The role of international and regional organisations in the regulation of veterinary biologicals

J. BLANCOU * and M. TRUSZCZYNSKI **

Summary: The authors discuss the role played by international and regional organisations in the registration and testing of veterinary biological products.

International organisations which contribute significantly to this field include the Office International des Epizooties (OIE) – through the work of the Standards Commission and the publication of the Manual of standards for diagnostic tests and vaccines –, the Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organisation (WHO) – through the work of the Joint FAO/International Atomic Energy Agency (IAEA) Division of Nuclear Techniques in Food and Agriculture in standardising enzyme-linked immunosorbent assay (ELISA) techniques, as well as through WHO Expert Committees.

In Europe, the most important regional organisations are the European Commission and the European Pharmacopoeia. In the Americas, the most significant contribution is made by the two specialised institutes of the Pan American Health Organisation (namely INPPAZ [Pan American Institute for Food Protection and Zoonoses] and PANAFTOSA [Pan American Foot and Mouth Disease Centre]), and by the Inter-American Institute for Cooperation in Agriculture. In Africa, PANVAC (the Pan-African Veterinary Vaccine Centre) continues to perform valuable work in testing veterinary vaccines. For the industrialised countries, the Organisation for Economic Co-operation and Development (OECD) is involved in the regulation of biotechnology products and in standardising 'good laboratory practice' for vaccine manufacture.

A table is presented which summarises and compares the respective roles of these organisations in the harmonisation of licensing and testing procedures, the distribution of reference reagents, vaccine testing and the creation of vaccine banks.


INTRODUCTION

Each nation has, or should have, a range of legislation which regulates the control, sale and use of veterinary medicinal products. Almost all of this legislation stipulates 'minimum requirements' for quality, innocuity and efficacy of veterinary biologicals.
(mostly vaccines), which are to be tested at independent laboratories, usually under state supervision.

Legislation and tests may differ from one country to another, and imply costs and restrictions for all involved, namely producers, users and testers.

The idea of harmonising testing procedures to simplify and reduce costs on a regional, or even world-wide scale is not new, and much has been accomplished in the past twenty years towards achieving this goal.

The purpose of this paper is to review the situation in the 1990s by describing the role of international and regional organisations in the regulation of veterinary biologicals.

In this paper, the term ‘international organisation’ refers to an organisation concerned with animal health on a world-wide scale. Such bodies include the Office International des Epizooties (OIE) and the twin United Nations specialised organisations, the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO).

Non-governmental associations which aim to harmonise activities in the control of biologicals are not considered in this study. The best known association of this nature is the International Association of Biological Standardisation (IABS), which was founded in 1955 to bring together state controllers, manufacturers and research workers interested in the control and standardisation of biological products. Since 1955, the IABS has organised more than seventy congresses and published over seventy books. In 1992, the IABS co-organised a meeting entitled ‘The First Steps towards an International Harmonisation of Veterinary Biologicals’, which was held in Ploufragan, France (1, 9).

ROLE OF INTERNATIONAL ORGANISATIONS

Office International des Epizooties

The OIE was founded in Paris in 1924 as the world organisation for animal health.

The three principal aims of the OIE are as follows:
- to provide information on animal health world-wide
- to promote international coordination of research into, and control of, certain animal diseases
- to harmonise import and export regulations for animals and animal products at an international level.

A measure of the development and growing recognition of the OIE is that there are now more than 140 Member Countries, compared to the twenty-eight founding countries in 1924. The OIE operates under an International Committee, composed of Delegates of Member Countries under the leadership of an elected President. The Central Bureau, located at the OIE headquarters in Paris, implements the decisions of the International Committee and of various Commissions.

There are five Regional Commissions for the following regions: Africa; the Americas; Asia, the Far East and Oceania; Europe; and the Middle East.

Within the OIE, there are also four ‘specialist commissions’ dealing with the following areas: International Animal Health Code; Standards; Foot and Mouth Disease and Other Epizootics; and Fish Diseases (including diseases of crustaceans and
molluscs). In addition, four OIE Working Groups deal with veterinary drug registration, biotechnology, animal health information systems and wildlife diseases. The first two of these Working Groups inform OIE Member Countries regarding problems linked to the registration and control of biologicals, and in 1991 the Working Group on Biotechnology published recommendations on the use of genetically-engineered vaccines.

The International Animal Health Code Commission draws up animal health recommendations for the import and export of animals and animal products. The Standards Commission establishes standards for diagnostic methods (including diagnostic preparations) and vaccines. The Commission for Foot and Mouth Disease and other Epizootics contributes to the development of vaccines and eradication strategies to combat foot and mouth disease (FMD). The Fish Diseases Commission aims to establish standards for diagnostic methods and vaccines applicable to diseases of fish. This brief description shows that all the specialist commissions are interested in international harmonisation and standardisation of vaccines.

The specialist commission most closely connected with standardisation is the Standards Commission (9), the terms of reference of which involve participation in the standardisation of biological products, including vaccines used for prophylactic purposes. This aim is supported by the preparation of the OIE Manual of standards for diagnostic tests and vaccines and the organisation of Reference Laboratories for many of the diseases contained in OIE Lists A and B.

The purpose of the Manual (6) is to facilitate the use of uniform diagnostic procedures relevant to international trade in animals and animal products in veterinary laboratories throughout the world, and also uniform methods for evaluating biological products. The idea is that once procedures are standardised, laboratories can 'speak the same language', a prerequisite for international trade in animals and animal products.

The Manual was first published in three volumes, each covering approximately thirty diseases of OIE Lists A and B. These volumes were subsequently revised and combined to form a single volume, published in 1992. The Standards Commission plans to produce an updated edition every four years; the next edition is due in 1996.

The Manual, which has been distributed throughout the world, recommends 'prescribed tests' for diagnosis and requirements for biological products for use against OIE Lists A and B diseases. This publication has undoubtedly helped OIE Member Countries to follow an internationally unified approach to the diagnosis and immunoprophylaxis of these diseases.

However, full standardisation of vaccine testing can be achieved only when the necessary standards have been devised. It is hoped that the goal of standardisation and wide availability of standards will be reached through the participation of OIE Reference Laboratories.

These laboratories fulfil a specific function, or range of functions, related to the diagnosis of infectious diseases of animals (especially the most important diseases causing heavy economic losses). Laboratories are designated by the OIE International Committee.

The functions and responsibilities of experts at OIE Reference Laboratories include the following:
- provision of a centre of excellence in a designated activity
- standardisation of methods
- preparation, storage and distribution of standard antisera, antigens and other reagents
- development of new methods
- provision of consultancy assistance to the OIE
- training in the designated activity
- organisation of scientific meetings on behalf of the OIE
- coordination of collaborative studies
- assistance to the OIE in collecting and disseminating specific information.

At present, ninety-seven experts are employed in OIE Reference Laboratories throughout the world, several of whom are involved directly in preparing reagents for evaluating immunity following infection with, or vaccination against, the following diseases: FMD, rinderpest, contagious bovine pleuropneumonia, bluetongue, African horse sickness and classical swine fever (List A); and Aujeszky's disease, rabies, paratuberculosis, brucellosis, equine infectious anaemia, infectious bovine rhinotracheitis, enzootic bovine leukosis and infectious arteritis of horses (List B).

**Food and Agriculture Organisation of the United Nations**

The FAO was created in 1945, with headquarters in Rome, and is responsible for agricultural development and food production. The Animal Production and Health Division (AGA) of the Agriculture Department of the FAO is concerned with livestock development. Within AGA itself, the Animal Health Service (AGAH) has the principal function of assisting FAO member countries in the control of animal diseases, with the objective of improving livestock production as an integral component of general social, economic and agricultural development (2).

The FAO is not directly involved in testing vaccines for veterinary use, although AGAH is currently preparing the *FAO Veterinary vaccines manual*. Nevertheless, the following auxiliary services can be asked to intervene on matters related to veterinary vaccines:

*a) Codex Alimentarius* operates the United Nations Joint FAO/WHO World Food Standards Programme. This global intergovernmental body was established almost thirty years ago to promote standards to facilitate international trade in food commodities. The work of Codex Alimentarius is governed by the Codex Alimentarius Commission (which meets every two years), the Secretariat of which is based at the FAO headquarters in Rome. The ‘World Consultation of the Animal Health Industry’ (COMISA) was organised in 1987 to provide, among other things, a means of communication between the world-wide animal health products industry, the Codex Alimentarius Commission and JECFA (the Joint Expert FAO/WHO Committee on Food Additives).

To date, Codex Alimentarius and its various committees have made no examination of veterinary immunological products (vaccines). However, if use of a vaccine should ever result in hazardous residues in food, this organisation could determine the precautions necessary to protect human health.

*b) The Division of Nuclear Techniques in Food and Agriculture* is operated jointly by the FAO and the International Atomic Energy Agency (IAEA), and is based in Vienna, Austria. The Animal Production and Health Section of this Division helps Veterinary Services and research institutes in developing countries to establish radio-
immunoassay (RIA) and enzyme-linked immunosorbent assay (ELISA) techniques, and provides deoxyribonucleic (DNA) probes for diagnosis and surveillance of animal diseases.

This programme is implemented by the Animal Production Unit at the IAEA Laboratories in Seibersdorf (near Vienna). The Unit is responsible for the development, production and distribution of standardised kits for diagnostic tests and serological surveillance, in collaboration with institutes which have internationally-recognised expertise in a given disease. In 1992, this Unit was designated as an OIE Collaborating Centre for ELISA and Molecular Techniques in Animal Disease Diagnosis.

Linked to this activity is a quality assurance scheme for ELISA kits, under which laboratories in receipt of FAO/IAEA ELISA kits are required annually to test a batch of serum samples, and to forward the results to IAEA to ensure that the kits are performing correctly.

At present, kits and protocols for diagnosis or surveillance of a number of major epizootic diseases are available or are being developed by the laboratories at Seibersdorf. Since 1990, the Division has been conducting an extensive survey of the serological response of African cattle to vaccination against rinderpest.

World Health Organisation

The WHO is another specialised United Nations agency, created in 1946 with headquarters in Geneva. The general objective of the WHO is to bring to all people the highest possible quality of health, including the specific aim of promoting the adoption of international standards for food, biological and pharmaceutical products.

The WHO is not directly involved in standardising or testing vaccines for veterinary use. However, some of its departments and divisions (e.g. Biological Standardisation, Veterinary Public Health, Food Safety) could become involved in work on a pathogen which is transmissible to human beings (i.e. zoonoses, toxins in food). The following texts have been prepared by WHO Expert Committees, in certain cases in close collaboration with the IABS:

- The WHO Expert Committee on Biological Standardisation has issued general documents on standardisation, which could apply to veterinary vaccines, including the most recent report for 1992 (10). The WHO catalogue entitled *Biological substances: international standards and reference reagents* (latest edition dated 1990) contains a list of some reference reagents for sera and vaccines against zoonoses (botulism, brucellosis, rabies) and against certain diseases confined to animals (e.g. canine distemper, classical swine fever, Newcastle disease).

- Certain WHO texts apply to specific diseases common to human beings and animals, notably brucellosis and rabies. For example, chapters on veterinary vaccines against brucellosis are contained in the reports of the Joint FAO/WHO Expert Committee on Brucellosis (3), and chapters on veterinary vaccines against rabies are contained in the Eighth report of the WHO Expert Committee on Rabies (11).

In every case, the WHO and OIE take care to ensure that the texts issued by both organisations are complementary (and not contradictory), and that reference reagents distributed by both organisations are of uniform quality.
ROLE OF REGIONAL ORGANISATIONS

Many regional organisations are involved in testing vaccines for veterinary use, whether in the drafting and application of regulations, in setting up testing facilities, or in the distribution of laboratory reagents (see Table I).

Some of these regional organisations are listed below.

Europe

Two organisations are active in the regulation and testing of vaccines for veterinary use:

a) The Commission of the European Union (formerly European Community), established in 1965, has special working groups on matters related to veterinary immunological preparations. The European Commission (EC) has already published many general and specific documents on vaccine production and testing, as well as on the harmonisation of procedures (1); these documents are applicable to Member States of the European Union.

b) The European Pharmacopoeia is a body created (under the aegis of the Council of Europe) by a treaty signed in 1964 by eight nations (six Member States of the European Community, plus the United Kingdom and Switzerland). The number of signatories has now increased to nineteen (twelve from the European Union, six from the European Free Trade Area, plus Cyprus), in addition to representatives from the EC. Five Eastern European countries are represented by observers (Hungary, Poland, Bulgaria, Czech Republic and Slovak Republic). Canada has also requested observer status.

The contracting parties have made the following undertakings:

a) to elaborate progressively a standard pharmacopoeia which will be common to the countries concerned;

b) to take the necessary measures to ensure that the monographs which constitute the European Pharmacopoeia will become the official standards applicable within the respective countries.

Countries of the Central and Eastern European Region (Belarus, Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Russia, Slovak Republic, Ukraine) have no common organisation for the regulation and testing of veterinary vaccines or other biologicals used in veterinary medicine. Every new vaccine or other biological product developed in one of these countries or imported from another country has to be registered in accordance with the legislation in force in the country where the product will be used. The necessary tests and investigations are generally performed in state laboratories or national veterinary institutes. The data obtained are sent to the Commission for Veterinary Drugs in each country, acting within the framework of the Ministry of Health. When the data necessary for registration are satisfactory, the Commission for Veterinary Drugs gives a favourable assessment to the Minister of Health and the product is registered for commercialisation.

Directives, recommendations and other documents published by the OIE, FAO and WHO play an important role in the regulation of veterinary biologicals in these countries, while the European Pharmacopoeia serves as a reference for the preparation of national regulations for veterinary biologicals. National documents concerning requirements for veterinary biologicals are increasingly influenced by the EC and its special working groups on veterinary immunologicals.
### Table I

**Summary of the respective roles of national and regional organisations in regulation or testing for the purposes of licensing or quality control of veterinary vaccines**

<table>
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<tr>
<th>Organisation</th>
<th>Harmonisation of licensing procedures</th>
<th>Harmonisation of testing procedures</th>
<th>Distribution of standard reagents</th>
<th>Vaccine testing</th>
<th>Training courses</th>
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+ important role
± minor role, or occurring irregularly/indirectly
- no role, or only as an exception
* role at world level
** role at the level of a region or a group of countries

FAO: Food and Agriculture Organisation of the United Nations  
IAEA: International Atomic Energy Agency  
OIE: Office International des Epizooties  
WHO: World Health Organisation  
EC: European Commission  
INPPAZ: Pan American Institute for Food Protection and Zoonoses  
OECD: Organisation for Economic Co-operation and Development  
PANAFTOSA: Pan American Foot and Mouth Disease Centre  
PANVAC: Pan-African Veterinary Vaccine Centre
In summary, Central and Eastern European countries show an increasing interest in preparing national regulations in accordance with the directives of the above-mentioned international and regional organisations.

**Americas**

Two major animal health organisations for the Americas have produced occasional documents on the manufacture, testing and use of veterinary vaccines.

**Pan American Health Organisation**

The Pan American Health Organisation (PAHO) was created in 1920 to continue the work of the Pan American Sanitary Bureau (formed in 1902) in organising the control of epidemics which threaten the American continent (7). This objective includes harmonisation of the production and testing of vaccines against zoonoses. This objective has been entrusted, in particular, to the following organisations affiliated with PAHO:

a) The Pan American Institute for Food Protection and Zoonoses (INPPAZ) replaced the Pan American Zoonosis Centre (CEPANZO) in 1991, which was formed in 1956 for the control of zoonoses. INPPAZ subsequently extended the scope of its activities to include food-borne diseases, but is still actively engaged in the control of zoonoses, particularly through vaccine improvement. The Institute is not responsible for formulating regulations on vaccine licensing and testing, but does organise training courses on vaccine production and testing. INPPAZ also distributes reference reagents (notably for brucellosis, leptospirosis and rabies), and can undertake the testing of certain batches of vaccine if requested to do so by a country of the region.

b) The Pan American Foot and Mouth Disease Centre (PANAFTOSA) was opened in 1951 in Rio de Janeiro, Brazil. This Centre has an industrial pilot plant for producing FMD virus antigens from cell cultures. PANAFTOSA responds to the need for training in vaccine production and control, and for the development and transfer of associated technology. The Centre produces vaccines for emergency situations and priority programmes, in co-operation with the official Veterinary Services of the country concerned.

PANAFTOSA takes a direct and active part in developing production units and in defining quality control standards for FMD vaccine in every country of the Americas. The Centre has developed a technique for producing oil-adjuvanted vaccine, has standardised conditions for culture in roller tubes and suspensions on an industrial scale, and has examined antigen quality, virus inactivation and the development of an easily-injectable fluid emulsion.

A national laboratory network has been created in conjunction with PANAFTOSA member countries; these coordinated laboratories collaborate with other scientific institutions within the region and elsewhere. The network includes a cell bank, a serum bank and a supply of reference reagents to aid in the diagnosis of vesicular diseases and other viral diseases of animals; it also advises on vaccine production and testing in local laboratories. PANAFTOSA is developing indirect methods for assessing the efficacy of FMD vaccines (antibody production, expected percentage of protection, etc.).

The Centre has a laboratory animal colony for its own use and for the use of national laboratories and research institutes. Specialist refresher courses are provided every year on subjects such as immunochemical aspects of FMD virus, diagnosis, vaccine production and vaccine testing.
Inter-American Institute for Cooperation on Agriculture

The Inter-American Institute for Cooperation on Agriculture (IICA) is a specialised agency within the Inter-American system. IICA was founded in 1942 by the Council of Directors of the Pan American Union, together with the Inter-American Institute of Agricultural Sciences. The initial role of IICA was in agricultural research and graduate training in the field of tropical agriculture. In response to changing needs, the Institute evolved into an agency for technical co-operation and the development of agricultural institutes, embodied in a new Convention (dated 1980). IICA is now responsible for encouraging, facilitating and supporting co-operation in agricultural development and rural prosperity among 32 member states.

One IICA programme (Programme V: Agricultural health) focuses on the development of equivalent and compatible laws, and regulations to facilitate trade. Model laws and regulations are developed from a compilation of laws, regulations and rules existing in each Latin American and Caribbean country, and strategies for introducing these model laws are drawn up. Collaboration is also provided in preparing a regularly-updated database of laws and regulations, which assists international trade.

In this connection, IICA has published *Guidelines for the use and safety of genetic engineering techniques or recombinant DNA technology* (4), prepared in co-operation with the OIE, PAHO and the Organisation of American States. Another publication, in Spanish, deals with the regulation of biotechnology, particularly the release into the environment of genetically-modified organisms (5). The Institute does not distribute reagents for testing veterinary vaccines, nor is it involved in licensing or testing vaccines.

The activities of PAHO, IICA and the OIE with regard to the regulation and testing of vaccines in the Americas are coordinated by an Inter-American Group for Coordination in Animal Health (GICSA). This group meets once a year within the region to discuss action required by smaller regional structures, such as the following: the Inter-Regional Organisation for Farm Health (OIRSA), which serves countries of Central America; the *Junta del Acuerdo de Cartagena* (JUNAC), which serves Andean countries; the Caribbean Animal and Plant Health Information Network (CARAPHIN), which serves countries of the Caribbean; and the Common Market of the South (MERCOSUR), which serves Argentina, Brazil, Paraguay and Uruguay.

Africa

Before independence (until the end of the 1950s), most African countries south of the Sahara depended on regional laboratories for supplies of vaccine. These state laboratories produced the veterinary vaccines needed within the region, mainly those against rinderpest, contagious bovine pleuropneumonia, blackleg, anthrax, bovine pasteurellosis, rabies and poultry diseases. They were located at Dakar (Senegal), Farcha (Chad), Kabete (Kenya), Onderstepoort (South Africa), Antananarivo (Madagascar) and Vom (Nigeria). These regional laboratories performed their own quality control checks, in accordance with international (mostly European) standards.

Most African countries have now established their own laboratories (a total of approximately twenty on the continent), and testing is no longer centralised. This also applies to countries of North Africa (Algeria, Egypt, Morocco, Libya and Tunisia).

The only progress made in Africa south of the Sahara towards harmonising licensing procedures, production and testing techniques, and vaccine quality, has been the creation of the Pan-African Veterinary Vaccine Centre (PANVAC) in 1991, with the assistance of
the FAO and aid from the European Union. Two centres were established: in Dakar (Senegal) and Debre Zeit (Ethiopia). By 1994, however, only the latter was still operating. The main function of this Centre has been to test the quality of rinderpest vaccines used during the Pan-African Rinderpest Campaign (PARC). Each producing laboratory in Africa submitted samples of batches destined for PARC, and the Centre verified the conformity of these vaccines with OIE standards (titre of vaccine virus). This verification was checked against the results of serological surveillance in countries which used the vaccine; this surveillance was conducted using an ELISA provided by the IAEA (see above). PANVAC also tests contagious bovine pleuropneumonia vaccines and certain poultry vaccines, and provides training for specialists from African countries in the production and testing of veterinary vaccines. The Centre also publishes the quarterly *Panvac Vaccine Bulletin*.

**Asia, the Far East and Oceania**

No organisation for coordinating or harmonising the testing of vaccines exists in this region. The Animal Production and Health Commission for Asia and the Pacific (APHCA) plays an indirect role in testing vaccines for veterinary use. Based at the FAO Regional Office in Bangkok since 1975, this Commission has the task of creating a common forum for ways of solving major livestock problems, based on the principles of ‘collective self-reliance’, ‘mutual assistance’ and ‘technical co-operation among developing countries’.

APHCA also operates a vaccine bank. During each annual session of APHCA, member countries (all of which are developing countries) undertake to hold stocks of locally-produced vaccines, ready for use in case of an emergency in other member countries.

**Non-geographical organisations**

Certain organisations do not cover a specific region, but cover a group of countries at the same stage of development and with common problems. An example of such a body is the Organisation for Economic Co-operation and Development (OECD), formed in 1960. The policies of the OECD are as follows:

- to achieve the highest sustainable economic growth and employment, and a rising standard of living in Member Countries, while maintaining financial stability, thereby contributing to development of the world economy;
- to contribute towards sound economic expansion in Member Countries and other countries which are in the process of economic development;
- to contribute to the expansion of world trade on a multilateral, non-discriminatory basis in accordance with international obligations.

The OECD is concerned with the implications of biotechnology for agriculture, livestock and the environment. The organisation has published two documents on safety considerations in the field of biotechnology which could affect the testing of vaccines for veterinary use derived from this technology (7, 8).

The document *Safety considerations for biotechnology* deals with the following priority concerns arising from the development of industrial production in biotechnology and field trials in Member Countries (8):

- good large-scale industrial practice in relation to scientific criteria for safe development (originally published in 1986 [7]) for products derived from fermentation
good developmental principles for the design of safe small-scale field trials with plants and microorganisms possessing newly-introduced traits.

The OECD has also produced many technical documents on 'good laboratory practice' (GLP), which is widely used by vaccine manufacturers to ensure high quality production.

However, the OECD has no direct regulatory role in licensing or testing veterinary vaccines produced by biotechnological methods.

CONCLUSION

This overview of the role of the various international and regional organisations involved in the regulation of veterinary biologicals may give the impression that there is an excessive profusion of regulations or, indeed, needless duplication of these regulations.

This may be true in certain cases, but such cases remain rare; the aim of all these organisations is not to accumulate regulations unnecessarily in seeking to arrive at ever stricter control. On the contrary, their aim is to choose an acceptable common system of regulations for the biologicals industry, which is easily applied and based on solid scientific foundations.

It must also be noted that international regulations (with the exception of certain directives of the EC) only truly take effect when incorporated into national laws or regulations. National authorities thus have the responsibility of choosing between the recommendations of the various international organisations, adopting the texts which are best suited to the local situation. It is clear, however, that closer correspondence between national regulations and international recommendations will increase the probability of improvements in the national biologicals industry, and hence increase export potential.

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Résumé : Les auteurs passent en revue le rôle joué par les organisations internationales et régionales dans l'enregistrement et le contrôle de produits biologiques à usage vétérinaire.

Les organisations internationales largement impliquées dans ce domaine sont l'Office international des épizooties (OIE) – par le biais de sa Commission des normes et de la publication du Manual of standards for diagnostic tests and vaccines –, l'Organisation des Nations Unies pour l'alimentation et l'agriculture (FAO) et l'Organisation mondiale de la santé (OMS). Ces deux dernières organisations interviennent notamment dans le cadre de l'action menée par la Division mixte FAO/Agence internationale de l'énergie atomique (AIEA) sur les techniques nucléaires appliquées à l'alimentation et à l'agriculture qui est
chargée de la standardisation des techniques immuno-enzymatiques (enzyme-linked immunosorbent assay : ELISA), ainsi que dans le cadre des Comités d'experts de l'OMS.

En Europe, les organisations régionales les plus importantes sont la Commission européenne et la Pharmacopée européenne. Sur le continent américain, ces tâches relèvent essentiellement des deux instituts spécialisés de l'Organisation panaméricaine de la santé (OPS), à savoir le INPPAZ (Instituto Panameño de Protección de Alimentos y Zoonosis) et le PANAFTOSA (Centre panaméricain de la fièvre aphteuse), et de l'Institut interaméricain de coopération pour l'agriculture (IICA). En Afrique, les contrôles sont effectués par le PANVAC (Pan-African Veterinary Vaccine Centre) qui continue de rendre de précieux services dans ce domaine. Dans les pays industrialisés, la réglementation des produits issus de la biotechnologie et la standardisation des « bonnes pratiques de laboratoire » en vue de la fabrication des vaccins, sont assurées par l'Organisation de coopération et de développement économiques (OCDE).

Un tableau comparatif résume les rôles respectifs de ces organisations dans l'harmonisation des procédures d'agrément et de contrôle, la distribution des réactifs biologiques de référence, le contrôle des vaccins et l'établissement de banques de vaccins.


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EL PAPEL DE LAS ORGANIZACIONES INTERNACIONALES Y REGIONALES EN LA REGULACIÓN DE LOS PRODUCTOS BIOLÓGICOS DE USO VETERINARIO. - J. Blancou y M. Truszczynski.

Resumen: Los autores examinan el papel de las organizaciones internacionales y regionales en el registro y pruebas de control de los productos biológicos de uso veterinario.

Entre las organizaciones internacionales que intervienen activamente en este campo se encuentran la Oficina Internacional de Epizootias (OIE) –tanto por el trabajo de su Comisión de Normas como por la publicación del Manual de Standards for Diagnostic Tests and Vaccines–, la Organización de las Naciones Unidas para la Agricultura y la Alimentación (FAO) y la Organización Mundial de la Salud (OMS); conviene destacar el trabajo realizado por la División de Técnicas Nucleares en Alimentación y Agricultura, división mixta integrada por la FAO y por el Organismo Internacional de Energía Atómica (OIEA), en la estandarización de técnicas inmunoenzimáticas (enzyme-linked immunosorbent assay: ELISA), así como la labor de los Comités de Expertos de la OMS.

En Europa, las organizaciones regionales más importantes son la Comisión Europea y la Farmacopea Europea. En el continente americano, las contribuciones más significativas provienen de los dos institutos especializados de la Organización Panamericana de la Salud (a saber, el Instituto Panamericano de Protección de Alimentos y Zoonosis [INPPAZ] y el Centro
Panamericano de Fiebre Aftosa (PANAFTOSA) y del Instituto Interamericano de Cooperación para la Agricultura (IICA). En África, el Pan-African Veterinary Vaccine Centre (PANVAC) continúa realizando una valiosa labor en la aplicación de pruebas sobre vacunas veterinarias. Para los países industrializados, la Organización de Cooperación y Desarrollo Económicos (OCDE) interviene en la regulación de los productos de biotecnología y en la elaboración de estándares sobre las «buenas prácticas de laboratorio» en el proceso de fabricación de vacunas.

Los autores presentan un cuadro que resume y compara los respectivos papeles de estas organizaciones en cuanto a la armonización de procedimientos de control y de concesión de licencias, a la distribución de reactivos de referencia, a la práctica de pruebas sobre las vacunas y a la creación de bancos de vacunas.


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REFERENCES


