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THE INTENTIONAL INTRODUCTION OF ORGANISMS TO THE ENVIRONMENT

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ABSTRACT

A number of countries have regulations pe .ining to the release of non-indigenous organisms. Thes.e are based on previous experience and have as a general theme the need to be very careful. This is because it is not usually possible to predict with any degree of certainty if a particular species will become established, and if it does, whether it will become a pest or not.

For genetically engineered organisms there are as yet no internationally recognized regulations or guidelines for their safe use. Some countries, such as the USA, Australia and the UK, have nationally binding regulations. Much effort is being put into developing regulations which will apply in all states in the European Economic Community. Guidelines that member states of the Organization of Economic Co-operation and Development will be expected to follow are expected to be published in 1990.

Developing Countries, and all nations with a relatively small science base, will have great difficulty in establishing, running and policing national regulatory systems. Therefore, there is a need to establish multinational committees and inspection agencies as soon as possible to ensure that genetically engineered organisms can be exploited safely.

INTRODUCTION

Ever since the human race first started to exploit animals and plants it has been responsible for the introduction of non-indigenous organisms into different environments. In many cases this has been highly beneficial for humans. For example, the widespread cultivation of cereal crops and the domestication of farm animals. From an environmental point of view human interference has been extremely damaging, so that in almost all countries in the world there are almost no areas of easily cultivatable land that carry "natural" plant and animal communities.

In general, we tend to look upon introductions as benign if they do not harm agriculture and the mostly man-made environments that are considered "natural". The introduction of rabbits to Australia, rats to small islands and the spread of diseases are often quoted examples of harm. Now that such problems are generally

recognized, the potential for accidental harm through the introduction of plants, animals, fish etc. is greatly reduced. Many regulations exist in different countries to control introductions, and there is an international convention (The Geneva Convention, 1984) to control the movement of non-indigenous species. The challenge with the new technology of genetic engineering is to ensure that the modified organisms that are produced are of benefit to mankind and are, at worst, no more harmful to the environment than existing exploited organisms.

DISCUSSION

Existing regulations

In most of the industrialized countries in the world laboratory-based research involving genetic manipulation is subject to strict regulation. Some countries have developed their own regulations (eg Australia, UK, Ireland, France and the USA), while others have been happy to use existing regulations produced by other countries; the most common being those from the USA. The OECD has published a book (1986) which gives guidelines that are approved by all member countries and many other nations. This publication also includes some suggestions for releases of genetically engineered organisms which are being revised and expanded at present; draft proposals for good developmental practice will be published early in 1990.

It is probably true to say that most of the main problems pertaining to the safety of laboratory-based work have been resolved, although there is still a need to ensure that new vectors and hosts are assessed carefully so that the conditions required to handle them are at least as safe as those for existing ones. In general human health and the environment should be equally safe because all procedures are designed to contain the manipulated organisms and the cloned DNA. However, for organisms that are not pathogens, pesticides, or are subject to special licences for use, there is a potential environmental problem because requirements to contain them for genetic engineering (which are based on human health risks) may not take into consideration their potential to harm the environment. An example would be work on a mycorrhizal fungus. It would be possible, at the lowest level of laboratory containment, to introduce a gene for a toxin that only affects plants because the humans involved in the work would not be at risk. However, even if a few spores were to enter the environment it is conceivable (although extremely unlikely) that a major plant pathogen with the wide host range of a mycorrhizal fungus might be released. This type of experimentation need not cause problems if guidelines recognize the potential problem.

The guidelines and regulations for releases of genetically engineered organisms to the environment that

exist at present have been developed without experience of the release of such organisms; although there will usually be considerable experience of the release of the parent from which they were derived, and with which they are genetically almost identical. They represent one of the few occasions when regulations and legislation have developed in advance of the exploitation of a new technology. As a result they tend to be rather restrictive and do not always appear to be logical scientifically. For example, in the UK protoplast fusion is considered to be genetic engineering, whereas in the USA it is not. As a result, it is necessary in the UK to obtain approval before releasing plants derived from this technique, whereas in the USA they may be grown without approval.

The main problems in harmonizing guidelines and regulations are the difficulties in defining "genetic manipulation" and the need to be seen to regulate organisms that are a cause of "public concern". Most scientists feel that the logical way to determine what should be subject to regulation is to regulate products, rather than the technique used to develop them. In which case the definition of genetic engineering becomes irrelevant. This is the way that the regulatory process in the USA is moving.

However, it is necessary to consider public opinion which is driven by concern about new technologies, rather than an understanding of the science and real risks involved. This is probably why the latest definition in the EEC draft regulations is: *" a genetically modified organism (GMO) means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."* Because the definition is so broad a list of techniques not considered to be genetic modification is being prepared.

This definition demonstrates that the EEC intends to regulate on the basis of the method of production. Interestingly, the definition would not include the only release in Europe that has led to press complaints about lack of regulatory approval. This release was part of an EEC-funded project in France, Germany and the UK, and involved the inoculation of field-grown peas with a strain of the bacterium *Rhizobium* which contained a mobile drug resistance gene in a plasmid. The strain was constructed by "classical" mating techniques and thus in Germany and France was not considered to be "genetically engineered". In the UK, which has a broad definition of genetic engineering, it was subject to assessment and release was approved. In both France and Germany the releases were criticized in the press on the basis that they should have been reviewed. I have stressed this issue because it clearly demonstrates the difficulty of separating logical product-based regulations from those that attempt to satisfy public concerns about technology.

Despite these minor problems, there is a very high level of agreement between different countries' guidelines. Differences are so minor that to date there has been no criticism that a particular country will allow "risky" releases. There is a need for regulatory committees to take into consideration local climatic and ecological conditions, but this almost always is part of the assessment process and does not require guidelines to be produced locally.

FUTURE PROSPECTS

I have no doubts that regulations in the major industrialized countries will develop rapidly over the next few years. There is every reason to believe that the release of engineered organisms will proceed reasonably smoothly and that there will be very few risks.

I am much more concerned about countries that at present do not have regulations. If they do not adopt regulations from other countries they will have to develop their own. Most countries with small scientific communities (and some with large ones) will have great difficulty in doing this. Even if they are able, it is not at all clear how they will be able to man regulatory committees and monitor releases.

In the absence of local committees and regulations there are major problems in exploiting genetic engineering. A typical example of this at present is the difficulty of conducting collaborative experiments between laboratories in countries with regulations and those that do not. It is not morally or practically desirable to release genetically engineered organisms in a country without regulations. Furthermore, it would not be at all desirable for such a country to fly in the face of world opinion and allow releases without regulating them.

The absence of local regulations poses serious problems for the industries that have the potential to market genetically engineered organisms throughout the world. They cannot risk international criticism if they release without proper assessment and they cannot plan for the future if there is no indication when regulatory mechanisms will be in place. The potential for harm if a released organism proves to be a serious pest is such that it will be very unwise for any country to try to regulate releases with an inadequate committee, and equally unwise for a company to have made a release in such a country.

Because the release and use of genetically engineered organisms will become commonplace in agriculture and industry within a few years, it is essential that all countries are prepared to handle the legislative and practical problems that such releases will involve as soon as possible. If this is not done they will lose out from the benefits that will be gained from the new

technology, and will delay efforts to produce organisms that will be useful to them.

I believe that this problem can be overcome if countries are willing to participate in regional schemes for assessment and monitoring. These would require regulatory committees that could handle proposals for a number of countries. Such committees must be given the authority and finance to regulate releases and monitor work to ensure the safe use and development of the technology in the region. Because living organisms do not recognize national boundaries it will be essential to ensure that the release committees have international backing. This can best be done by utilizing international agencies, such as UNEP, UNDP, FAO, UNIDO and WHO to provide support and resources to help in the establishment and running of the committees and also to have a role in monitoring their work. For this latter role it will be desirable to seek advice, and perhaps help, from the IAEA which already has the experience and administrative structure needed to provide a monitoring service in different countries.

There appears to be no need for such committees to develop regulations in a vacuum. The most sensible approach will be to take existing guidelines (such as those produced by the OECD) that have wide international acceptance and use them. Locally these will need to be converted into regulations which reflect the legal systems of the countries concerned. The most important local problems are going to lie in the assessment of the risk of particular organisms to local agriculture and the environment. For example a tropical weed that has been exploited in a temperate climate may not be acceptable in the tropics where its weedy characteristics may be a problem.

The composition of such committees will raise nationalistic and scientific problems. It will be essential to have a good balance of scientific disciplines and, in particular, people with a good understanding of the ecology of the region concerned. If individual countries wish to be represented, but are unable to fill specialist positions, they should be offered "observer" positions to allow their representatives to be present and represent their national interests. In an attempt to ensure international harmonization and to override local animosities it may be sensible to have a quarter to a third of the people on the committees who are, or have been, members of such committees in other regions or countries. In this way experience of the procedures and working of other committees could be obtained as well as providing people with scientific expertise that may not be available locally. Furthermore, these people would have an important role in harmonizing the activities of such committees world-wide.

There is a precedent to this idea of a regulatory body for a number of countries in the EEC proposals for the release of genetically engineered organisms. These define regulations that all countries must implement and require that for commercial releases approval obtained in one country be subject to review by the other countries who may object. In case of dispute, community wide approval or refusal for use will be determined by a transnational committee in Brussels.

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