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REPORT FROM PROFESSOR D.C. ELLWOOD ON GENETIC MANIPULATION MISSION IN INDIA AND BRAZIL : JULY 1987

I presented in my preliminary report in Geneva an analysis of the guidelines prepared by various countries for the control of genetic manipulation experiments. The analysis suggested that there were two main sets of guidelines, one produced by the National Institute of Health in Washington (NIH) and those prepared by the British Genetic Manipulation Advisory Group (GMAG).

At this meeting in Geneva I was asked to visit two third world countries in which Biotechnology was an expanding area of scientific and public concern. There were some administrative difficulties in making these arrangements, however, visits to India and Brazil took place in July of this year. Following directly on from these visits I reported back to UNIDO offices in Vienna. There had been some changes in administrative officials and I was not able to establish to whom I should report, or indeed, if the subsequent follow up meeting in Nairobi was to take place. I informed Dr. V. Oviatt in NIH (formerly of WHO) of the position by telephone and letter. He was unable to clarify the position in that he was unaware of any funding for a future meeting to discuss the results of my mission. From the above it is clear that there is some confusion of the present status of my brief.

However, there are a number of points which emerged from my discussions in India and Brazil that are of some importance. I was able through the good offices of the local UN field officers in Delhi and Brasilia to meet both government ministers, whose responsibilities encompassed biotechnology. Further meetings were also arranged with their civil servants to discuss legal implications of this technology. Visits also took place to active research centres, government and university, in Biotechnology for discussions with scientists involved in the area. It was clear that the Governments of Brazil and India had a major commitment to Biotechnology as both ministers had a real appreciation of the potential benefits that the technology could bring to their respective countries. With this enthusiasm the legal framework in both countries had been examined to identify if the implication of such work was adequately covered. In both India and Brazil it was felt by ministers and their advisors that the technology was broadly

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covered by the present legal framework. This was true for all aspects of applications of recombinant DNA technology be it laboratory, industrial or agricultural release purposes.

These discussions took place because it related to the appreciation of the guidelines for the control of activities in the genetic manipulation area. In both countries, the ministers, their civil servant advisors, and the working scientists were extremely strong in their view that the NIH guidelines were perfectly satisfactory. They could see no need for any new set of guidelines at all. This was the position with respect to laboratory work, but they felt that for industrial purposes the OECD guidelines in this area were of value. Deliberate release of genetically manipulated organisms is still a contentious issue in Europe and the USA. Within India and Brazil the governments are well aware of this debate and were following it closely. However, they recognised that such release may well be of important benefit to their agricultural industries. It should be noted here that viral control of a number of plant pests is widely used in Brazil particularly in the coffee industry.

There was however a major point that arose in discussion with laboratory workers in both countries. They suggested that a major brake on their progress was in the supply of the necessary reagents such as restriction enzymes. Import controls, high costs, erratic supply were all causes of this difficulty. Furthermore, they also indicated that microbial contamination of both their reagents and their own preparations was a major problem, often ruining six months work. This contamination often occurred in laboratories which should have been working under conditions of good microbiological practice. In a number of the laboratories this was very evidently not the case. NIH guidelines do, of course, set out a specific set of guidelines for good microbiological practice. However, in the laboratories these guidelines with respect to wearing laboratory coats, eating, smoking etc. were often ignored. There are a number of reasons for this, the lowest category guidelines are regarded as trivial, wearing laboratory coats in tropical temperatures appears as an imposition. If we add to this the self image of molecular biologists of being "laid back" then simple GMP guidelines are often forgotten.

It should be possible to persuade the laboratory staff of the advantages of working to these good microbiological practice guidelines. The major advantage would be that in a properly run laboratory the incidence of microbial contamination of the laboratories reagents and preparations would be markedly reduced. This would increase the laboratories work output and markedly reduce the costs for the supply of reagents etc. Further it would also keep public confidence in the laboratory personnel.

Training in good microbiological practice could be given if required by the ICGEB. It should also be recognised that much of the work that scientists in the third world countries would wish to carry out would be plant based and in the NIH system this would be classified as good microbiological practice. There are a number of guidelines set up for good microbiological practice, NIH, WHO etc all of which have slight variations in them.

With the general relaxation of the classifications of experiments in genetic manipulation it seems likely that most experiments in this field ~90% will fall into the GPM or the PI classification.

In both countries, particularly in India, it was thought that the use of genetically manipulated organisms to produce pharmaceutical materials was highly desirable. For such activities they were looking to OECD report on large scale fermentation systems for guidelines. In India the view was also expressed that by using brewing yeast as the host most problems of containment would be minimal.

Finally, it must be fully recognised that in India and Brazil the major thrust of this genetic manipulation area is to improve their agricultural industry. It follows from this that modified organisms will be released into the environment in the near future. This then becomes a global problem which suggests that the UN and its daughter bodies should take an active role in considering the implications of such release.

SUMMARY

1. NIH guidelines acceptable and new guidelines not required.
2. Laboratories working at good microbiological practice level do not work to guidelines.
3. They should be assisted to do so because (a) that is what guidelines are for and (b) by lowering laboratory contamination, costs could be cut.
4. Training in GMP should be given by ICGEB
5. Physical injection of DNA into cells should be included in definition of genetic manipulation
6. ICGEB to take lead role in defining problems associated with and guidelines for deliberate release of genetically manipulated organisms.

NOTE

Does this require a meeting to discuss these points?

D.C. ELLWOOD
October 1987