

The five priority areas in biotechnology that have been identified are: Agriculture, Aquaculture, Health, Industry, and Environment. For each of these areas, the following research thrusts have been recognized:

A. Agriculture

1. Fertilizer substitutes
2. Tissue culture for planting stock
3. Biological control agents
4. Animal production/improvement
5. Tissue culture for secondary metabolites

B. Aquaculture

1. Feeds
2. Diagnostic agents
C. Health

1. Vaccines
2. Drugs
3. Diagnostic agents

D. Industry

1. Enzymes
2. Organic acids
3. Industrial chemicals
4. Structured lipids or tailored fats
5. Coconut oil modification
6. Coconut husk bioconversion

E. Environment

1. Urban waste management
2. Industrial waste treatment
3. Biosafety

V. POLICY RECOMMENDATIONS

For the development of the sector, the following policies are recommended:

Science and Technology (S & T) Policies

A. In view of the availability of an initial manpower pool for R & D in biotechnology, which is probably the biggest pool among the emerging technologies and the presence of abundant raw materials or substrates and organisms for biological transformations, it is strongly suggested that BIOTECHNOLOGY BE MADE THE FLAGSHIP AMONG THE LEADING EDGE TECHNOLOGIES FOR THIS DECADE.

B. Establishment of monitoring mechanisms and biosafety guidelines especially for recombinant DNA work.

C. Address and resolve issues related to patenting and intellectual property rights.

D. Tax exemptions for scientific R & D equipment and materials.
BIOTECHNOLOGY IMPLEMENTATION PLAN

Dr. William Padolina
Chairman, STCC Sectoral Technical Panel on Biotechnology
(As of 15 November 1990)

The biotechnology sector's overall strategy for harnessing biotechnology for national development was presented to the Science and Technology Coordinating Council last August 15, 1990. The sector has agreed to set forth the following objectives and targets:

A. Provide R & D support towards the establishment of biindustries. Included are pharmaceuticals, food, diagnostics and vaccines, new products from coconut and sugar.

B. Develop and/or adapt new techniques for self-sufficiency in food specially in livestock and in the production of some antibiotics.

C. Augment and upgrade the existing pool of experts on biotechnology. This will include producing at least additional 30 PhD's and 60 MS's in biotechnology.

D. Strengthen research institutions.

E. Adapt appropriate biotechnological methods to protect and maintain the integrity of the environment.

In line with these objectives, the sector has identified key mega-projects for implementation starting 1991-1995. The mega-projects are on:

- Penicillin Production
- Diagnostics and Vaccines
  * Human Diagnostics and Vaccines
  * Plant Diagnostics
  * Animal Diagnostics and Vaccines
- Coconut Tissue Culture
- Coconut Tailored Fats
- Urban Wastes
- Reforestation
PROGRAM TITLE: PILOT PLANT PRODUCTION OF PENICILLIN USING LOCAL RAW MATERIALS

PROBLEM:
No local production of antibiotics, especially penicillin

PROGRAM GOAL:
To initiate the development of a local pharmaceutical industry by establishing a pilot plant for the production of penicillin and its derivatives.

PROJECT:
Pilot Plant Scale Penicillin Production

Objectives:
1. To determine the optimum fermentation conditions for cell growth and product(s) formation on the pilot-scale level.
2. To determine conditions for optimum product recovery on the pilot scale level
3. To gather data necessary in the further scaling-up to the industrial level of the developed production and purification process.
4. To conduct toxicological evaluation of the product.
5. To establish pilot plant facilities for the production and purification of penicillin.
6. To develop the manpower for local capability of penicillin production.

Duration of Project: Five (5) Years

Coordinating and Implementing Agencies:
Institute of Biological Sciences (IBS), UPLB
National Institutes of Biotechnology and Applied Microbiology (BIOTECH), UPLB
Institute of Chemistry (IC), UPLB
Industrial Technology Development Institute (ITDI), DOST
University of Sto. Tomas (UST)
DOST Sectoral Councils
Financial Requirements: P 25 M. (purchase of industrial strain not included)

Purchase of Strain: PANLABS
  Entrance Fee = US $500,000
  Annual Dues = US $ 70,000
  (minimum of five years)
PROGRAM TITLE: DIAGNOSTICS AND VACCINES

PROBLEM:

Need for control of human, animal and plant diseases

PROGRAM GOAL:

1. Using new biotechnological techniques, develop diagnostic methods for important human, animal and plant diseases.

2. Develop processes to produce human and animal vaccines under local conditions.

SUB-PROGRAMS (Subject to Restructuring):

A. Human Diagnostics

Duration of Projects: Five (5) years

Coordinating and Implementing Agencies:

College of Medicine (CM), UP

Philippine General Hospital (PGH), UP

National Kidney Institute (NKI), DOH

Advanced Medical Biotechnology Action Program (AMBAP), UP Diliman

Bureau of Research Laboratories (BRL), DOH

Research Institute for Tropical Medicine (RITM), DOH

National Science Research Institute (NSRI), UP Diliman

DOST Sectoral Councils

B. Human Vaccines

Duration of Projects: Five (5) years

Coordinating and Implementing Agencies:

Advanced Medical Biotechnology Action Program (AMBAP), UP Diliman

Bureau of Research Laboratories (BRL), DOH

Research Institute for Tropical Medicine (RITM), DOH
DOST Sectoral Councils

Financial Requirements: P 16.25 M (for sub-programs A & B)

C. Development of Diagnostic Techniques For Animal Disease Monitoring and Prevention

Duration of Projects: Five (5) years

Coordinating and Implementing Agencies:

Animal Disease Diagnostic Laboratory, College of Veterinary Medicine, UPLB

Bureau of Animal Industry (BAI), DA

Natural Science Research Institute (NSRI), UPD

DOST Sectoral Councils

Financial Requirements: P 16 M

D. Development of Bacterial and Viral Vaccines

Duration: Five (5) years

Coordinating and Implementing Agencies:

BAI, DA

BIOTECH, UPLB

College of Veterinary Medicine, UPLB

Regional Offices, DA

DOST Sectoral Councils

Financial Requirements: P 5.0 M

E. Development of Diagnostic Kits - Bacterial and Viral Antigens/Conjugates

Duration: Five (5) years

Coordinating and Implementing Agencies:

BAI, DA

BIOTECH, UPLB

College of Veterinary Medicine, UPLB

DOST Sectoral Councils
Financial Requirements: P 2.0 M

F. Serologically-Based Diagnostic Kits for Detection of Plant Diseases

Duration: Five (5) years

Coordinating and Implementing Agencies:

BIOTECH, UPLB
Dept. of Plant Pathology, CA, UPLB
Dept. of Entomology, CA, UPLB
National Crop Protection Center (NCPC), UPLB
DOST Sectoral Councils

Financial Requirements: P 11.3 M
PROGRAM TITLE: COCONUT TISSUE CULTURE

PROBLEM:

Lack of planting materials of high yielding and elite cultivars and hybrids

PROGRAM GOAL:

To undertake a program in research and development in tissue culture for the clonal propagation of coconut to provide planting materials for superior cultivars.

PROJECTS:

A. Coconut Tissue Culture at the UPLB Department of Horticulture

Objectives:

1. To establish and maintain nodular callus proliferations from inflorescence for use in regeneration experiments.
2. To determine the optimum culture media and environmental conditions for high frequency plantlet development.
3. To stimulate subsequent plantlet development.
4. To establish appropriate environmental conditions for hardening and greenhouse establishment.

Duration of Project: Three (3) years

Coordinating and Implementing Agencies:

Philippine Coconut Research and Development Foundation (PCRDF) - available support of P1.2 M for three years

DOST Sectoral Councils

Financial Requirements: P2.9 M

B. Coconut Tissue Culture at the UPLB National Institutes of Biotechnology and Applied Microbiology (BIOTECH)

Objectives:

1. To establish tissue culture techniques for cloning high yielding elite cultivars using young shell as explant.
2. To establish culture techniques for single cell
3. To establish cell lines of coconut for use in experiments like induction of resistance to pests and chemicals and possibly cell modification through genetic engineering.

Duration of Project: Five (5) years

Coordinating and Implementing Agencies:

BIOTECH, UPLB
DOST Sectoral Councils

Financial Requirements: P 610,000

C. Coconut Tissue Culture at the Philippine Coconut Authority (PCA) - Agricultural Research Center (Albay)

Objectives:

1. To establish a laboratory and greenhouse for tissue culture studies.

2. To train technical staff for the conduct of tissue culture research.

3. To establish the protocol for clonal propagation of coconut by tissue culture.

4. To establish satellite laboratories in various parts of the country for massive clonal propagation and distribution of elite coconut cultivars and hybrids.

Duration of Project: Twenty (20) years

Coordinating and Implementing Agencies:

PCA - Agricultural Research Center (Albay)

PCA - GTZ (funding from Germany)
PROGRAM TITLE: TAILORED FATS FROM COCONUT OIL

PROBLEM:

Need to diversify products from coconut oil to produce high valued fats for diet and therapeutic purposes

PROGRAM GOAL:

Determination of specific tailored fats

PROJECTS:

A. Selection and Genetic Improvement of Lipase Producing Microorganisms

Duration of Project: Four (4) Years

Coordinating and Implementing Agencies:

Natural Sciences Research Institute (NSRI), U.P. Diliman

Molecular and Biotechnology Program (MBB), CS, U.P. Diliman

DOST Sectoral Councils

Financial Requirements: P1.2 M

B. Microbial Production of Food Enzymes (LIPASES)*

Duration of Project: Two (2) Years

Coordinating and Implementing Agencies:

National Institutes of Biotechnology and Applied Microbiology (BIOTECH), UPLB

DOST Sectoral Councils

Financial Requirements: P280,000.00 (Second year funding)

C. Fermentation Engineering, Enzyme Reaction Engineering and Product Separation / Purification of Tailored Fats

Duration of Project: Four (4) Years

* On-Going PCASTRD Funded Project
Coordinating and Implementing Agency:
College of Engineering, U.P. Diliman
DOST Sectoral Councils

Financial Requirements: P1.65 M

D. Development of Lipase Purification System

Duration of Project: Four (4) Years

Coordinating and Implementing Agency:
College of Engineering, U.P. Diliman
DOST Sectoral Councils

Financial Requirements: P1,510,000.00

E. Lipase Catalyzed Synthesis of Tailored Fats from Coconut Oil*

Duration of Project: Four (4) Years

Coordinating and Implementing Agency:
Institute of Chemistry, U.P. Diliman
DOST Sectoral Councils

Financial Requirements: P2.0 M

F. Industrial Monitoring of Process, Products and Markets for Tailored Fats

Duration of Project: Two (2) Years

Coordinating and Implementing Agency:
Center for Research and Communication (CRC), Pasig
DOST Sectoral Councils

Financial Requirements: P712,000.00

* On-Going PCASTRD Funded Project
G. Acceptability and Nutritional Studies of Tailored Fats

Duration of Project: Two (2) Years
Coordinating and Implementing Agency:
   Food and Nutrition Research Institute (FNRI), DOST
   DOST Sectoral Councils
Financial Requirements: P800,000.00

H. Utilization of Tailored Fats in Food

Duration of Project: Two (2) Years
Coordinating and Implementing Agency:
   College of Home Economics, U.P. Diliman
   DOST Sectoral Councils
Financial Requirements: P744,000.00
PROGRAM TITLE: APPLICATION OF BIOTECHNOLOGY IN URBAN WASTES

PROBLEM:
Urban Waste Management in Metro Manila

PROGRAM GOAL:
To undertake biodegradation studies (particularly biomethanation) of common urban wastes initially from the wet market areas.

PROJECT:
Urban Waste Disposal and Management in a Wet Market

Objectives:
1. To design a process to convert wastes in a wet market to biogas and biofertilizer. This will include the use of the biogas to fuel a cold storage plant. The sludge of the biogas generator will be used as liquid biofertilizer.

Duration: Three (3) years but to start with detailed design activities for the first year

Coordinating and Implementing Agencies:
Natural Sciences Research Institute (NSRI), UPD
BIOTECH, UPLB
Metro Manila Authority (MMA)
Department of Environment and Natural Resources (DENR)
DOST Sectoral Councils

Financial Requirements: P 10 M (Year 1 - P500,000)
PROGRAM TITLE: APPLICATIONS OF BIOTECHNOLOGY IN REFORESTATION

PROBLEMS:

- Lack of information on species-site compatibility
- Availability of good quality seeds
- Marginal fertility of areas
- Pests and diseases

PROGRAM GOAL/IMPACT:

To use current breakthroughs in biotechnology to help speed up the reforestation efforts of both government and the private sector.

PROJECTS:

A. Seed Technology

Objectives:

To isolate, screen, identify and mass propagate microorganisms that can break dormancy and hasten seed germination.

Duration of Project: Five (5) years

Coordinating and Implementing Agencies:

- College of Forestry, UPLB
- Environmental Research and Development Bureau (ERDE), DENR
- Forest Management Bureau (FMB), DENR
- DOST Sectoral Councils

Financial Requirements: P 2.13 M

B. Seedling Technology

Objectives:

1. To develop tissue culture techniques for species of dipterocarps, bamboos, rattan, and other reforestation species.

2. To improve and utilize tissue culture techniques which has already been developed for rattans, A. falcatoria, Cratoxylon sumatranum in mass producing high quality seedlings of these species.

3. To develop other micropropagation techniques.
Duration of Project: Five (5) years

Coordinating and Implementing Agencies:

Dipterocarps - College of Forestry, UPLB

Bamboo - Environmental Research and Development Bureau (ERDB), DENR

Rattan - College of Forestry / Institute of Plant Breeding (IPB), UPLB

Other Species - College of Forestry, UPLB

DOST Sectoral Councils

Financial Requirements: P 8.03 M

C. Fertilizer Substitution

Objectives:

To test the efficacy of mycorrhiza, nitrogen-fixing organisms and organic fertilizers as substitute to chemical fertilizers in all the political regions of the country.

Duration of Project: Five (5) years

Coordinating and Implementing Agencies:

College of Forestry, UPLB

BIOTECH, UPLB

DENR

DOST Sectoral Councils

Financial Requirements: P 9.9 M

D. Bio-control

Objectives:

1. To collect, isolate, identify and mass produce microorganisms that are antagonistic to pests and disease-causing organisms of seeds, seedlings, and trees.

2. To test the effectiveness of the antagonistic microorganisms in the control of pests/diseases.

3. To field-test the biocon agents in various regions
of the country.

Duration of Project: Five (5) years

Coordinating and Implementing Agencies:

College of Forestry, UPLB

BIOTECH, UPLB

ERDB. DENR

DOST Sectoral Councils

Financial Requirements: P 11.55 M
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<th>PROGRAM/PROJECT TITLE</th>
<th>BUDGETARY REQUIREMENTS (P'000)</th>
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<td>2. Urban Waste Disposal and Management</td>
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<td>3. Coconut Tissue Culture</td>
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<td>6. Applications of Biotechnology in Reforestation</td>
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Total budget for five years. No budget breakdown per year given.

Total budget for three years only.

Budget of proposals from UPLB-Dept. of Horticulture and BIOETH only.

Total budget for five years.
PROPOSED MECHANISM FOR THE MANAGEMENT OF THE MEGA PROJECTS

SCIENCE AND TECHNOLOGY COORDINATING COUNCIL

MEGA PROJECT TECHNICAL PANEL

SECTORAL COUNCILS

- Mega Project Coordinating Comm.

- Mega Project Coordinating Comm.

- Mega Project Coordinating Comm.

- Mega Project Coordinating Comm.

- Mega Project Coordinating Comm.

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Technical Secretariat:

Dr. Susana Chua - Chief, Advanced Technology Division
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Department of Science and Technology
General Santos Avenue
Bicutan, Taguig, Metro Manila

Mr. Caesar Guevara - Science Research Specialist II
Philippine Council for Advanced Science and Technology
Research and Development
DOST Complex, Bicutan
Taguig, Metro Manila

Sectoral Panel Coordinator:

Fr. Bienvenido Nebres - President
Kavier University
Cagayan de Oro
Title of Program: **Pilot Plant Production of Penicillin**

Program Goal: To initiate the development of a local pharmaceutical industry by establishing a pilot plant for the production of penicillin and its derivatives.

Project Objectives:

1. to determine the optimum fermentation conditions for cell growth and product(s) formation on the pilot-scale level.
2. to determine conditions for optimum product recovery on the pilot scale level.
3. to gather data necessary in the further scaling-up to the industrial level of the developed production and purification process.
4. to conduct toxicological evaluation of the product.
5. to establish pilot plant facilities for the production and purification of penicillin.
6. to develop the manpower for local capability of penicillin production.
Projects and Their Duration

I. Optimization of a pilot plant scale penicillin fermentation and its derivatives
   2nd - 5th year

II. Optimization of pilot plant scale penicillin recovery and purification process
    2nd - 5th year

III. Production of pen-acylase
     3rd - 5th year
     First year
     Ordering, delivery and installation of equipment
     construction of infrastructure

Financial requirement - P25M

Purchase of strain - not included
Constraints/Issues:

1. Local penicillin production might be viable only if volume of production is high enough to allow export. If we export, can we compete with multinationals?

2. If the Philippine government finances pilot plant production, will there be private investors interested in financing commercial production?

3. Chemfilcos is a company that can possibly go into penicillin production. Since it is partly government owned, will the government be able to put up the required financing?

4. Can an international company be tapped who will provide the strain, help develop the technology using local materials and be given the incentive of being a partner in the industrial scale production?
Coordinating and Implementing Agencies - BIOtech

Members of the group

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<tr>
<th>Name</th>
<th>Expertise Needed</th>
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<tbody>
<tr>
<td>Dr. A.R. Raymundo</td>
<td>Microbiology</td>
<td>ULS, UPLB</td>
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<td>(Convener)</td>
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<tr>
<td>Dr. Romulo Calilo</td>
<td>Fermentation Engineering</td>
<td>BIOtech, UPLB</td>
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<tr>
<td>Dr. Evar Portostino</td>
<td>Isol. of Natural Products</td>
<td>IC, UPLB</td>
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<tr>
<td>Mr. Sefarhin Cons</td>
<td>Antibiotic Processing</td>
<td>Chemfields, Sta Rosa</td>
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<tr>
<td>Dr. Lydia Jocson</td>
<td>Antibiotic Production</td>
<td>ITDI</td>
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<tr>
<td>Dr. Marile E. Santos</td>
<td>Mycology, Genetics</td>
<td>ULS, UPLB</td>
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<tr>
<td>Dr. Patrocinto Santos</td>
<td>Antibiotic Production</td>
<td>UST</td>
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<tr>
<td>Dr. Agnes F. Zamora</td>
<td>Pen-acylase Production</td>
<td>ULS, UPLB</td>
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(will join on the 3rd year)

Reps. from diff. councils

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<tr>
<td>Caesar Guevara</td>
<td>PCASTRD</td>
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<tr>
<td>Ronnie Trias</td>
<td>PCHRD</td>
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<tr>
<td>Eva Baldeceta</td>
<td>PCHRD</td>
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<tr>
<td>Glenn Mirandilla</td>
<td>PCI ERD</td>
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*Permission needed from Chemfields Mgt.
TOP 30 HOSPITALS IN METRO MANILA

PRIVATE:

1. Capitol Medical Centre
2. Cardinal Santos Hospital
3. Children's Medical Centre
4. Chinese General Hospital
5. Delgado Clinic
6. FEU Hospital
7. Hospital of the Infant Jesus
8. Our Lady of Lourdes Hospital
9. Makati Medical Centre
10. Manila Doctors Hospital
11. Manila Sanitarium
12. Mary Chiles Hospital
13. MCU Hospital
14. Medical Centre Manila
15. The Medical City
16. Metropolitan Hospital
17. Perpetual Help Hospital (Manila, Las Piñas, Biñan)
18. Delos Santos Medical Centre
19. St. Lukes Medical Centre
20. United Doctors Medical Centre (UDMC)
21. UERRM Hospital
22. U.S.T. Hospital

GOVERNMENT:

1. Army General Hospital
2. Kidney Centre
3. Fabella Hospital
4. Jose Reyes Memorial Medical Centre (JRMMC)
5. Lung Centre of the Philippines
6. Philippine General Hospital
7. Philippine Heart Centre
8. Veterans Memorial Hospital
9. V. Luna Medical Centre
10. Bāông Lipunan Medical Centre
HD&V Biotechnology Network  PCASTRD

1990

Advanced Medical Biotechnology Action Program (AMBAP) and the Bureau of Research Laboratories of the Dept. of Health

National Kidney Institute (NKI)

Research Institute for Tropical Medicine (RITM)

UP College of Medicine

UP Diliman

University of Santo Tomas, College of Medicine

FEU College of Medicine
1. UP COLLEGE OF MEDICINE & UP-PGH

1.1 DEVELOPMENT OF A SIMPLE IMMUNOASSAY FOR THE CLINICAL DETECTION OF SERUM TRANSFERRIN AND PREALBUMIN

1.2 DEVELOPMENT OF A PREGNANCY TEST KIT: SOURCE PURIFICATION AND PACKAGING OF KITS (NETWORKS WITH 13.1)

1.3 DEVELOPMENT OF BIOCHEMICAL AND MOLECULAR GENETICS PROCEDURES FOR THE STUDY OF GENETIC DISORDERS

1.4 DEVELOPMENT OF A RAPID DIAGNOSTIC KIT FOR SALMONELLOSIS INVOLVING AN AGGLUTINATION TEST

1.5 DEVELOPMENT OF PROTOCOLS FOR THE ISOLATION AND PURIFICATION OF IMPORTANT ENZYMES (ALKALINE PHOSPHATASE, UREASE & URICASE) FROM INDIGENOUS SOURCES AND THEIR USE IN THE PRODUCTION OF TEST KITS

1.6 DEVELOPMENT OF A MAMMALIAN TISSUE, CELL CULTURE AND HYBRIDOMA BANK

1.7 DEVELOPMENT OF A TOXICOLOGY LABORATORY IN SUPPORT OF THE PCIC (POISON CONTROL AND INFORMATION CENTER)

12 ADVANCED MEDICAL BIOTECHNOLOGY ACTION PROGRAM (AMBiP) AND THE BUREAU OF RESEARCH LABORATORIES OF THE DEPARTMENT OF HEALTH: UP DILIMAN

12.1 DESIGN & DEVELOPMENT OF THE DNA PROBES FOR THE DETECTION OF THE EPSTEIN-BARR VIRUS SPECIFICALLY TARGETED AGAINST THE VIRAL DIRECT REPEATS

12.2 DESIGN & DEVELOPMENT OF A HEPATITIS B SYNTHETIC PEPTIDE VACCINE CARRYING BOTH B-CELL AND T-CELL EPITOPES (NETWORKS WITH 14.2)
12.3 Design & Development of DNA Probes for the Detection of the Toxigenic (Exotoxin A-producing) Strain of Pseudomonas aurigenosa.

13 National Kidney Institute (NKI)

13.1 Development of a Monoclonal Test Kit against Beta-Human Chorionic Gonadatropin for the Diagnosis of Pregnancy and Trophoblastic Tumors: Antibody Component Production (Networks with 11.2)

13.2 Development of a Test Kit for the Detection of Human Cytomegalovirus

13.3 Development of a Reliable Test Protocol for the Detection of Cytogenetic Toxicity of Drugs Using Human Lymphocyte Cultures

13.4 Development of an In situ Hybridization Kit for the Detection of Markers for Lung Cancer in Tissue Sections (Frozen & Paraffinized)

14 University of Santo Tomas College of Medicine, FEU College of Medicine

14.1 (FEU) Comparative Testing of the Immunogenicities of Commercially Available Plasma-Derived and Imported Synthetic (Recombinant) Hepatitis B Vaccines in Comparison with Locally Developed Synthetic Vaccines (Networks with 12.2)
GOALS OF PROGRAMS (2.1 - 2.4)

2.1 UP COLLEGE OF MEDICINE & UP-PGH

2.1.1 The objective of this project is to develop simple, sensitive and inexpensive immunoassay kits for the clinical diagnosis of serum transferrin and prealbumin.

Specifically, the project aims to: a) isolate and purify human transferrin and prealbumin; b) prepare monoclonal antibodies against these proteins; and c) develop and standardize simple immunoassay procedures for the preparation of the immunoassay kits.

2.1.2 This initial endeavor aims to develop a fast, simple, and sensitive pregnancy test utilizing a sandwich method of enzyme-linked monoclonal antibody for a qualitative determination of beta-HCG in urine samples. This would entail local development, and production of the different components/reagents i.e., polyclonal and monoclonal antibodies for the pregnancy test; and assembly and packaging of the test kit.

2.1.3 The project aims to develop the following biochemical and genetic procedures: a) chemical or chromatographic assay of accumulated serum and urine metabolites b) quantitative determination of serum amino acid profiles c) protein electrophoretic patterns to identify variants d) direct enzyme assays e) DNA restriction endonuclease analysis to establish linked restriction fragment length polymorphisms.

2.1.4 To evolve a standardized agglutination test procedure that is specific, precise and which makes use of simple equipment based on commonly used and proven test procedure currently in the market.

2.1.5 The main objectives of this project are:

1. To isolate, purify and characterize the following enzymes (from indigenous sources) for use as standards in clinical diagnosis and in research (particularly as an immunochemical).
A) Alkaline phosphatase (from bovine intestinal mucosa, calf liver, chicken intestine and Escherichia coli)
B) Urease (from soybean and watermelon seed)
C) Uricase (from porcine liver, Aspergillus flavus and Candida utilis)

2. To develop clinical diagnostic kits using these enzymes.

2.1.6 The main goals of this project are to A) develop a mammalian tissue culture bank that can supply tissue cultures cell samples and cell lines which have wide applications in biomedical/clinical diagnosis, in pharmaceutical production and agricultural researches; and B) establish a mammalian tissue culture service laboratory that can perform various assays/tests researchers or institutions that may not have the facilities for cell cultured-related assays. Specifically, this project, firstly, aims to gather and culture established cell lines, and other tissues cells (i.e., tumor cells), prepare hybridomas (if needed) and to determine the optimum conditions for their expansion, maintenance, cryogenic preservation, and quality testing. These cultured cell samples and cell lines will be maintained and preserved and will be made available for other researchers. The second aim is to standardize some assay procedures which require cell culture such as cytotoxicity testing, anti-inflammatory testing, mutagenicity and carcinogenicity testing, toxicity testing, etc. for use in the service laboratory. The third aim is to train personnel and set up the mammalian tissue culture service laboratory in the department.

2.1.7 The Poison Control Committee of UP-PGH has drafted a project proposal with regards to pilot testing a Poison Control and Information Service Network (PCISN) a system that will be involved with data collection, monitoring, evaluation, prevention and control of acute poisoning cases in two high risk regions of the country. The PGH will serve as the central monitoring body with two selected regions functioning as satellites.

The setting up of a toxicology laboratory will be in line with the objectives of the PCISN project since establishment of the network would entail strengthening of the Poison Control and Information Center. This will include training of health
PERSONNEL IN THE EARLY RECOGNITION AND MANAGEMENT OF
ACUTE POISONING CASES: TRAINING IN POISON INFORMATION
AND TOXICOLOGY LABORATORY TECHNIQUES.

2.2 ADVANCED MEDICAL BIOTECHNOLOGY ACTION PROGRAM (AMBAP) AND THE
BUREAU OF RESEARCH LABORATORIES OF THE DEPARTMENT OF HEALTH;
UP DILIMAN

2.2.1 THE EPSTEIN-BARR (EB) VIRUS HAS RECENTLY BECOME A
FOCUS OF MEDICAL ATTENTION DUE TO ITS INCREASINGLY
APPRECIATED ROLE AS CAUSATIVE AGENT OF
NASO-PHARYNGEAL CANCER IN THE COUNTRY. WE PROPOSE TO
DEVELOP Oligonucleotides (DNA) probes targeted
SPECIFICALLY AGAINST SOME HIGHLY REPEATED, OR
REPEATED, PARTS (LOCI) OF THE EB VIRUS GENOME FOR
WHICH THE PRIMARY SEQUENCE DATA ARE NOW AVAILABLE TO
US.

RAPID DETECTION OF THE EPSTEIN-BARR VIRUS IS OF SOME
CONCERN. ON THE ONE HAND, DETECTION OF THE VIRUS CAN
BE ACCOMPLISHED USING MONOCLONAL ANTIBODIES, AS FOR
INSTANCE, USING ANTIBODIES AGAINST THE D- AND
R-COMPONENTS OF THE EB VIRUS EARLY ANTIGEN AND THE
125 KD AND 160 KD COMPONENTS OF THE VIRAL CAPSID
ANTIGEN, FOR WHICH KITS ARE ALL AVAILABLE
COMMERCIALY. IN THE PRESENT PROJECT, HOWEVER, WE
PROPOSE TO DESIGN AND DEVELOP PANELS OF DNA PROBES
TARGETED SPECIFICALLY AGAINST THE WELL CHARACTERIZED
ITERATED LOCI IN THE EB VIRUS GENOME.

2.2.2 USING THE SEQUENCE DATA ON THE SURFACE AND CORE
ANTIGENS OF HEPATITIS B VIRUS, AND USING VERY RECENT
RESEARCH DATA ON ITS T-CELL DETERMINANTS, A NEW
SYNTHETIC PANEL OF VACCINE DIFFERENT FROM THE ONE
MARKETED BY SMITH, KLINE & FRENCH WILL BE DESIGNED
AND DEVELOPED FOR TESTING. THIS ENVISIONED NEW
SYNTHETIC POLYVALENT VACCINE WILL BE SUCH AS TO
STIMULATE BOTH HUMORAL (B-CELL) AND CELL-MEDIATED
(T-CELL) IMMUNE RESPONSES -- DESIGNED TO BE OPTIMAL.

2.2.3 PSEUDOMONAS AERUGINOSA INFECTION IS A COMMON
NOSOCOMIAL INFECTION IN THE PHILIPPINES. PATIENTS
INFECTED WITH THE TOXIGENIC (OR EXOTOXIN A-PRODUCING)
STRAIN OF P. AERUGINOSA FACE THE PROSPECT OF HIGHER
MORBIDITY AND MORTALITY THAN PATIENTS INFECTED WITH
THE NON-TOXIGENIC STRAIN. THEREFORE, THE EARLY
DETECTION OF INFECTION CAUSED BY THE TOXIGENIC STRAIN
WOULD BE OF GREAT VALUE IN PREVENTING FATALITIES FROM
SUCH INFECTIONS IN PATIENTS WITH CYSTIC FIBROSIS.
P. aeruginosa, once established in the patient, produces a number of toxins that are of etiologic importance. One of these toxins is exotoxin A, which has adenosine diphosphate (ADP)-ribosyl transferase activity that inactivates EF-2 (the elongation factor 2) of eukaryotic cells -- resulting in total cessation of cellular protein synthesis (notably in the liver).

Since the complete nucleotide sequence of the structural gene coding for the exotoxin A is already known (Proceedings Nat'l. Acad. Sci(USA), 81(1984),2645), the project will make use of this information in the design of an appropriate panel of oligonucleotide detection probes.

2.3 NATIONAL KIDNEY INSTITUTE (NKI)

2.3.1 General Goals (same as 2.1.2)

2.3.2 To develop an immunofluorescence assay kit for human cytomegalovirus using a synthetic peptide (from a known surface protein sequence of the virus that is predicted to be immunodominant.

Initially, polyclonal antibodies will be developed so that the kit design can be tested early on. Eventually, monoclonal antibodies will be developed so that a continuous supply of well-characterized antibodies can be developed, available for use in the test kits.

2.3.3 Human lymphocyte cultures are always available at the NKI because transplant patients have blood extracted prior to transplant operation, for various immune function tests. It is therefore proposed to develop a reliable test protocol for the detection of cytogenetic toxicity of drugs using human lymphocyte cultures. The protocol can be transferred and used by the Bureau of Food and Drugs (BFAD) for testing the safety of new drugs submitted to BFAD.

2.3.4 It is proposed to develop locally a specific and sensitive assay for identifying tumor markers will allow the classification of the following specific subtypes of lung cancer. Recent recombinant DNA
TECHNIQUES HAVE MADE POSSIBLE THE PRODUCTION CUSToM-TAILORED -DNA PROBES. THE USE OF DNA PROBES IN IN SITU HYBRIDIZATION REPRESENTS A NEW DIAGNOSTIC TECHNOLOGY WITH MANY POTENTIAL APPLICATIONS THAT HERETOFORE HAVE REMAINED UNTAPPED IN THE PHILIPPINES.
# BUDGET FOR THE PROGRAMS (3.1 - 3.3)

(All figures are in pesos)

## 3.1 UP COLLEGE OF MEDICINE & UP-PGH PROGRAM

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## 3.2 ADVANCED MEDICAL BIOTECHNOLOGY ACTION PROGRAM (AMBAP) AND THE BUREAU OF RESEARCH LABORATORIES OF THE DEPARTMENT OF HEALTH; UP DILIMAN PROGRAM [Includes FEU-NRMF Coll. of Med. Project]

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## 3.3 NATIONAL KIDNEY INSTITUTE (NKI) PROGRAM

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ROCK BOTTOM BUDGET REQUIREMENTS WITH MINIMAL EQUIPMENT

4.1 UP COLLEGE OF MEDICINE & UP-FGH PROGRAM

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4.3 NATIONAL KIDNEY INSTITUTE (NKI) PROGRAM

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IMPLEMENTING AGENCIES OF PROGRAMS
(11 - 14)

5.1 FOR PROGRAM 11

5.1.1 FOR PROJECT 1.1.1

PROPOSENT UNIT: Department of Biochemistry & Molecular Biology, U.P. College of Medicine, Manila.

RESEARCH GROUP: Milagros B. Leano, Asst. Prof.
Angelita G. Reyes, Assoc. Prof.

5.1.2 FOR PROJECT 1.1.2

PROPOSENT UNIT: Department of Biochemistry & Molecular Biology, U.P. College of Medicine, Manila.

RESEARCH GROUP: Felicitas L. Lacbawan, MD.
Richard Chu, Ph.D.
Joven O. Tanchuco, M.D.

5.1.3 FOR PROJECT 1.1.3

PROPOSENT UNIT: Department of Biochemistry & Molecular Biology, University of the Philippines College of Medicine.

RESEARCH GROUP: Marita V.T. Reyes,
Rhodora C. Estaci,
Racquel G. Zafra

5.1.4 FOR PROJECT 1.1.4

PROPOSENT UNIT: Department of Biochemistry & Molecular Biology, U.P. College of Medicine.

RESEARCH GROUP: Teresita de Guzman, M.S.
5.1.5 FOR PROJECT 1.1.5

PROPOSENT UNIT: Department of Biochemistry & Molecular Biology, UP College of Medicine, Manila.

RESEARCH GROUP: Angelita G. Reyes, Assoc. Prof. Milagros Bautista-Leano, Asst. Prof.

5.1.6 FOR PROJECT 1.1.6

PROPOSENT UNIT: Department of Biochemistry & Molecular Biology, UP College of Medicine, Manila.

RESEARCH GROUP: Angelita G. Reyes, Assoc. Prof. Milagros Bautista-Leano, Asst. Prof.

5.1.7 FOR PROJECT 1.1.7

PROPOSENT UNIT: UP-PGH Poison Control Committee (PCC).

RESEARCH GROUP: Dr. Nelia P. Cortes-Maramba
Dr. Kenneth Y. Hartigan-Go
Dr. Lynn Crisanta R. Pangniban

5.2 FOR PROGRAM 1.2

5.2.1 FOR PROJECTS 1.2.1 - 1.2.3

PROPOSENT UNIT: Advanced Medical Biotechnology Action Program (AMBAP) jointly with the Bureau of Research and Laboratories (BRL), Department of Health.

RESEARCH GROUP: Dr. Apolinario Nazarea (AMBAP)/BRL
Dr. Marietta Carpio-Bacay (BRL)
Dr. Criselda Abesamis (BRL)

5.3 FOR PROGRAM 1.3

5.3.1 FOR PROJECT 1.3.1

PROPOSENT UNIT: Tissue Culture Section, Immunology Laboratory of the National Kidney Institute.
5.3.2 FOR PROJECT 1.3.2

PROPOSER UNIT: Tissue Culture Section, Immunology Laboratory of the National Kidney Institute and the Advanced Medical Biotechnology Action Program (AMBAP) of the Department of Health.

RESEARCH GROUP: Dr. Romulo J.S. de Villa

5.3.3 FOR PROJECT 1.3.3

PROPOSER UNIT: Tissue Culture Section, Immunology Laboratory of the National Kidney Institute.

RESEARCH GROUP: Dr. Romulo J.S. de Villa

5.3.4 FOR PROJECT 1.3.4

PROPOSER UNIT: Tissue Culture Section, Immunology Laboratory of the National Kidney Institute.

RESEARCH GROUP: Gloria Bernas, Asst. Prof. (UST)

5.4 FOR PROGRAM 1.4

5.4.1 FOR PROJECT 1.4.1

PROPOSER UNIT: Department of Biochemistry, RRMF College of Medicine, Far Eastern University, Manila

RESEARCH GROUP: Dr. Rebecca M. Monte
Advanced Medical Biotechnology Action Program (AMBiP) and the Bureau of Research & Laboratories of the Department of Health

University of the Philippines, Manila
College of Medicine and
Philippine General Hospital

National Kidney Institute (NKI)

University of the Philippines, Diliman
College of Science

Research Institute for Tropical Medicine (RITM)

University of Santo Tomas
College of Medicine
and
Far Eastern University
NEUF College of Medicine
Problems that hinder the study of palms are their long-lived nature, growth habit, and peculiar growth habitats. Suckering and flowering phenomena frequently do not occur until the third through seventh year of development. Most palms have tropical or semitropical habitats that often prevent their critical study in temperate climates. Size of adult palms in itself, presents a problem in experimental work. There is no known procedure to control lateral bud initiation thus far (28). Nor are methods available that can accelerate vegetative lateral bud outgrowths or reverse the adult to the juvenile life cycle. Outgrowth of flower and vegetative buds were obtained from cultured embryos, shoots, and asexual plantlets. Only three species—Cocos nucifera, Metroxylon sp., and Phoenix dactylifera (34)—produced lateral bud outgrowths in vitro.

The mechanism for their production was only preliminarily explored. Probably, the major point concerning their occurrence is that they are produced at all. Several major life cycle events of some palms can now be performed through tissue-culture techniques. This technique, however, needs to be studied for use on other species.

Plant tissue culture was studied as a technique that could be used to potentially mass produce desirable palms. Studies on date and oil palm tissue culture are more developed than for other palms because (1) they have been the focus plant in several intense research programs (for example, date (2, 5, 66, 68) and oil palm (16, 17, 18, 42, 54) and (2) both date and oil palm meristematic tissues appear to be highly totipotent. Coconut palm although continually studied over the last few decades still has yet to yield easily produced embryogenic callus (7, 9, 33, 41). Several palm species were cultured in this publication using either zygotic or somatic explant source material with the in vitro techniques developed for date palm.

Generally, direct transfer of date palm techniques to other palms can be performed to obtain plantlets from germinated excised embryos, tips, or callus. Those palms that grew poorly using the described techniques are candidates for more intensive study. Extremely small explant populations were used in this study; however, the poor results could reflect artifactual effects.

Tissue culture techniques were applied to 62 species representing 36 genera in the Arecaceae with varying degrees of success. Initiation of callus from embryo and shoot-tip explants should be considered only preliminarily helpful in obtaining plantlets via callus.

As restated in a previous review (81), meaningful research directions in this field should be directed at (1) determining the genetic stability of plantlets produced from tissue culture, (2) elucidating the mechanism of lateral bud differentiation on demand, and (3) maximizing plantlet production with minimum labor requirements. Endeavors into some of these projects now lie outside the aims of publicly funded research and become the responsibility of commercial enterprises.
Program

1. Diagnostic Tools/Procedures

1.1 Infectious Diseases

1.1.1 Development of a Rapid Diagnostic Kit for Salmonellosis Involving Agglutination Test

1.1.2 Design and Development of DNA Probes for the Detection of the Toxigenic (Exotoxin A-Producing) Strain of Pseudomonas aeruginosa

1.1.3 Development of a Test Kit for the Detection of Human Cytomegalovirus

1.1.4 Design and Development of the DNA Probes for the Detection of the Epstein-Barr Virus Specifically Targeted Against the Viral Direct Repeats

1.2 Nutritional/Genetic/Metabolic Disorders/ Pregnancy

1.2.1 Development of a Simple Immunoassay for the Clinical Detection of Serum Transferin and Prealbumin

1.2.2 Development of Protocols for the Isolation and Purification of Important Enzymes (alkaline phosphatase, urease, uricase) from Indigenous Sources and Their Use in the Production of Test Kits

Implementing Agency

UP-CM-PGH

AMBAP-UP Diliman

BRL-DOH

NKI

AMSAP-UP Diliman

ERL-DOH
1.2.3 Development of a biochemical and molecular genetic procedures for the study of genetic disorders

1.2.4 Development of a pregnancy test UP-CM-PGH kit: Anti-beta-HCG monoclonal antibody based testing of urine

2. Vaccines

2.1 Design and development of a Hepatitis B synthetic peptide vaccine carrying both B-cell and T-cell epitopes

2.2 Comparative testing of the immunogenecities of commercially available plasma-derived and imported synthetic (recombinant) Hepatitis B vaccines in comparison with locally developed synthetic vaccines

3. Support Projects

3.1 Development of a mammalian tissue cell culture and hybridoma bank

3.2 Development of toxicology laboratory for poison diagnosis

3.3 Screening for suitable substitutes for fetal calf serum

Budget: As presented earlier by Dr. Nazarea
BUDGET FOR THE PROGRAMS  
(CALL FIGURES ARE IN PESOS)

1. UP COLLEGE OF MEDICINE & UP-PGH PROGRAM

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3. NATIONAL KIDNEY INSTITUTE (NKI) PROGRAM

<table>
<thead>
<tr>
<th>YEAR 1</th>
<th>YEAR 2</th>
<th>YEAR 3</th>
<th>YEAR 4</th>
<th>YEAR 5</th>
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BUREAU SPECIAL ORDER
No. 02 s. 1991

SUBJECT: Biotechnology Lectures for Six Wednesdays

Three (3) sets of BRL Lectures on the following topics are scheduled to be held at the BRL Conference Room starting January 30 up to March 2, 1991, 3:00 - 5:00 P.M. with Dr. Apolinario D. Nazarea, PHIDP Consultant, as the lecturer.

Jan. 30 & Feb. 6 - Development of RNA & DNA Probes: "Design & Construction"
Feb. 13 & Feb. 20 - "PCR (Polymerase Chain Reaction) Methodology: Principles and Applications"
Feb. 27 & Mar. 6 - "Molecular Methods of Epitope Mapping: Principles and Applications"

The following are required to attend these lectures:
1. Dr. Criselda Abesamis - Medical Specialist I
2. Dr. Marilyn Barza - Medical Specialist I
3. Dr. Gracela Mina Ramos - Medical Specialist I
4. All TIC’s of Lab. Divisions I and II
5. Immunology Section Personnel

Please be guided accordingly.

Director IV

"Kalusugan ay Kayamanan"
MEDICAL BIOTECHNOLOGY PACKAGE
Executive Summary

1 EXPECTED OUTPUT

Strengthening of the institutional capabilities of the BRL through equipment acquisition and in-house current awareness training and modern applied research in SUPPORT OF THE NOW ON-GOING STRATEGIC TRANSFER to the BRL OF CURRENT TECHNIQUES IN MEDICAL BIOTECHNOLOGY FROM ABROAD, pipelined through the Advanced Medical Biotechnology Action Program (AMBAP).

1.1 Such mission-oriented transfer of selected technologies from abroad is targeted ultimately towards modernization; in order to ENHANCE THE SERVICE DELIVERY CAPACITY OF THE DOH.

1.2 Such enhancement cannot be accomplished without the concomitant upgrading of both equipment and in-house current awareness of selected BRL staff on new technologies and the initiation of modern hands-on research within the BRL.

2 GENERAL OBJECTIVES

The Medical Biotechnology Package is intended to allow the BRL to actively assist the DOH by modernizing its technological capabilities up to a level that would make it more responsive and more capability-oriented in line with national priority thrusts for modernization and self-reliance in medical/pharmaceutical products and technologies.

3 MAIN COMPONENTS OF PACKAGE

3.1 Equipment acquisition to support the rapid implementation of external technology transfer through AMBAP.
3.1.1 Recurring expenditures: equipment maintenance and continuing provisions for consumable reagents.

3.2 In-house CURRENT AWARENESS TRAINING of selected staff members on modern trends in medical biotechnology, in the following topics:

3.2.1 Modern trends in the design of synthetic RNA/DNA Probes for rapid identification of toxigenic Bacteria and Viruses.

3.2.2 Modern Trends in the design of Synthetic Multivalent Peptide Vaccines targeted against viral and other pathogenic agents.

3.2.3 Modern trends in the laboratory-scale production of DNA fragments (such as specially designed synthetic probes) by the Polymerase Chain Reaction (PCR) methods.

3.2.4 Modern trends in the laboratory-scale Production of peptide fragments using automated peptide synthesis methods.

3.3 Initiation (using the newly acquired equipment in 3.1) of PRODUCT-ORIENTED RESEARCH in Medical Biotechnology utilizing outside funding.

3.3.1 Design of Synthetic RNA/DNA Probes to detect rapidly toxigenic strains of Pseudomonas aeruginosa.

3.3.2 Design of Synthetic DNA Probes to detect rapidly the Epstein-Barr virus.

3.3.3 Design and Synthesis of Multi-valent synthetic Hepatitis B Vaccine containing both B-cell and T-cell determinants.
GENERAL RECOMMENDATIONS

The panel visited the Biologicals Production Service (BPS) and reviewed the Intercare Study on the Alabang Vaccine Complex as a basis: or recommending the Philippine Government’s future development activities in accordance to the needs for implementing the EPI.

The panel discussed all of the relevant aspects of vaccine production and formulated its recommendation in line with the Guide Questions/Issues which were agreed by its members.

1. The BPS shall continue to produce the following biological products: BCG, tetanus toxoid, DPT, anti-venom, cholera, typhoid, diagnostic antigens and anti-sera, animal and human rabies vaccine and PPD. However, it is recommended that these products should be tested by an independent recognized reference laboratory in order to confirm that these products meet the minimum requirements of international standard.

2. It was the opinion of the panel that cholera/typhoid combination should be discontinued. Instead of Semple rabies vaccine, veroceil rabies vaccine should be produced.

3. New vaccines such as DT (Diphtheria-Tetanus) and possibly Td (adult) could be considered to be produced in BPS.

So far as the production of other EPI vaccines (OPV and measles), and Hepatitis B or any other are concerned, the creation of the proper basic infrastructure in BPS is a prerequisite.

4. As a first stage, the building of facilities to carry out blending, filling, packaging and storage properly serviced with utilities and with a new quality control department and support facilities, operating at the highest standards of G.M.P. should be established. This would enable the government to adopt a very flexible policy regarding filling of imported bulk concentrates and locally produced vaccines.

5. As a second stage, the BPS could contemplate the production of the vaccines from basic and or intermediate raw materials, for example polio, measles and Hepatitis B.

6. A feasibility study should be undertaken to confirm the suitability and the economic and financial viability of the suggested approaches in items 4 and 5.

7. Until vaccines mentioned in paragraph 3 are produced locally importation should continue.

8. A Sub-group of the Panel worked out specific recommendations concerning immediate measures to be taken and introduced at BPS to improve the safety of the operations and quality of the product.
9. The establishment of a National Quality Control Authority with its own laboratory in addition to the Quality Control Department of BPS is recommended. Appropriate regulations should be promulgated and the necessary staff recruited and trained as soon as possible.

10. The training of the BPS staff in all disciplines of production, quality control and management is highly recommended. Such training programmes carried out overseas and with consultant advice locally could be secured from United Nations agencies.

11. The staff of the National Quality Control Authority and the Quality Control Department of BPS may be trained within the scope of the International Federation of Pharmaceutical Manufacturers Association's special training programme for such staff.

12. Technology transfer for biologicals production (imported bulk or basic) from reputable manufacturers, as listed in UNIDO's Directory, or from appropriate institutions could be considered. Different modalities of such technology transfer can be agreed upon. While joint venture might be the best option, this requires mutually acceptable conditions.
SPECIAL RECOMMENDATIONS

The sub-group made the following specific recommendation for immediate action which apply for both the production and quality control facilities, equipment, processes and safety measures.

I. FACILITIES

1. All the building facilities of BPS should be revamped in order to minimize the potential contamination of the product and the risk of personnel being exposed to contaminants.

2. All surfaces (walls, floors, ceilings, laboratory benches, etc.) should be covered by materials which can easily be cleaned and disinfected, e.g.:
   a. all working bench tops should be covered by formica,
   b. floors and walls should be covered by epoxy paint or by latex,
   c. wires and any other exposed connections should be covered with a duct or conduit and properly identified as per fermentation suit of DP product.

3. Wooden surfaces should be sealed and painted and/or replaced with aluminum structure.

4. Proper light fixtures should be installed in order to improve lighting.

5. Remove non-productive equipments and accessories such as desk, chairs, books, etc. from working area (production and/or quality control).

6. Proper areas should be selected for the storage of equipment, accessories and reagents that are utilized for production and processing such as vessels, connections, etc.

II. EQUIPMENT

1. Install sterilizers for decontamination in the production units.

2. All sterilizers, cold rooms, freezers, incubator rooms, autoclaves, etc. should have proper recorders and charts which should be signed and stored in the proper record and for validation purposes.

3. The generous use of laminar flow modules should be introduced at critical operations such as inoculation, fermentation, filling, etc.

4. All equipment not involve in the production task should be removed and stored in proper areas.

5. Steam traps should be installed for condensate throughout the feeding lines into the production units.
6. Proper incinerators should be built into the facilities.

7. Exhaust from the fermenters should be passing through the incinerator prior to final removal.

III. PROCESS

1. Proper product description and standard operating procedures for each step of the production, processing and quality control should be prepared.

2. Proper forms and other documentation should be established and implemented for recording of each step of manufacture and validation of the process.

3. Validation and internal audits should be performed in order to standardize all of the production and processing activities.

4. Continuous monitoring of the production environment should be established.

IV. SAFETY

1. All different warning signs identifying particular hazards should be placed throughout the facilities.

2. Clothing policy should be established in the laboratory: a common uniform should be worn and people have to change to different uniforms when entering hazardous areas.

3. Movement of personnel should be restricted to their actual working unit.

4. Immunization policy should be established for all personnel working within the laboratories.

5. Policy utilizing protective devices should be implemented when personnel are working with glass containers and air pressure and/or vacuum.

6. Protective attire such as shoes, gloves, caps, masks, glasses, etc. should be worn in production areas whenever required.

7. Safety regulators for pressure air lines should be installed throughout the facility.

8. Pipetting devices should be mandatory in order to avoid mouth pipetting.

9. A circle of quality should be introduced involving regular meeting of staff to discuss norms, policies and procedures, and internal audit and self-criticism.

V. MAINTENANCE

Regular and preventive maintenance procedures should be established.
THE
LABORATORY SERVICES
DIVISION
In line with the mandate of the *Bureau of Animal Industry* to intensify campaign for the prevention and eradication of dangerous diseases throughout the country particularly in the isolated and rural areas, the *Laboratory Services Division* plans to move forward in a new direction. Aside from continuing and strengthening its regular activities, the *LSD* for the year ahead intends to expand its horizons to meet the exigent demands of the times and the people.
SECTION 18. BUREAU OF ANIMAL INDUSTRY - The Bureau of Animal Industry Shall:

(1) Formulate programs for the development and expansion of the growing populace;

(2) Recommend the specific policies and procedures governing the flow of livestock product through the various stages of marketing, as well as the proper preservation and inspection of such products;

(3) Coordinate and monitor the activities and projects relating livestock and allied industries;

(4) Prescribe standards for quality in the manufacture, importation, labelling, distribution of veterinary biologicals for livestock, poultry, and allied industries; and

(5) For its own sector, recommend plans, program, policies, rules and regulation to the Secretary and provide technical assistance in the implementation of the same.
The Laboratory Services Division provides for the laboratory diagnosis of animal diseases, chemical analysis of feed and feed ingredients and for the quality control of locally manufactured as well as imported veterinary biological products. It manufactures and develops vaccines for the immunization against the major diseases of livestock and poultry. The regulatory function is carried out through registration, inspection and monitoring of local as well as imported veterinary biological products. Technical assistance in the form of training in the operation and maintenance of diagnostic and chemical feed analysis laboratories is regularly offered to the regional laboratories and other private laboratories. Gives assistance in the formulation of guidelines and policies for the control, prevention and eradication of diseases. Conducts researches to find basic information about agents that cause disease and to improve immunization, prevention, treatment and eradication of animal diseases.
GENERAL PROGRAMS OF LSD FOR CY 1990

I. To provide prompt and accurate diagnosis of diseases using the latest technologies available.

II. To standardize all laboratory procedures for vaccine production/reconstitution, quality control, disease diagnosis and chemical analysis for use in all laboratories.

III. To intensify evaluation/monitoring of regional vaccine production/reconstitution, diagnostic and chemical analysis laboratories to fast-track development and improvement in terms of physical and technical capabilities.

IV. To ensure the quality of veterinary biological products available through more intensive quality control testing and field monitoring of these products.

V. To improve and develop new biological products and technologies to assure the consuming public of safe and wholesome food products.

VI. To gather and provide the relevant data required in the formulation of plans and programs, policies, rules and regulations concerning the disease control activities of the Bureau of Animal Industry.
ACTIVITIES OF LSD FOR 1990

I. SERVICE/ROUTINE
   Laboratory Examinations
   ** Chemical analysis of feeds and feed ingredients (complete proximate)
   ** Diagnostic testing of samples (serological, parasitological, rabies exam.,
     microbiological, pathological, aflatoxin/toxicological and serotyping).

II. PRODUCTION
   ** Bacterial Vaccine
   ** Viral Vaccine
   ** Pharmaceutical products
   ** Production of unvaccinated/minimum disease-free laboratory animals

III. REGULATORY
   ** Registration of veterinary biological products – local and imported
   ** Registration of biological establishments/laboratories
   ** Accreditation of diagnostic, vaccine production/reconstitution laboratories
     in terms of minimum requirements and prioritization of laboratory
     examination
   ** Confiscation of unregistered biological products, expired, unlabelled
     through A.O. No.2 deputized biological inspectors.

IV. OUTREACH ACTIVITIES
   ** Provide on-the job-training/lectures for veterinary clinicians, technicians,
     veterinarians, nurses, medical technologists, chemists, husbandmen, students
     from government institution and private sector.

V. STANDARDIZATION/QUALITY CONTROL
   ** Perform routine testing of veterinary biologicals (sterility, safety, potency)
     of locally manufactured and imported biological products.

VI. INSPECTION
   ** Veterinary biological product establishment, e.g. poultry
     supplies, veterinary clinics and hospitals for products
     not conforming with the standard
   ** Local vaccine manufacturing establishments
   ** Regional laboratories
   ** Farms requesting permit to import vaccines for emerging diseases in the
     country
VII. MONITORING ACTIVITIES

** Monitor and assess regional diagnostic laboratories, its activities and output
** Monitoring vaccine reconstitution/production in 8 regions including quality assurance of their products (I, II, V, VI, VII, IX, X, XI, XII)
** Monitor/evaluate the 13 regional laboratories in terms of the minimum requirements and prioritization of its capabilities.

VIII. PUBLICATION

** Publication of quarterly biologics notice (update of registered biological products in the market)
** Publication of LSD bulletin (quarterly)
** Publication of other researches

IX. RESEARCH AND DEVELOPMENT

** Product development/field trials of rabies and Newcastle disease oil-adjuvant vaccines
** Antigen production
** Production of diagnostic kits
** Determination of procedures and methods for residue testing
** Studies on emerging diseases (to collaborate with the Research Division)
** Studies on the improvement of vaccines and quality control testing.

X. WORKSHOP/SEMINAR

** Biologics Quality Control Programme in the Region (joint with Animal Feed Standards Division)
** National Workshop for Feeds and Biological Product Inspectors (joint with Animal Feed Standards Division)
** 2nd National Workshop on Disease Diagnosis, Vaccine Production/Reconstitution, Quality Control and Laboratory Animal Management.
**LSD Appropriation**

**FUNCTION:**

FOR 1990

7. DEVELOPMENT OF LIVESTOCK, POULTRY AND DAIRY

H. Biological/Pharmaceutical production, standardization and chemical analysis of biologicals and feeds, vaccine quality control and laboratory animal production.

<table>
<thead>
<tr>
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<td>1,921,000</td>
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<tr>
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C.II Diagnosis of Animal Disease

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FOR 1989

7.H Biological/Pharmaceutical production

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C.II Diagnosis of Animal Diseases

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<td><strong>TOTAL</strong></td>
<td>1,243,000</td>
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LABORATORY SERVICES DIVISION
OPERATIONAL PLAN FOR 1990

7.G.11 DIAGNOSIS OF ANIMAL DISEASES

I. TARGET PLAN

<table>
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<tr>
<th>ACTUAL 1989</th>
<th>TARGET 1990</th>
<th>1 QTR.</th>
<th>2 QTR.</th>
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</table>

A. DISEASE DIAGNOSIS

1. Provide accurate and reliable laboratory diagnosis of animal diseases
   - 24,909
   - 22,000
   - 5,500
   - 5,500
   - 5,500
   - 5,500

2. Provide technical assistance to the Regional Diagnostic Laboratories according to their capabilities, priorities and areas of specialization
   - 6
   - 13
   - 3
   - 3
   - 3
   - 4

3. Prepare guidelines of laboratory procedures. Minimum requirements of a diagnostic laboratory
   - 2
   - 1
   - 1
   - 1

4. Assist in making programs for animal disease control, prevention and eradication
   - 1
   - 1

5. Provide on the job training for veterinary clinicians, technicians and veterinarians from government institutions and private sector
   - 205
   - 30
   - 70
   - 35
   - 50

II. BUDGET PLAN

| PERSONAL SERVICES | 649 | 861 | 215 | 215 | 215 | 216 |
| M O E | 829 | 751 | 186 | 189 | 187 | 189 |
| T O T A L | 1,478 | 1,612 | 401 | 404 | 402 | 405 |
7.1: Biological/Pharmaceutical production, standardization and chemical analyses of biologics and feeds, vaccine quality control and laboratory animal production

I. TARGET PLAN

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<th>ACTUAL 1989</th>
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**A. BACTERIAL VACCINE PRODUCTION SECTION**

<table>
<thead>
<tr>
<th>1. Production of bacterial vaccines/in-house quality control</th>
<th>1,034,325</th>
<th>2,600,000</th>
<th>650,000</th>
<th>650,000</th>
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<tbody>
<tr>
<td>(doses)</td>
<td></td>
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2. Monitoring of/technical assistance to regional bacterial vaccine reconstitution/production laboratories

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<td>8</td>
<td>12</td>
<td>3</td>
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3. Product development

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**B. VIRAL VACCINE PRODUCTION SECTION**

<table>
<thead>
<tr>
<th>1. Production of viral vaccines incl. quality control (doses)</th>
<th>7,152,140</th>
<th>10,950,144</th>
<th>2,769,500</th>
<th>2,627,144</th>
<th>2,772,500</th>
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</table>

2. Monitoring of/technical assistance to regional laboratories for viral vaccine production

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3. Product development/field trials

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<td>-</td>
<td>15,000</td>
<td>5,000</td>
<td>2,000</td>
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**C. VETERINARY BIOLOGICAL STANDARDIZATION SECTION**

<table>
<thead>
<tr>
<th>1. Perform routine testing of veterinary biologics (sterility, safety, potency)</th>
<th>-</th>
<th>524</th>
<th>99</th>
<th>136</th>
<th>135</th>
<th>84</th>
</tr>
</thead>
</table>

2. Monitoring of/technical assistance to regional laboratories to do in-house quality control of reconstituted vaccine including production from local vaccine manufacturers:

<table>
<thead>
<tr>
<th>Government</th>
<th>Private</th>
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<tr>
<td>8</td>
<td>280</td>
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<tr>
<td>12</td>
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<td>100</td>
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<td>3</td>
<td>50</td>
</tr>
<tr>
<td>3</td>
<td>100</td>
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</table>

3. Registration of biological products

<table>
<thead>
<tr>
<th>425</th>
<th>500</th>
<th>200</th>
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4. Publication of Biologics Notice

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5. Publication of LSD Bulletin

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6. Researches on vaccines

<table>
<thead>
<tr>
<th>-</th>
<th>14</th>
<th>4</th>
<th>2</th>
<th>5</th>
<th>3</th>
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</table>

7. Development of tests

| - | 9  | -   | 3   | 3   | 3   |
D. CENTRAL ANIMAL FEED ANALYSIS SECTION

1. Analysis of feed samples
   - 10,897
   - 12,000
   - 3,000
   - 3,000
   - 3,000
   - 3,000

2. Monitoring/evaluation of 12 RFLs' activities
   - 8
   - 12
   - 3
   - 3
   - 3
   - 3

E. PHARMACEUTICAL PRODUCTION UNIT

1. Production of Pharmaceutical products and in-house quality control
   - ml: 7,668,500
   - 1,754,000
   - 438,500
   - 438,500
   - 438,500
   - 438,500
   - gm: 22,125
   - 116,000
   - 29,000
   - 29,000
   - 29,000
   - 29,000

2. Improvement of products
   - 2
   - 8
   - 2
   - 2
   - 2
   - 2

F. LABORATORY ANIMAL PRODUCTION

1. Production of high quality laboratory animal
   - 5,166
   - 12,119
   - 2,863
   - 3,019
   - 3,269
   - 2,968

2. Develop disease-free laboratory animals
   - 5,228
   - 1,130
   - 1,290
   - 1,080
   - 1,623

II. BUDGET PLAN

<table>
<thead>
<tr>
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<th>PS</th>
<th>1,362,000</th>
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<td>5,472,000</td>
<td>1,366,000</td>
<td>1,370,000</td>
<td>1,366,000</td>
<td>1,371,000</td>
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<td>7,394,000</td>
<td>1,845,000</td>
<td>1,850,000</td>
<td>1,847,000</td>
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LABORATORY SERVICES DIVISION
Semi-Annual Accomplishment Report
January - June 1990

<table>
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<tr>
<th>PARTICULARS</th>
<th>ACCOMPLISHMENT</th>
<th>TARGET</th>
<th>%</th>
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<tbody>
<tr>
<td>A. PRODUCTION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Biologicals for livestock produced/manufactured (in doses)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HS Vaccine</td>
<td>169,990</td>
<td>360,000</td>
<td>47.2</td>
</tr>
<tr>
<td>HS Concentrate</td>
<td>386,000</td>
<td>1,500,000</td>
<td>25.7</td>
</tr>
<tr>
<td>Swine Plague Vaccine</td>
<td>52,750</td>
<td>120,000</td>
<td>43.9</td>
</tr>
<tr>
<td>Anthrax Spore Vaccine</td>
<td>65,063</td>
<td>120,000</td>
<td>54.2</td>
</tr>
<tr>
<td>ND La Sota Strain Vac.</td>
<td>2,615,600</td>
<td>10,000,000</td>
<td>37.5</td>
</tr>
<tr>
<td>ND Hitchner Bl Vaccine</td>
<td>1,133,200</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hog Cholera Vaccine</td>
<td>128,425</td>
<td>567,000</td>
<td>22.2</td>
</tr>
<tr>
<td>Fowl Pox Vaccine</td>
<td>112,800</td>
<td>500,000</td>
<td>22.6</td>
</tr>
<tr>
<td>ND Oil-Adjuvant Vaccine</td>
<td>3,760</td>
<td>15,000</td>
<td>25.1</td>
</tr>
<tr>
<td>2. Pharmaceutical Products (in ml.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBG</td>
<td>85,600</td>
<td>560,000</td>
<td>15.3</td>
</tr>
<tr>
<td>Tincture of Iodine</td>
<td>20,250</td>
<td>120,000</td>
<td>16.9</td>
</tr>
<tr>
<td>Tresulzine</td>
<td>311,600</td>
<td>594,000</td>
<td>52.5</td>
</tr>
<tr>
<td>Venusin</td>
<td>3,000</td>
<td>67,680</td>
<td>4.4</td>
</tr>
<tr>
<td>3. Animal Production (in head)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White Mice</td>
<td>2,180</td>
<td>10,230</td>
<td>21.3</td>
</tr>
<tr>
<td>Guinea Pig</td>
<td>21</td>
<td>270</td>
<td>7.8</td>
</tr>
<tr>
<td>Chicken</td>
<td>71</td>
<td>1,348</td>
<td>5.3</td>
</tr>
</tbody>
</table>
B. LABORATORY EXAMINATION

1. Chemical Analysis

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples Received</td>
<td>5,696</td>
<td>12,000</td>
<td>47.5</td>
</tr>
<tr>
<td>Analysis Done</td>
<td>16,227</td>
<td>16,500</td>
<td>98.3</td>
</tr>
<tr>
<td>Fees Collected</td>
<td></td>
<td>P 662,498.00</td>
<td></td>
</tr>
</tbody>
</table>

2. Diagnosis Performed

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Serology-Virology</td>
<td>10,975</td>
<td>14,220</td>
<td>77.2</td>
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<tr>
<td>Toxicology</td>
<td>275</td>
<td>336</td>
<td>81.8</td>
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<tr>
<td>Microbiology-Mycology</td>
<td>944</td>
<td>900</td>
<td>104.9</td>
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<tr>
<td>Rabies Examination</td>
<td>854</td>
<td>1,344</td>
<td>63.5</td>
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<tr>
<td>Parasitology</td>
<td>1,037</td>
<td>720</td>
<td>144.0</td>
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<tr>
<td>Pathology</td>
<td>351</td>
<td>480</td>
<td>73.1</td>
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<tr>
<td>FMD Diagnosis</td>
<td>185</td>
<td>300</td>
<td>61.7</td>
</tr>
<tr>
<td>Vet./Clinicians Trained</td>
<td>41</td>
<td>205</td>
<td>20.0</td>
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</tbody>
</table>

C. VACCINES EVALUATED

1. Vet. Biologics Tested

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Sterility</td>
<td>159</td>
<td>200</td>
<td>79.5</td>
</tr>
<tr>
<td>Safety</td>
<td>153</td>
<td>200</td>
<td>76.5</td>
</tr>
<tr>
<td>Potency</td>
<td>147</td>
<td>200</td>
<td>73.5</td>
</tr>
</tbody>
</table>

2. Monitoring Quality of
Reconstituted Vaccine

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>11</td>
<td>12</td>
<td>91.7</td>
</tr>
</tbody>
</table>
3. Issuance of Permit and Establishment Licenses

<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporary</td>
<td>233</td>
</tr>
<tr>
<td>Special</td>
<td>80</td>
</tr>
<tr>
<td>Regular</td>
<td>232</td>
</tr>
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</table>

4. Monitoring and Inspection

<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vet. biologics importers</td>
<td>6</td>
<td>50</td>
<td>12.0</td>
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<tr>
<td>Vet. biologics wholesalers</td>
<td>37</td>
<td>200</td>
<td>18.5</td>
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<tr>
<td>Vet. biologics manufacturers</td>
<td>11</td>
<td>22</td>
<td>50.0</td>
</tr>
<tr>
<td>Vet. clinics/hospitals</td>
<td>-</td>
<td>100</td>
<td>0</td>
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</table>

D. RESEARCH AND DEVELOPMENT

<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
<th>Count</th>
<th>All On-Going</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Development</td>
<td>5</td>
<td>5</td>
<td>All On-going</td>
</tr>
<tr>
<td>In coordination with other divisions</td>
<td>7</td>
<td>7</td>
<td>All On-going</td>
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</table>

E. CONTINUING EDUCATION PROJECTS/PROGRAMS

<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regional Laboratory Staff</td>
<td>42</td>
<td>52</td>
</tr>
<tr>
<td>Veterinary Students/Others</td>
<td>205</td>
<td>34</td>
</tr>
<tr>
<td>N G O's</td>
<td></td>
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</tr>
</tbody>
</table>
VACCINES EVALUATED

January - June 1990

Sterility

Safety

Potency

TARGET
TESTS PERFORMED
ACCOMPLISHMENT

VET BIOLOGICS ESTABLISHMENTS MONITORED

January - June 1990

Importers

Wholesalers

Manufacturers

Clinics/Hospitals

Regional Labs.

TARGET
ACCOMPLISHMENT
DISEASE DIAGNOSIS

SEMIANUAL REPORT 1990

(Thousands)

TARGET

ACCOMPLISHMENT

Sarology-VirologyToxicology Microbiology Rabies Exam. Parasitology Pathology FMD Diagnosis
FEED ANALYSIS
January-June 1990

- TARGET
- ACCOMPLISHMENT

Samples received

Analysis Done

(Thousands)
### REGIONAL LABORATORIES BEING MONITORED

<table>
<thead>
<tr>
<th>Region</th>
<th>Location</th>
<th>Diagnostic</th>
<th>Reconstitution</th>
<th>Q.C</th>
<th>Feed Lab.</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Sta. Barbara, Pangasinan</td>
<td>x</td>
<td>x</td>
<td>a,b</td>
<td>x</td>
</tr>
<tr>
<td>II</td>
<td>Cagayan, Tuquegarao</td>
<td>x</td>
<td>x</td>
<td>a,b</td>
<td>x</td>
</tr>
<tr>
<td>III</td>
<td>San Fernando, Pampanga</td>
<td>x</td>
<td>--</td>
<td>--</td>
<td>x</td>
</tr>
<tr>
<td>IV</td>
<td>Lipa City, Batangas</td>
<td>x</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>V</td>
<td>Camalig, Albay</td>
<td>x</td>
<td>x</td>
<td>a,b</td>
<td>x</td>
</tr>
<tr>
<td>VI</td>
<td>Parola, Iloilo City</td>
<td>x</td>
<td>x</td>
<td>a</td>
<td>x</td>
</tr>
<tr>
<td>VII</td>
<td>Cebu City, Bohol</td>
<td>x</td>
<td>x</td>
<td>a,b,c</td>
<td>x</td>
</tr>
<tr>
<td>VIII</td>
<td>Bo. Diit, Tacloban City</td>
<td>x</td>
<td>x</td>
<td>a</td>
<td>x</td>
</tr>
<tr>
<td>IX</td>
<td>Tumaga, Zamboanga City</td>
<td>x</td>
<td>x</td>
<td>a</td>
<td>x</td>
</tr>
<tr>
<td>X</td>
<td>Cagayan de Oro City</td>
<td>x</td>
<td>x</td>
<td>a,b</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td><strong>Misamis Oriental</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>XI</td>
<td>Fr. Selga St., Davao City</td>
<td>x</td>
<td>x</td>
<td>a,b</td>
<td>NF</td>
</tr>
<tr>
<td>XII</td>
<td>Nuling Sultan Kudarat</td>
<td>x</td>
<td>--</td>
<td>--</td>
<td>x</td>
</tr>
<tr>
<td>XIII</td>
<td><strong>DA Car</strong></td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

**LEGEND:**
- x - Existing
- NF - Non-Functional
- a - Sterility Test
- b - Safety Test
- c - Potency Test
- -- - Non-Existing
BSO's comments on Dr. Fari's report

During Dr. Fari's stay in Manila, he had the opportunity to visit several centres which perform research and development work in the field of biotechnology and had technical discussions with the personnel involved in the programming and development of 6 mega projects on biotechnology which the Government of the Philippines would like to develop.

The expert's task were emphatically addressed to biotechnology activities related to health and pharmaceutical production. Upon arrival at the project site, the national authorities requested him to extend his advice to the whole range of National Programmes on Biotechnology. Dr. Fari also gave some recommendations on projects related to agro-biotechnology.

For the implementation of the programme, it is important to plan activities carefully in order to ensure the optimal results with the minimum inputs. One important aspect of the planning and implementation of the activities could be to involve universities, research institutions and production enterprises in specific themes in which they could work in coordinating manner and/or following specific aspects of the theme which could be used as input information and scientific material for the working programme of the other party.

Specific recommendations on ways of implementation of the programme were given by the expert in his report.

We would like to emphasize the importance to have the industrial sector involved in the programme from its beginning as a way to ensure the application of the products for the benefit of the national economy.

Another aspect which would be followed at the planning stage is the detailing of activities of each one of the mega projects, definition of its objectives, availability of human and material resources, expected outputs, timing schedule for implementation, cost estimation, possible industrial utilization and estimation of economic benefits.

The above mentioned exercises would help in making appropriate decisions, would save time, and would be beneficial to the national economy.

In relation to the mega projects, it seems to be important to analyze the specific comments presented in the expert's report:

**Pilot plant scale penicillin production:**

The development of the production of antibiotics in the Philippines is both of social and economic importance. Having a multipurpose pilot plant where the scientific and technical personnel could perform research and development work in the field of traditional and new generation antibiotics.
The on-going feasibility studies would give specific recommendations on
the antibiotics which could be introduced into production, market tendencies, prices, etc. Having a multipurpose fermentation pilot plant, it could be easier to develop and transfer technologies for new antibiotics. Recommendations given by the expert related to purchase, conservation and utilization of strains must be considered for the decision-making exercise.

The expert also recommended the approval and development of other projects included in the national programme such as projects related to coconut tissue culture and oils. Special attention must be dedicated to the biotechnology activities oriented to the production of vaccines and diagnostics. It would be also advisable to analyze and plan the improvement of production and technologies in the Alabang Vaccine Complex and in the future development of the centre.