Regulation of biotechnology in the United States and Canada

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Summary: The regulation of biotechnology in the United States and Canada is based on principles that reflect respect for the new technology, yet also recognize that most traditional approaches to regulation, employing sound science and common sense, still apply.

Four specific principles form the framework on which regulatory schemes are based: (1) the products of biotechnology will not differ fundamentally from unmodified organisms or from conventional products; (2) the product rather than the process shall be regulated; (3) regulation should be based on the end use of the product and will be conducted on a case-by-case basis; and (4) the existing laws provide adequate authority for regulating the products of biotechnology.

This report summarizes the regulatory approaches taken in various organisms and products. Special emphasis is given to: (1) issuance of entry permits for genetically-engineered plants and micro-organisms; (2) licensing of genetically-engineered veterinary biological products; and (3) permits for movement and release into the environment.

A three-category classification system is described for dealing with hybridomas and recombinant-derived products, based on their biological characteristics and safety concerns. Categories range from relatively simple inactivated recombinant animal vaccines to products using live vectors to carry recombinant-derived foreign genes that code for immunizing antigens and/or other immune stimulants.

This paper stresses that few fields of contemporary science and technology hold forth more possibilities and greater expectations than biotechnology. It is therefore of utmost importance that animal health officials and scientists ensure that the products of biotechnology will not cause or transmit infectious disease, adversely affect the environment or adulterate food products.

KEYWORDS: Animal health - Biological products - Biotechnology - Diagnostic kits - Genetic engineering - Recombinant DNA - Regulation.

INTRODUCTION

There are key dates in the history of any revolution, and scientific revolutions are no exception. For scientists, the year 1953 was a key date, because in that year

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James Watson and Francis Crick announced their discovery that the structure of deoxyribonucleic acid (DNA) was a "double helix". For government officials and the public at large, however, the significance of this discovery became apparent in the early 1970's, when biologists developed techniques to clone any gene and to transfer genetic material from one species to another. Since the 1970's, in fact, the excitement that accompanied the news of each new breakthrough in molecular genetics was followed by calls for controls on the uses of genetic engineering technology.

The concern expressed by scientists resulted in the now famous international conference on recombinant DNA molecules at Asilomar, California, which in turn led to the publication in 1976 of the first National Institutes of Health (NIH) Guidelines for research involving recombinant DNA molecules (NIH Guidelines).

Some prohibitions contained in the early guidelines were gradually relaxed in the late 1970's, and the level of concern in the scientific community and the public at large also decreased, as laboratory experiments were carried out without incident. Though adherence to the NIH Guidelines has never been mandated by statute, recipients of Federal research funds are required to comply with the guidelines' provisions, and voluntary compliance by industry has been widespread.

US FEDERAL POLICY

Public concern was again aroused in the early 1980's by proposals to test and use genetically-engineered organisms in the environment. The US Congress was also stimulated to reexamine the issues surrounding widespread commercial development of the products of biotechnology. The issues ranged from speculation about the long-term ecological effects of environmental releases of genetically-engineered organisms to warnings that unwarranted restraints on the biotechnology industry would deprive the American public of the benefits of the new technology. In addition, the NIH Guidelines, which were originally written to deal with NIH grantees doing biomedical research in the laboratory, were increasingly proving inadequate to the task of reviewing applications for testing in the environment of the broad spectrum of genetically-engineered organisms and commercial products (49 FR 697, January 5, 1984).

It was in this climate of renewed interest and potential concern that an interagency working group was formed in April 1984 within the Executive Office of the President. The working group's charge included identifying the existing laws and regulations applicable to biotechnology and determining their adequacy for regulating the products of the new technologies. The results of these efforts were first published for public review and comment in December 1984, and in final form in June 1986 as the Coordinated framework for regulation of biotechnology (11 FR 23302-23393, June 16, 1986). This document included an index of laws applicable to biotechnology products in the various stages of research, development, marketing, shipment, use and disposal. This index of laws was published in final form on November 14, 1985 (50 FR 47177-47195).

US Federal policy has been and continues to be based on several conclusions:

1. the products of biotechnology will not differ fundamentally from unmodified organisms or from conventional products
2. the product, rather than the process, should be regulated
3. regulation should be based on the end use of the product and conducted on a case-by-case basis
4. the existing laws provide adequate authority for regulating the products of biotechnology.

An important corollary to this policy is the Federal commitment to promoting the safe development of the products of biotechnology. Each Federal agency is committed to ensuring protection for public health and the environment from any potentially harmful effects of the technology.

The Coordinated framework, published in June 1986, contained final policy statements by the US Federal agencies that share a major responsibility for regulating the products of biotechnology. The agencies are the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) and the US Department of Agriculture (USDA).

It is important to note that the authority of these three agencies for regulating biotechnology is based on statute and that the implementing regulations are published in the US Code of Federal Regulations. In most instances, sanctions for noncompliance with these regulations are based on statutory authority and include administrative, civil and/or criminal penalties. By contrast, the NIH Guidelines have a contractual rather than a statutory basis. In recognition of this fact, and to avoid duplication, the NIH proposed amendments of the Guidelines in December 1986 to provide that if certain experiments are submitted to another Federal agency for approval or official clearance, NIH review is not required (51 FR 45650, December 19, 1986). This amendment, which applies only to experiments covered by Section III-A of the Guidelines, was adopted on August 24, 1987 (52 FR 31848-31849). This discussion, then, will focus on the activities of US Federal agencies with specific statutory authority for regulating biotechnology products.

FDA AUTHORITY AND POLICY FOR REGULATING BIOTECHNOLOGY

FDA, which is part of the Health and Human Services Department of the US Federal Government, regulates foods, human and animal drugs, cosmetics and medical devices under the authority of the Food, Drug and Cosmetic Act of 1938, as amended (the Act). Key amendments to the Act have given FDA authority to require premarket approval of the food and color additives used in food, and premarket safety and efficacy testing for all drugs. While the Act generally limits FDA jurisdiction to products involved in interstate commerce, the latter is broadly defined to include importation and exportation. FDA’s statutory and regulatory authority places the burden of proof of product safety on the manufacturer.

FDA policy is that regulation of products developed through biotechnology should be based on scientific evaluation of products and case-by-case review. FDA does not consider that recombinant-derived products require a special or unique review procedure based on process. FDA’s organizational units review products developed
through many different processes, with attention to scientific concerns, specific tests and "points to consider". "Points to Consider Documents" have been made available on such subjects as interferons, monoclonal antibodies, recombinant DNA-derived products and use of mammalian cell lines. As of January 1989, FDA had approved or licensed over 200 monoclonal antibody-based diagnostic kits and half a dozen each of therapeutic drugs and recombinant DNA probes for infectious agents. In addition, FDA's Center for Food Safety and Applied Nutrition has filed three Generally Recognized as Safe (GRAS) affirmation petitions for products developed using genetically-engineered micro-organisms.

Some FDA actions, including food additive and GRAS affirmation petitions, are subject to the requirements of the National Environmental Policy Act of 1969, or NEPA, as amended, and require production of an assessment of the risk to human health and the environment before approval is granted for marketing (50 FR 16636, April 26, 1985). Such assessments examine the alternatives to a given action and evaluate data on the potential risks of the favored alternatives.

USDA REGULATION OF BIOTECHNOLOGY

USDA organization

USDA has major responsibilities both for research in agricultural biotechnology and for regulating genetically-engineered organisms and products. A delegation of authority by the Secretary of Agriculture published on July 19, 1985 (50 FR 29367-29368) assigned responsibility for USDA biotechnology research activities to the Assistant Secretary for Science and Education, and responsibility for Departmental regulation of biotechnology to the Assistant Secretary for Marketing and Inspection Services. The USDA research agencies engaged in biotechnology research include the Agricultural Research Service (ARS) and the Cooperative State Research Service (CSRS). The USDA regulatory agencies directly concerned with biotechnology regulation are the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS).

The Committee on Biotechnology in Agriculture (CBA), co-chaired by the Assistant Secretary for Science and Education and the Assistant Secretary for Marketing and Inspection Services, functions as a policy-making body and a coordinating body for jurisdictional matters within the Department. It reports to the Secretary of Agriculture on internal matters, and to the Biotechnology Science Coordinating Committee (BSCC) on matters of overall Federal policy for biotechnology.

The Office of Agricultural Biotechnology (OAB) has been established as a focal point for USDA in the development of policies and procedures for agricultural biotechnology research. The OAB coordinates reviews of the environmental safety of proposed research involving genetically-engineered organisms. The OAB also provides staff support for the CBA and the Agricultural Biotechnology Research Advisory Committee, a committee established by the Department to review research proposals and guidelines, and to provide scientific advice on biotechnology matters, as required, to research and regulatory agencies.
APHIS has established the Biotechnology, Biologics and Environmental Protection (BBEP) component and, within that component, the Biotechnology, Coordination and Technical Assistance (BCTA) staff coordinates biotechnology regulatory activities within USDA. BCTA assures that biotechnology applications and environmental assessments are handled on a case-by-case basis, and also takes the lead in liaison between APHIS and other Federal agencies on biotechnology regulatory matters.

The Biological Permit Unit (BPU) and the Veterinary Biologics staff are also within BBEP. BPU is responsible for issuing permits for the field testing of genetically-engineered plants and micro-organisms. Among other responsibilities, the BPU reviews and processes permit applications under 7 CFR 340; maintains liaison with State departments of agriculture, the academic community and scientific societies; and provides technical information for environmental analysis for permits allowing field testing of regulated articles. The Veterinary Biologies staff issues licenses for veterinary biologies produced through biotechnology. The Environmental Document staff assures that APHIS's biotechnology regulatory activities are in compliance with environmental statutes.

There has been a rapid expansion in the number of release applications made to BBEP. Since the publication of our regulations in July 1987, there have been 477 approved movement permits and 54 release permits. In the latter category, fifty were for genetically-engineered plants, three were for engineered endophytic bacteria, and one was for a live virus-vectored recombinant vaccine. Based on the current influx of applications, we predict that the number of applications we will consider in 1990 will be roughly triple the number in 1988. The release applications to BBEP encompass an ever-increasing variety of engineered plant species, including tobacco, tomato, soybean, poplar, cotton, potato, alfalfa and rice, and modifications that have been, or are being, field tested involve traits such as resistance to viruses, insects or herbicides, and alterations in metabolic or ripening parameters. The increasing complexity of the modifications and the range of organisms modified dictate that we must be concerned not only with potential subtle effects on the organism directly modified, but also with effects on other organisms in the surrounding environment.

As more genetically-engineered products move toward commercialization, it becomes increasingly important to consider environmental effects of individual modifications in the context of large-scale introductions. Much valuable information about such effects comes back to the Agency after field tests, as a result of conditions attached to the permits for small-scale tests themselves.

Collection of field data during the trial about particular growth or dispersal properties of a given modified organism is often required. Such information, along with constant monitoring of new developments in, and uses for biotechnology, will be essential for our regulations to remain adequate to ensure safe testing of genetically-engineered organisms in the environment.

USDA authority

USDA has broad regulatory authority to protect US agriculture against threats to animal health, to protect against the adulteration of food products made from livestock and poultry, and to prevent the introduction and dissemination of plant pests. This authority is applicable to genetically-engineered animals, plants and micro-organisms.
Animal health

In the area of animal health, the Virus-Serum-Toxin Act (VSTA) of 1913, as amended, provides USDA’s APHIS with the authority to regulate all veterinary biologicals that are imported into the United States, shipped or delivered for shipment interstate, intrastate and for export. USDA also has enforcement mechanisms such as the power to detain and seize products. The VSTA is administered by APHIS in the same manner for genetically-engineered and naturally-occurring organisms and products. APHIS issues US Veterinary Biological Product Licenses after satisfactory completion of all requirements to assure purity, safety, potency and efficacy. Veterinary biological products produced by recombinant methods are evaluated on a case-by-case basis using the same stringent standards for licensing employed for conventionally produced biologicals.

The APHIS application procedure for licensing veterinary biological products requires that an “outline of production” describing the procedures used to produce each serial of a product accompany each application. For recombinant-derived products, the manufacturer must provide the specific cloned nucleotide segment coding for the product or other DNA segments. Licensees are required to establish a Master Seed of bacteria, viruses or other micro-organisms at a specific passage level to be used as the source of seed materials. Immunogenicity of vaccines must be supported by statistically valid host animal immunization, challenge and safety studies. Firms are required to show that they can produce each product in a consistent manner. Three consecutive satisfactory serials of a product must be produced in the licensed production facility. To confirm results, samples are sent to the National Veterinary Services Laboratories in Ames, Iowa, for testing.

A three-category classification scheme for hybridomas and recombinant-derived products based on biological characteristics and safety concerns was published in the Federal Register as a part of the final USDA policy statement on biotechnology in June 1986 (51 FR 23339, June 26, 1986).

- The first category includes inactivated recombinant DNA-derived vaccines, bacterins, bacterin-toxoids, virus subunits or bacterial subunits. These non-viable or killed products pose no risk to the environment and present no new or unusual safety concerns. Monoclonal antibody (hybridoma) products used prophylactically, therapeutically or as components of diagnostic kits are included in this category.

- The second category includes those products containing live micro-organisms that have been modified by the addition or deletion of one or more genes. Precautions must be taken to ensure that the addition or deletion of specific genetic information does not impart increased virulence, pathogenicity or survival advantages in these organisms which are greater than those found in natural or wild-type forms. Modifications must not impart undesirable new or increased adherence or invasion factors, colonization properties or intrahost survival factors.

The genetic information to be added or deleted must consist of well-characterized DNA segments. Required licensing data may include base pair analysis, sequence information, restriction endonuclease sites and phenotypic characterization of the altered organism. A comparison is also required between the genetically-engineered organism and the wild-type form for factors affecting pathogenicity.
The third category includes products using live vectors to carry recombinant-derived foreign genes that code for immunizing antigens and/or other immune stimulants. Live vectors may carry multiple recombinant-derived foreign genes because they can carry large quantities of new genetic information.

APHIS has issued 38 licenses for veterinary biological products manufactured from biotechnological processes. Thirty-three are from Category I, which includes bacterins (5), monoclonal antibodies for therapeutic or prophylactic use (2) and diagnostic kits (26). These Category I products have been used successfully since the first, a bacterin, was licensed in October 1983. Three Category II product licenses have been issued, all for recombinant-derived pseudorabies virus vaccines for use in swine. APHIS is currently reviewing a field test authorization application for a genetically-engineered live vaccinia virus vaccine which expresses the glycoprotein of rabies virus.

Before approval is granted for field testing or licensing of Category II and III live virus vaccines derived through recombinant DNA techniques, APHIS conducts an environmental analysis of the proposed action in accordance with the provisions of NEPA and Departmental regulations. The availability of resulting environmental documents is announced to the public through publication in the Federal Register. The environmental assessments provide the public with a discussion of scientific data on safety and a thorough analysis of environmental impacts.

Other authority

No biological materials of animal origin such as cell cultures, monoclonal antibodies, organisms, vectors or related material may be imported without a permit from USDA. The VSTA and general animal quarantine laws also provide APHIS with the authority to regulate transgenic animals that may pose a risk to animal health. This authority is strengthened by Executive Order 11987 of May 24, 1977, which provides executive agencies with authority to restrict the introduction of exotic species into the natural ecosystem of the United States.

FSIS

The Federal Meat Inspection Act and Poultry Products Inspection Act provide FSIS with the authority to regulate livestock and poultry used for research in order to prevent the possible adulteration of food products made from them. The regulations require that before livestock or poultry used in research can be slaughtered in an official establishment, data must be submitted to demonstrate that use of a biological product, animal drug or chemical will not result in the adulteration of the resulting food products.

THE IMPLICATIONS OF BIOTECHNOLOGY AND ITS PRODUCTS TO ENHANCE ANIMAL HEALTH WITHOUT ADVERSE EFFECTS ON THE ENVIRONMENT

Regulatory agencies throughout the world either have or will be faced with the difficulty of developing a supervisory system for biotechnology products that will protect the public interest and environment yet be flexible and efficient so that product
development will not be inhibited. Biotechnology products for veterinary medicine do not differ significantly from products produced by conventional methods. The emphasis is on the product and its intended use rather than the method used in development. In the United States, procedures have been developed to facilitate the movement of live genetically-engineered biological products from stringent containment levels through a series of both biological and physical constraints to ensure that veterinary biological products remain safe, pure, potent and efficacious.

The diagnostic tests used in veterinary medicine and derived from biotechnological processes vary in complexity from highly sophisticated tests using automatic equipment to simple "litmus test-like" tests for use in the field. More and more, however, the trend is towards simple-to-use kits which combine specificity and sensitivity with speed and economy. Although the principles and technology involved in the development of these tests may be highly sophisticated, they can be used by people without specialized training or equipment.

There are many questions raised by the use of this technology. How will their use be regulated? No doubt that within the next decade large livestock producers will have the capability to determine the infectious and genetic disease profile on their own farms. They will then be able to ask their own computers for the options on how to handle the disease problem on their farm. One question is certain to come up: how will the diagnoses generated by these "on the farm" probes and monoclonal antibody kits be reported? Needless to say, the veterinary practitioner and disease control officials will be required to interpret the total health/disease picture on a farm, but biotechnology will raise some thorny issues.

Biotechnology has made possible the commercial use of bovine growth hormone (bGH, now called bovine somatotropin) to increase milk production. Two US companies have applied for approval from the FDA for its use. It is anticipated that there will be some consumer resistance in the United States and in other countries to dairy products that are derived from bovine somatotropin.

In an Associated Press report (May 1, 1985), R.J. Kalter of Cornell University said "bGH will be a mixed blessing". He estimated that the national dairy herd could drop 30% from 11.2 million to 8 million cows if bGH is used extensively. Kalter further warned that increases in milk production through the use of bovine growth hormone will result in a fall in milk prices and the number of dairy cows and dairy farms will have to decline substantially to restore market equilibrium. Kalter pointed out that "few policy makers are considering the broad impact of biotechnology, and little research in this area is underway".

The development of transgenic animals that are more efficient in utilizing feed, having leaner meat, and growing to market size quicker, as well as being immune to important diseases are intriguing possibilities. While the potential uses of transgenic animals are exciting, the regulation of introduced genes needs careful study.

The US Patent Office has recently ruled that new animals altered or mutated by genetic engineering or other scientific techniques are patentable. The April 1987 ruling allows protection for man-made animals no matter how they are made. The issue of whether or not transgenic animals should be patented and the effect on worldwide agriculture is currently being debated. Legislation has been introduced in the US Congress which permits farmers to breed and sell the offspring of patented genetically-engineered farm animals, without permission or payment to the patent
owner. While this may allay apprehensions of being required to pay patent royalties, the proposed law very possibly may discourage further research investment in genetically-engineered farm animals. Researchers should be aware of some current public perceptions of transgenic animal research, i.e. the creation of Frankenstein-like monsters or cows as big as elephants are figments in the imaginations of cartoonists and alarmists.

All biotechnologists must assume a greater responsibility for communicating the benefits to world-wide food animal production by transferring genes coding for economically important traits from one species to another. On the other hand, scientists must be certain that transgenic animals will not (1) cause or transmit infectious diseases, (2) adversely affect the environment or (3) adulterate food products.

Due to the broadly multidisciplinary aspects of biotechnology, communication between scientists and countries is an absolute necessity. This was pointed out in the recent publication, *Guidelines for the use and safety of genetic engineering techniques or recombinant DNA technology* (IICA, PAHO, OAS, OIE; 1989):

"Few fields of contemporary science and technology hold forth more possibilities and greater expectations than biotechnology."

"That potential alone is more than enough to justify that the term 'biotechnology' appear in the future planning and strategies of an ever-growing number of agencies and institutions. Similarly, it justifies that, in undertaking biotechnological activities, agencies and institutions orchestrate their work and, together, seek to achieve a maximum effect."

**COORDINATION**

Intra-agency and interagency coordination has been a key element in the successful implementation of the US Federal policy for regulating biotechnology. Within USDA, coordination has been achieved at the administrative level through the activities of the Committee on Biotechnology in Agriculture. Interagency coordination of policy issues has been assigned to the Biotechnology Science Coordinating Committee, which includes high level representation from each Federal agency with research or regulatory authority for biotechnology. The preparation of policy documents on biotechnology safety issues by US Federal agency representatives for presentation to the Organization for Economic Cooperation and Development has also fostered cooperation and communication.

The success to date of the US Federal regulatory effort to promote the safe development of products developed through biotechnology has been verified in assessments prepared by the US Office of Technology Assessment (May 1988) and the US Government Accounting Office (June 1988).

**CONCLUSION**

USDA/APHIS will continue to provide the resources necessary to review field test and product applications for genetically-engineered organisms on a case-by-case
basis, and to provide a thorough analysis of any potential effects of such organisms on the human environment. We feel that the procedures that have been established for conducting these reviews and analyses are reasonable, both from the perspective of the applicant and the concerned public. The information gained from the first field tests and product approvals is of vital importance to the future development of safe and beneficial products. It is in the interest of all concerned to maintain the relationship developed during this first stage of testing among industry, government, the research community and public interest groups on an international basis. Furthermore, the US is committed to promoting national and international harmonization and cooperation in the development and regulatory supervision of biotechnology activities.

Therefore, I would urge the members of this organization to endorse harmonization of national guidelines and regulations of biotechnological products as a long-term goal and establish a work program embodying the following objectives:

1. develop harmonization of biotechnological guidelines and regulations and measures on the basis of appropriate standards established by the International Office of Epizootics (OIE);

2. ensure that measures taken to protect human, animal or plant life or health are consistent with sound scientific evidence and use suitable principles of equivalency;

3. review existing notification and counter-notification procedures to ensure transparency and the existence of an effective notification process for national regulations and bilateral agreements;

4. develop a consultative process which ensures transparency and allows opportunity for the bilateral resolution of disputes;

5. for the OIE, as the leader for international veterinary cooperation, to work with the GATT to develop a stronger approach in the enhancement of the harmonization of guidelines and regulation of the products derived from biotechnology.

Appendix

CANADIAN REGULATION OF BIOTECHNOLOGY

The Canadian Government has adopted a similar approach for the regulation of biotechnology to that used in the United States. First, it is the product/organism that is regulated. Second, current statutes are deemed adequate to accommodate biotechnology products, with specific regulations and guidelines being developed to cover future needs and the specific requirements of the products of biotechnology. These products are regulated under the mandates of three federal departments: Agriculture Canada, Environment Canada, and Health and Welfare Canada. Third, the development of a coordinated approach to the regulation of biotechnology products is a primary objective.

This coordination has several levels: (1) between federal agencies; (2) internationally; (3) between the federal government and the provinces; and (4) scientifically with the same generic requirements for environmental release from each of the three agencies.
Development of biotechnology policy in Canada began in 1980 when the Ministry of State for Science and Technology (MOSST) established a Task Force on Biotechnology. Out of this task force several recommendations were made in 1983 which were collectively called the National Biotechnology Strategy. One of these recommendations initiated the establishment of the National Biotechnology Advisory Committee to provide input on policy development from representatives of industry and university and federal government departments. In addition, a federal Interdepartmental Committee was formed to coordinate activities affecting international, scientific, budgeting and regulatory issues.

The Bio-tech regulations user's guide to federal regulation on biotechnology was published by the three key regulatory departments out of a working group formed by the Interdepartmental Committee. This guide summarizes the mandates of the three departments, gives the products regulated and requirements for these products, and names and telephone numbers of contact persons. There are several other publications which describe the philosophy and regulations of biotechnology products published by the Canadian government. These are Guidelines for the regulation of veterinary biologics produced by biotechnology and Workshop on regulation of agricultural products of biotechnology. The Animal and Plant Health Inspection Service of the US Department of Agriculture and Agriculture Canada have sponsored three joint workshops with participants from many different federal agencies and departments on the regulation of agricultural products of biotechnology. This working relationship has had a positive influence on the similarity of approach to regulation by the two countries.

Canadian federal regulatory agencies have a working definition of biotechnology as follows: “the application of science and engineering to direct or indirect use of living organisms, parts of organisms or products of organisms in their natural or modified forms to provide goods and services.” Genetically-engineered products/organisms have necessitated the development of alternative or additional information requirements before approval of products for environmental application will be granted. Field-trial approval is granted on a case-by-case basis. Evaluation of data obtained from field trials is deemed necessary before granting a product approval. Interestingly, one of the criteria under consideration is that of comparing the benefits of the genetically-engineered product with those of other approaches to the same product use.

Specifically, over 90% of veterinary biologic products used in Canada come from the United States. These are regulated by the Animal Health Division of Agriculture Canada under the Animal Disease and Protection Act. The proposed guidelines for the licensing of biotechnology veterinary biologicals have followed procedures and methods of the United States with some modification.

In particular, where the United States has three licensing categories, Canada has two. Class II contains vaccines using a live vector carrying recombinant derived foreign genes or vaccines containing foreign DNA. Class I contains all other biotechnology biologic products. The acceptance and exchange of all agriculture products of biotechnology between Canada and the United States have been part of the technical discussions accompanying the Free Trade Agreement of 1989.

Résumé : La réglementation américaine et canadienne concernant les biotechnologies repose sur des principes qui reflètent un respect certain pour les nouvelles technologies, tout en reconnaissant la validité de la plupart des approches réglementaires traditionnelles fondées sur la rationalité scientifique et le bon sens.

Quatre principes spécifiques étayent les schémas réglementaires : 1) les produits issus de la biotechnologie n’apparaissent pas radicalement différents des micro-organismes vivants non modifiés ou des produits de fabrication classique ; 2) la réglementation doit porter plutôt sur le produit que sur le procédé ; 3) la réglementation doit être axée sur la destination finale du produit et être envisagée cas par cas ; 4) les lois existantes confèrent l’autorité nécessaire pour réglementer les produits de la biotechnologie.

Les auteurs récapitulent les approches réglementaires s’appliquant aux différents micro-organismes et produits, en mettant l’accent sur : 1) la délivrance de licences d’importation pour les végétaux et les micro-organismes obtenus par génie génétique ; 2) l’autorisation de mise sur le marché des produits biologiques vétérinaires préparés par génie génétique ; 3) les autorisations nécessaires pour le transport de ces produits et leur libération dans l’environnement.

Un système de classification en trois catégories est décrit pour les hybridomes et les produits obtenus par recombinaison de l’ADN, sur la base de leurs caractéristiques biologiques et des critères de sécurité. Ces catégories vont des vaccins recombinants inaktivés à usage vétérinaire, relativement simples, aux produits faisant appel à des vecteurs vivants porteurs de gènes recombinants étrangers codant pour des antigènes immunisants et/ou d’autres immunostimulants.

Cet article montre que peu de domaines scientifiques actuels recèlent davantage de potentialités et d’espoirs que la biotechnologie. Il est donc primordial que les autorités responsables de la santé animale et les scientifiques travaillant dans ce domaine veillent à ce que les produits biotechnologiques ne soient pas cause de propagation ou source de maladies infectieuses, ne soient pas nocifs pour l’environnement et n’affectent pas les produits alimentaires.

MOTS-CLÉS : ADN recombinant - Génie génétique - «Kits» de diagnostic - Produits biologiques - Réglementation - Santé animale.

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Resumen: La reglamentación relativa a las biotecnologías en los Estados Unidos y Canadá se basa en principios que reflejan el respeto por las nuevas tecnologías al mismo tiempo que reconocen la validez de la mayoría de enfoques reglamentarios tradicionales que aplican el raciocinio científico y el buen sentido.

Cuatro principios específicos constituyen el marco de base de los esquemas reglamentarios: 1) los productos de la biotecnología no difieren fundamentalmente de los microorganismos vivos no modificados ni de los
productos convencionales; 2) la reglamentación debe referirse más bien al producto y no al procedimiento; 3) la reglamentación debe considerar el destino final del producto y estudiarse caso por caso; 4) las leyes existentes confieren la autoridad necesaria para reglamentar los productos biotecnológicos.

El presente informe recapitula los enfoques reglamentarios que se aplican a los diferentes microorganismos y productos, subrayando: 1) el otorgamiento de licencias de importación de plantas y microorganismos obtenidos por ingeniería genética; 2) la autorización de comercialización de los productos biológicos veterinarios preparados por ingeniería genética; 3) las autorizaciones necesarias para su transporte y liberación en el medio ambiente.

Se describe un sistema de clasificación en tres categorías para los híbridos y los productos obtenidos por recombinación del ADN en base a sus características biológicas y a criterios de seguridad. Dichas categorías abarcan desde vacunas recombinantes inactivadas para uso veterinario, relativamente simples, hasta los productos que utilizan vectores vivos portadores de genes recombinantes extranjeros que codifican los antígenos inmunizantes y/u otros inmunostimulantes.

Este artículo hace hincapié en que pocos son los campos científicos actuales que ofrecen mayores posibilidades y esperanzas que la biotecnología. Es pues primordial que las autoridades responsables de la sanidad animal y los científicos que trabajan en este campo se aseguren de que los productos biotecnológicos no causen ni transmitan enfermedades infecciosas, no sean nocivos para el medio ambiente y no alteren los productos alimenticios.

PALABRAS CLAVE: ADN recombinante - Ingeniería genética - Kits de diagnóstico - Productos biológicos - Reglamentación - Sanidad animal.