Biotechnology in veterinary science: regulations in Asia and Oceania

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Summary: This review provides a summary of information on the status, in some countries of Asia and Oceania, of regulations governing research and the application of novel biotechnologies to veterinary science and associated industries.

KEYWORDS: Asia - Biotechnology - Legislation - Oceania - Regulations.

INTRODUCTION

Today no country can remain isolated from the developments of new technologies. Novel techniques in biotechnology offer prospects for a variety of products and changes in livestock management which can be of great benefit to veterinary science and animal production. Some examples are set out in Table I. In addition, recombinant DNA techniques are widely used in research to elucidate the control of gene expression, embryology, and in studies of cellular metabolism which involve the location of genes or their products in particular tissues.

Some of the applications listed in Table I are at the research and development stage, others are being evaluated clinically and still others are being considered for registration. The latter include applications involving live modified organisms and transgenic animals. However, many of the products of modified organisms are in wide use, especially diagnostic tools and vaccines.

If it is accepted that veterinary science and animal production in all countries will ultimately adopt this new technology, it is highly desirable for each country to establish an infrastructure which enables the novel applications to be developed safely. The importance of the international aspects of novel technologies to countries of Asia and Oceania is evidenced by their membership in UN-related organisations, the OECD and ASEAN. Many of these consortia are directed towards facilitating trade and exchange of information between countries. That process includes, inter alia, member countries becoming familiar with the regulatory procedures operating in the respective countries and developing ways of harmonising their regulations.

In 1979, the United States Office of Technology Assessment conducted a survey on the use of recombinant DNA techniques and the development of guidelines throughout the world. Some Asian countries responded to the questionnaire; Table II summarises the replies.

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### TABLE I

**Examples of applications of novel biotechnologies in veterinary science**

<table>
<thead>
<tr>
<th>Products from modified organisms or cells</th>
<th>Products</th>
<th>Vaccines</th>
<th>Vaccines</th>
<th>Vaccines</th>
<th>Vaccines</th>
<th>Vaccines</th>
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<th>Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hormones</td>
<td>Porcine, ovine, bovine growth hormones</td>
<td>Fimbral vaccines for control of scour in young stock</td>
<td>Fimbral vaccines for control of scour in young stock</td>
<td>Fimbral vaccines for control of scour in young stock</td>
<td>Fimbral vaccines for control of scour in young stock</td>
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<td>Fimbral vaccines for control of scour in young stock</td>
<td>Fimbral vaccines for control of scour in young stock</td>
</tr>
<tr>
<td>Enzymes</td>
<td>Diagnostic tests for diseases and disorders (ELISA)</td>
<td>Control of scour in young stock</td>
<td>Control of scour in young stock</td>
<td>Control of scour in young stock</td>
<td>Control of scour in young stock</td>
<td>Control of scour in young stock</td>
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<td>Control of scour in young stock</td>
</tr>
<tr>
<td>DNA probes</td>
<td>Diagnostic tests for infectious disease</td>
<td>Protective antigens cloned into bacteria, vaccinia, yeast or cells</td>
<td>Protective antigens cloned into bacteria, vaccinia, yeast or cells</td>
<td>Protective antigens cloned into bacteria, vaccinia, yeast or cells</td>
<td>Protective antigens cloned into bacteria, vaccinia, yeast or cells</td>
<td>Protective antigens cloned into bacteria, vaccinia, yeast or cells</td>
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<td>Protective antigens cloned into bacteria, vaccinia, yeast or cells</td>
<td>Protective antigens cloned into bacteria, vaccinia, yeast or cells</td>
<td>Protective antigens cloned into bacteria, vaccinia, yeast or cells</td>
</tr>
<tr>
<td>Monoclonal antibodies</td>
<td>Diagnostic tests for infectious disease, pregnancy testing, therapy or prophylaxis</td>
<td>Improve rate and range of degradation of feeds</td>
<td>Improve rate and range of degradation of feeds</td>
<td>Improve rate and range of degradation of feeds</td>
<td>Improve rate and range of degradation of feeds</td>
<td>Improve rate and range of degradation of feeds</td>
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<td>Improve rate and range of degradation of feeds</td>
<td>Improve rate and range of degradation of feeds</td>
</tr>
<tr>
<td>Amino acids</td>
<td>Feed supplements (lysine, methionine, tryptophan)</td>
<td>Stock breeding</td>
<td>Stock breeding</td>
<td>Stock breeding</td>
<td>Stock breeding</td>
<td>Stock breeding</td>
<td>Stock breeding</td>
<td>Stock breeding</td>
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<td>Stock breeding</td>
<td>Stock breeding</td>
<td>Stock breeding</td>
</tr>
<tr>
<td>Vaccines</td>
<td></td>
<td>Genetic maps, pedigree analyses, breeding programmes (disease/pest resistance, heat tolerance, milk, wool, meat production)</td>
<td>Genetic maps, pedigree analyses, breeding programmes (disease/pest resistance, heat tolerance, milk, wool, meat production)</td>
<td>Genetic maps, pedigree analyses, breeding programmes (disease/pest resistance, heat tolerance, milk, wool, meat production)</td>
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<td>Genetic maps, pedigree analyses, breeding programmes (disease/pest resistance, heat tolerance, milk, wool, meat production)</td>
<td>Genetic maps, pedigree analyses, breeding programmes (disease/pest resistance, heat tolerance, milk, wool, meat production)</td>
</tr>
<tr>
<td>Vaccines</td>
<td></td>
<td>Increase in gene copy</td>
<td>Increase in gene copy</td>
<td>Increase in gene copy</td>
<td>Increase in gene copy</td>
<td>Increase in gene copy</td>
<td>Increase in gene copy</td>
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<td>Increase in gene copy</td>
<td>Increase in gene copy</td>
<td>Increase in gene copy</td>
</tr>
<tr>
<td>Vaccines</td>
<td></td>
<td>Transgenic animals</td>
<td>Transgenic animals</td>
<td>Transgenic animals</td>
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<td>Transgenic animals</td>
<td>Transgenic animals</td>
<td>Transgenic animals</td>
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<td>Transgenic animals</td>
<td>Transgenic animals</td>
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</tr>
</tbody>
</table>

### TABLE II

**Recombinant DNA work in Asia and Oceania and its surveillance in 1979**

<table>
<thead>
<tr>
<th>Country</th>
<th>rDNA work in progress</th>
<th>Guidelines applying</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>India</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Korea</td>
<td>No</td>
<td>No response</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>No</td>
<td>No response</td>
</tr>
<tr>
<td>Singapore</td>
<td>No</td>
<td>No response</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>No</td>
<td>No response</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

In 1989, the World Bank published a technical report, *Agricultural Biotechnology Study*, which included an assessment of the use of biotechnology in the agricultural industry in various countries. From Table III, it appears that the application of novel biotechnology to agriculture and the related infrastructure are not fully developed in all Asian countries, although as the individual country summaries will show, the existing basic regulatory framework applying to the use of conventional products would be applicable to many products of the novel technologies.

### Table III

*Status of biotechnology in some countries of Asia and Oceania*

<table>
<thead>
<tr>
<th>Country</th>
<th>Public sector biotech. US $m</th>
<th>Well defined national programme</th>
<th>Private sector adequacy human resources</th>
<th>Patent protection</th>
<th>Environ. law</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>100</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Brunei</td>
<td>NA</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>NA</td>
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<tr>
<td>China</td>
<td>NA</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>India</td>
<td>31</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Indonesia</td>
<td>NA</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>NA</td>
</tr>
<tr>
<td>Japan</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Malaysia</td>
<td>0.4</td>
<td>1</td>
<td>3</td>
<td>NA</td>
<td>NA</td>
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<tr>
<td>Philippines</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Singapore</td>
<td>10</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
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<tr>
<td>Thailand</td>
<td>7-14</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

b) Australian Biotechnology Association (1989)
c) Science & Tech. in Japan, 1983 (1981 data)
d) Not available
e) 1 = favourable
2 = acceptable
3 = low*

In this review, it was hoped to provide information about the existing regulatory systems in all the countries of Asia and Oceania. However, in the event, it has proved very difficult to obtain information about the regulations prevailing in many countries; as a result this review is obviously incomplete. While every effort has been made to be accurate, it is very probable that there will be errors and omissions. I apologise in advance for such cases and would welcome correspondence on this subject at any time.

The information I have been able to gather on regulations in some countries is set out in summary form in Table IV; details for each country are presented in the text. A discussion follows of the factors I believe are most important for any country which is considering establishing a surveillance system for the use of genetically-modified organisms (GMO) or their products.
TABLE IV

Existing regulations which could apply to the use of novel biotechnologies in some countries in Asia and Oceania

<table>
<thead>
<tr>
<th>Area regulated</th>
<th>Country</th>
<th>GMO G/L</th>
<th>Vet. products</th>
<th>Pharm. products</th>
<th>Patent GMO</th>
<th>Plant variety</th>
<th>Quaran.</th>
<th>Safety at work</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Australia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>China</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Hong Kong</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>NA</td>
<td>NA</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>India</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
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<td>Yes</td>
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<tr>
<td></td>
<td>Indonesia</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Japan</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Korea</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
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<td>Malaysia</td>
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<tr>
<td></td>
<td>New Zealand</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>NA</td>
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<tr>
<td></td>
<td>Philippines</td>
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<td>Yes</td>
<td>Yes</td>
<td>NA</td>
<td>Yes</td>
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<tr>
<td></td>
<td>Singapore</td>
<td>NA</td>
<td>Yes</td>
<td>Yes</td>
<td>P</td>
<td>P</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Taiwan</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>NA</td>
<td>Yes</td>
<td>NA</td>
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<tr>
<td></td>
<td>Thailand</td>
<td>P</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

a) Guidelines or laws
b) Not available
c) Pending

REGULATORY SYSTEMS IN ASIA AND OCEANIA

AUSTRALIA

The Australian Academy of Science, recognising the significance of recombinant DNA, sent molecular biologists to the Asilomar Conference. In response to their report, the Academy published guidelines and undertook surveillance of contained experiments for small-scale work (culture volumes of < 10 l) from 1975 to 1980. These guidelines were based largely on those of the NIH and the Genetic Manipulation Advisory Group in the UK. They were non-statutory, but workers funded by the public sector were required to comply with them as a condition of receiving support. Work in volumes > 10 l and the release of live recombinant organisms were prohibited. In 1981 the Commonwealth government assumed responsibility for surveillance of the technology and established the Recombinant DNA Monitoring Committee (RDMC). The RDMC was charged with responsibility for ensuring that workers, the general public, agriculture and the environment were not endangered by research and developments using recombinant organisms. The Committee published guidelines for work on a small scale (< 10 l) in 1982 (revised 1983, 1985), and on a large scale in 1984 and established procedures for considering proposals for the release of live organisms in 1987. In response to a review by the RDMC, the Commonwealth government decided in 1987 to enlarge the scope of monitoring to include surveillance
of any genetic manipulation procedure which resulted in an organism containing foreign DNA which was unlikely to be formed by conventional breeding practices. To reflect this enlarged scope, the committee was renamed the Genetic Manipulation Advisory Committee (GMAC). GMAC published a revision of the RDMC's guidelines for small-scale work (1989) to accommodate the enlarged scope and changed perceptions of risk; large-scale and release guidelines are currently being revised.

The GMAC guidelines, like the RDMC guidelines, are non-statutory, but workers who receive Commonwealth grants must comply with them as a condition of receiving a grant.

Australia has a complex and extensive body of legislation (Commonwealth and State) which could be applied to the use or ultimate fate of GMO or their products. This includes controlling the conditions of production, efficacy, safety and quality of medical and veterinary therapeutic goods, agricultural chemicals and pesticides, biological control agents, toxic substances, the importation to Australia of exotic biological materials, food standards and environmental pollution.

In Australia, the States had a substantial body of legislation applying to these areas before the Commonwealth was established. The Commonwealth has since passed legislation in these areas also. In the face of this complex situation, the most cost-efficient way to link GMAC's guidelines to the existing regulatory structure was for GMAC to operate as a technical committee to advise whether there were any hazards associated with the genetic aspects of the organism which might prejudice its end use, and to provide that opinion to the proposer and to the agency with legal responsibility for regulating the particular end use. GMAC considered that the critical matter was the safety and efficacy of the organism, rather than the way in which it had been constructed.

Figure 1 presents the example of how a new chemical (for example, a modified, live biological pesticide) is cleared for registration in both the State of Victoria and the Commonwealth. Each State has its own procedures, but all use the same Commonwealth committees.

The Law Reform Commission of Victoria published a report (1989) on the existing guidelines and laws in Victoria and Australia which could be applied to genetic manipulation work. The report accepted that the existing surveillance mechanisms were appropriate for most work, but recommended that two areas be subjected to specific legislation. The first concerned the release of live organisms, where they recommend that proposers be required to notify GMAC and the agency legally responsible for the particular end use, and that there should be provision for an environmental assessment. The second concerned any use of a modified organism which belongs to a high-risk category (C2 or higher in the 1989 GMAC guidelines). They consider that the proposer should be required to notify GMAC and the Department of Labour which has responsibility for health and safety at work in the State of Victoria. The government has not as yet taken any action on these and other recommendations.

CHINA

The Institute of Genetics and the Chinese Academy of Agricultural Sciences have advised that no guidelines have been established for surveillance of GMO, as this field has as yet undergone little development in China. However, a quarantine system
An example of the complex pathway a new biological pesticide would need to take to be registered in the State of Victoria and the Commonwealth of Australia.
is operated by the Animal Drug Administrative Division of the Bureau of Animal Husbandry, Ministry of Agriculture in Beijing, which also handles the registration of veterinary products. Pharmaceuticals are registered by the State Pharmaceuticals Administration of China, also in Beijing. The Ministry of Labour administers laws relating to health and safety at work which would apply to the fabrication of biotechnology products. Patent protection is afforded to micro-organisms and provides for plant variety rights.

HONG KONG

The Government of Hong Kong has neither guidelines nor laws for surveillance of GMO. Vaccines and pharmaceuticals for human and veterinary use are controlled via the Pharmacy and Poisons Ordinance (Cap 138), and each consignment from overseas requires an import licence. All importations of biological materials, including live bacterial cultures and disease-causing organisms, require a permit which is issued by the Port Health Office of the Department of Health.

INDIA

The Department of Biotechnology of the Ministry of Science and Technology issued India’s first guidelines for the surveillance of GMO in 1990. The guidelines are non-statutory for contained research work and statutory for use in production and agriculture. They exclude consideration of surveillance of recent advances in human reproductive procedures. The guidelines define three categories of host/vector system, based on their perceived risk to humans and to the environment, and rely on in-house biosafety committees for ensuring safe working practices in the institution. Monitoring of compliance with the guidelines will be undertaken by a Review Committee for Genetic Manipulation. Breach of the guidelines will result in the loss of research grants given by the Indian government. The Department of Environment and Forests has established the Genetic Engineering Approval Committee, which has statutory authority to provide genetic-engineering surveillance and to grant approval for the release of live GMO. Violation of its provisions can lead to prosecution under the Environment Protection Act. Figure 2 sets out the framework for regulation.

The import of biological material is controlled by the Ministry of Agriculture, Krishi Bhavan, New Delhi, and the registration of veterinary and pharmaceuticals is controlled by the Department of Health, Nirman Bhavan, New Delhi. Living organisms may not be patented, but products are subject to Indian Patent Law (1970). There are no plant variety rights. The health of workers involved in the manufacture of biotechnology products is safeguarded by regulation.

INDONESIA

At present there are no guidelines for GMO, but the existing regulations, administered by the Ministry of Health for the safety of production and efficacy of products, could be used to control GMO. The Ministry of Justice controls the patents on GMO as well as plant variety rights. Quarantine is controlled by the Ministry of Agriculture and pollution is controlled by the State Ministry for Population and Environment.
FIG. 2

Procedure for the implementation of the guidelines for recombinant DNA work in India
Japan has a centuries-old tradition of using micro-organisms to enhance the flavour, storage life and nutritional value of foods. More recently, it has established a valuable high-technology fermentation industry; it dominates in the production of amino acids and pyrimidines world-wide and is a very important producer of enzymes, antibiotics and therapeutic agents. These industries have a strong research base in universities and institutes and in industry itself. In the period from the mid-1940's to 1970's, mutation and selection of high-yielding strains of micro-organisms were practised and widely applied in industry with no special surveillance or regulation, other than that applying to the efficacy and safety of the product.

Japanese scientists were initially reluctant to embark on extensive research and development projects using recombinant DNA techniques, because of social and ethical issues, the public perception of risk, the lack of expertise in the techniques and the high cost. However, the Council for Science and Technology advised the government that this new technology had great potential benefits, and significant financial support for research in the area began to be provided in 1980. This had been preceded in 1979 by the development of guidelines by the Ministry of Education, Science and Culture (MESC). The Japanese approach was to establish non-statutory guidelines rather than legal regulations and to use its existing funding and regulatory systems to administer the guidelines. The MESC guidelines were based largely on those of the National Institutes of Health (NIH) in the USA, and although non-statutory, any work supported by MESC (universities and research institutes) required compliance as a condition of the grant. These guidelines were amended twice in 1980 and again in 1982. The 1982 guidelines limited the volume of culture to 20 l, but allowed the MESC to give special approval for larger volumes. Guidelines were issued in 1983 by the Science and Technology Agency (STA) for work not supported by the Ministry of Education; these covered both small and large-scale cultures.

As the original concerns about the new technology were shown to be ill-founded, the ministries supervising the development of the bio-industries in Japan — STA, the Ministry of International Trade and Industry (MITI) and the Ministry of Health and Welfare (MHW) — agreed in 1986 to issue revised guidelines reflecting this lowered perception of risk.

MITI's guidelines provided for surveillance of industrial applications, including mining. In defining the conditions for physical containment, they included conditions for Good Industrial Large-Scale Production (GILSP), as well as for more stringent levels of containment, and set out the criteria for assigning GMO to the appropriate containment category.

The MHW provided guidelines for the production of drugs with recombinant organisms. The provisions of these guidelines were similar to those of MITI and included provision for the production under GILSP of nonpathogenic organisms with a long history of safe industrial use.

The STA guidelines for the experimental cultivation of recombinant organisms slightly reduced the requirements regarding physical containment for work on a large scale at the least stringent level, compared with their earlier requirements. They also added thirteen low-risk host/vector systems to their approved list.
It was becoming clear by the mid-1980’s that recombinant organisms would be useful for agriculture. The Ministry of Agriculture, Forestry and Fisheries (MAFF) published provisional guidelines for using recombinant organisms in agriculture, forestry, fisheries, the food industry and other related industries in 1986, and in 1989 the guidelines were published in their final form. These complemented the guidelines published by the STA (1988) on the criteria for greenhouses and net houses for plants.

From this abbreviated history of the development of guidelines in Japan, it is clear that different agencies or ministries have responsibility for surveillance of work with modified organisms, depending on the source of funding and the use of the organisms. This is in contrast to the situation in North America and in most EC countries where one national body develops guidelines which make provision for various applications or scales of operation. The Japanese arrangements have the advantage that the guidelines are administered by the same agency that is responsible for other aspects of the use of the organism. However, it is essential that the various sets of guidelines be internally compatible, and that workers not be required to obtain permits from a multitude of agencies. Whereas this is relatively easy to achieve when the guidelines are first established (as is the case now), in time the various agencies may revise their guidelines, and internal inconsistencies or unforeseen difficulties could arise. Figure 3 shows the framework for research and development in the life sciences.

The essential features of all the guidelines for contained work are that:

- the organism is first assigned to a particular category according to the perceived risk and a level of containment appropriate to that risk is recommended. This judgement is based on the nature of the host organism, donor DNA, its characterisation, and the properties of the constructed organism. Various levels of biological containment are defined;

- the criteria for the various levels of physical containment are provided;

- systems of surveillance at the work place, including the designation of a responsible manager and a biosafety committee, are established along with procedures for health care, the training of personnel and reporting.

The guidelines list the properties of organisms intended for release, which are considered in assessing possible risks. In addition they provide information about the conditions for step-by-step evaluation of the behaviour of the organism in greenhouse, net house and/or simulated model environment (microcosm) for plants or micro-organisms.

KOREA

Although no guidelines for GMO exist at present in Korea, the Director General for Livestock in the Ministry of Agriculture, Forestry and Fisheries will administer them once they are implemented. The same Ministry is responsible for all quarantine matters and for registering veterinary products. Pharmaceuticals are registered under the Pharmaceutical Laws administered by the Ministry of Health and Social Welfare. The Industrial Office of the Ministry of Trade and Industry oversees all patents, and it is considered that this power would enable plant varieties and GMO to be protected.
FIG. 3

The institutional framework for research and development in the life sciences in Japan.
The surveillance of novel biotechnologies follows this framework
MALAYSIA

There are no guidelines at present for GMO, but the import of all biological materials to Malaysia is controlled by the Plant Quarantine Regulations (1981), administered by the Department of Agriculture. The Ministry of Health is responsible for the control and registration of all pharmaceuticals, drugs and vaccines. At present there are no regulations for health and safety at work, nor patent protection for GMO or plant variety rights.

NEW ZEALAND

Soon after the Asilomar Conference in 1975, the New Zealand government conducted an enquiry into the need for surveillance of work with GMO. In 1978 it established an Advisory Committee on Novel Genetic Techniques (ACNGT), administered by the Department of Scientific and Industrial Research. In 1982 ACNGT published guidelines which required all workers in the public sector to establish surveillance committees in-house, notify ACNGT of proposals, seek their advice on containment and limit the volume of cultures to 10 l. ACNGT could also consider, case by case, proposals for large-scale work. Release of live organisms was prohibited and the guidelines were not legally binding for the private sector.

The agricultural industry is essential to the economy of New Zealand, and as it became clear that GMO would have significant benefits for agriculture, a working party was established in 1986 to consider field testing of live modified organisms. In 1988, the Ministry for the Environment published a discussion document, New organisms in New Zealand, which encompassed the proposed procedures and legislation for importing new organisms and for developing, field testing and releasing GMO.

New Zealand already has a good deal of specific legislation directed to protecting or promoting particular sectors of the agricultural industry. The existing Animals Act (1967) and Plants Act (1970), which includes guidelines for insects and microorganisms, are administered by the Ministry of Agriculture and Fisheries (MAF), and these control the importation of exotic organisms to prevent the introduction into New Zealand of plant and animal diseases, noxious or nuisance animals, plants, insects or micro-organisms, and inferior, weak or undesirable strains.

The Plants Act allows post-importation conditions of use to be stipulated, but the Animals Act does not contain these provisions, except for control of disease. Animals can only be controlled by law once they have become established as a feral population; they then come under the Wild Animal Control Act (1977).

The New Zealand government, through the Ministry for the Environment, has prepared a draft bill intended to control the importation of GMO, the construction of GMO in contained systems and their release to the environment. The bill, if passed, will confer statutory powers and sanctions on a commission to be known as the Hazards Control Commission. This Commission will be advised by a technical committee regarding genetic aspects, and will work with MAF on agricultural and environmental aspects. Figure 4 shows the proposed procedure by which a GMO might be considered.
FIG. 4

Proposed pathways for reviewing and approving both the import of novel organisms, and work with GMO in New Zealand
SINGAPORE

In Singapore, permits to import live organisms are issued by the Commissioner of Public Health through the Infectious Diseases Act. The Ministry of Health administers the Medicines Act, which provides for the registration, safety and efficacy of pharmaceuticals, while the Veterinary Division of the Division of Primary Production deals with veterinary products. Safety at work is enforced by the Ministry of Health. Patent protection is based on the model of UK patent laws, but Singapore is currently preparing its own patent law for this area and for a Plant Variety Act.

TAIWAN

Taiwan established its Guidelines for Research Involving Recombinant DNA Molecules in 1978. These are administered by the Council of National Sciences, Executive Yuan. They cover work both on a small scale and with culture volumes > 20 l. Although these guidelines are not legally binding, persons receiving grants from the government must comply with them. The release of GMO and their products to the environment will be controlled in the future by regulations currently being drafted by the ministries responsible for the protection of the environment and human health. Import or use of GMO in animals, for example as vaccines, is controlled via the Law of Animal Drugs, on advice from the Council of Agriculture, which considers each case on its merits, as there are no formal guidelines.

Procedures for processing applications to use GMO in animals are as follows:
1. The research granting body assesses the work according to the Guidelines
2. Work involving field research is further considered by the Council of Agriculture
3. A licence for work with GMO in animals is issued by the Council of Agriculture.

THAILAND

As yet, Thailand has not published guidelines for GMO, but individual workers are encouraged by their institutions to adopt procedures which ensure the safety of workers and the environment. The Ministry of Science, Technology and Energy is now collecting information about the laws and guidelines developed in other countries to assist them in formulating their own surveillance system. The registration of vaccines and therapeutic agents is required by law which is administered by the Department of Livestock. There are quarantine regulations, but no plant variety rights or provisions for patenting GMO.

DEVELOPING A SURVEILLANCE SYSTEM FOR GMO

Many Asian and OECD countries already have systems to monitor the development of novel biotechnologies which can serve as models for other countries. In particular the NIH, UK and OECD guidelines, supplementary notes and position papers have provided great assistance to others who are developing guidelines.
The substance of the guidelines in most countries is very similar. Host/vector systems are assigned to a category of risk, depending on the properties of the host and the donor DNA and the stability of the construct (so called biological containment). Different degrees of stringency in physical containment are defined, and organisms posing potential risks are assigned to the appropriate level of containment. All systems depend heavily upon an in-house biosafety committee to ensure that the recommended procedures and facilities are used and on expert committees to provide advice and to identify any potential hazards associated with the various novel constructs. However, the administrative framework in which the systems operate is different in different countries, varying according to local circumstances.

It is first necessary to decide whether the monitoring system should take the form of non-statutory guidelines linked to an existing legal framework or come under a law peculiar to work associated with the novel technology. The factors to consider in these two approaches are set out below.

**Statutory vs. non-statutory systems**

Special legislation to regulate research and development associated with novel biotechnology has the advantage of providing a clear definition of:

- the scope of surveillance
- the types of construct to be regulated
- the types of work to be undertaken
- process for making decisions
- prohibitions or restraints
- day-to-day surveillance
- ultimate responsibility
- sanctions and appeals
- links with existing legislation.

Furthermore, if the country does not have a well developed infrastructure to regulate biological products generally, special laws may be essential.

The disadvantages are:

- that most countries have existing legislation which regulates the use of biological products (registration of vaccines, pesticides, quarantine, etc.). Novel products of biotechnology can be readily controlled with this legislation. Passing new laws results in costly duplication or even conflicting requirements, whereas the important matter is the safety and efficacy of the organisms or products, not how they are constructed;

- it is difficult to frame legislation to address hazards that have not yet been demonstrated;

- the technology is complex and expanding rapidly, and the law does not respond quickly to innovations;
there is considerable debate as to whether GMO are any more hazardous (and thus merit special legislation) than the organisms from which they were derived;

- employers can require compliance with non-statutory guidelines as a condition of employment;
- grants and tax incentives can be made conditional on compliance with guidelines.

In deciding between these two approaches, other factors which are peculiar to the particular country may be important, for example:

- ethical, religious or moral attitudes;
- whether the country has one central body of law, or a mixture of central and provincial and state laws;
- whether the country has a strong body of environmental law and a tradition of concern and observance among its industrialists and practitioners;
- whether the country has appropriate numbers of scientifically qualified civil servants;
- whether there is a well established code of law to provide citizens with a means of redress for damage they may suffer from the activities of others.

CONCLUSION

Clearly, it is for each country to consider its own special circumstances and decide whether a statutory or non-statutory monitoring system for GMO and other novel procedures suits their needs best. In either case, the expert advice from practising molecular biologists, reproductive specialists and ecologists is an important element of successful surveillance. I believe it is very difficult for scientific administrators to remain at the forefront of molecular biology and other rapidly expanding fields, and at the same time provide the day-to-day administration of the system. Unless the scientific community and practising veterinarians have confidence in the expert advice which guides the administrators, the monitoring systems will fall into disrepute.

ACKNOWLEDGMENTS

It is with much pleasure that I thank the members of the Australian Trade Commission who assisted me greatly by providing information on the regulations prevailing in a number of countries of Asia and Oceania.
Appendix

ADDRESSES OF SOME DEPARTMENTS ADMINISTERING GUIDELINES FOR GMO

Australia
Secretary, Genetic Manipulation Advisory Committee, Department of Administrative Services, PO Box 2183, Canberra, ACT 2601.

India
Dr K. Narayanaswami, Director, Department of Biotechnology, Block 2, 7th Floor, CGO Complex, Lodi Road, New Delhi 110003.

Japan
Mr R. Higashiuchi, Deputy Director, Ministry of Health and Welfare, Tokyo.
Mr H. Hiramatsu, Director, Bio-industry Office, Ministry of International Trade and Industry, Tokyo.
Dr T. Takahashi, M.D., Director, Life Sciences Division, Science and Technology Agency, Tokyo.
Dr S. Tsuru, Secretariat, Council of Agriculture, Forestry and Fisheries, Tokyo.
Prof. H. Uchida, Advisor, University of Tokyo, Tokyo.

OECD

Philippines
Dr Ricardo M. Lantican, National Committee on Biosafety, Department of Science and Technology, DOST Compound, Bicutan, Taguig, Metro Manila.

New Zealand
Dr Lin Roberts, Ministry for the Environment, 84 Boulcott Street, PO Box 10362, Wellington.

Taiwan
Mr Yong-Da Fan, (Department of Biological Sciences), Council of National Sciences, Executive Academy, Building 21, 106 Section 2 Heping (East) Road, Taipei 10636.

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BIOTECHNOLOGIE EN SCIENCE VÉTÉRINAIRE : RÉGLEMENTATIONS EN ASIE ET OCÉANIE. – N.F. Millis.

Résumé: L'auteur présente un résumé des informations disponibles sur l'état des réglementations existant dans quelques pays asiatiques et qui peuvent concerner la recherche et les applications des nouvelles biotechnologies, au domaine des sciences vétérinaires et des industries qui lui sont associées.

MOTS-CLÉS : Asie - Biotechnologie - Législation - Océanie - Réglementation.
Resumen: El autor presenta un resumen de las informaciones disponibles acerca del estado de las reglamentaciones existentes en algunos países asiáticos con respecto a la investigación y las aplicaciones de las biotecnologías más recientes en las ciencias veterinarias y las industrias conexas.

PALABRAS CLAVE: Asia - Biotecnología - Legislación - Oceanía - Reglamentación.