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Biotechnology - Microorganisms - Examination of the various existing lists of animal pathogens and production of a report

Biotechnik - Mikroorganismen - Überprüfung der unterschiedlichen Listen von tierpathogenen Organismen und Erarbeitung eines Berichtes

Biotechnologie - Microorganismes - Examen des différentes listes existantes de pathogenes pour les animaux et production d'un rapport

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Biotechnology - Microorganisms - Examination of the
various existing lists of animal pathogens and
production of a report

Biotechnologie - Microorganismes - Examen
des différentes listes existantes de pathogènes
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REPUBLIKA SLOVENIJA
MINISTRSTVO ŠOLSKEGA
ŠOLSKEGA IN ŠOLSKEGA
SISTEMA
REPUBLIKA
SLOVENIJA

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Foreword

This report was prepared by the Technical Committee CEN/TC 233 "Biotechnology", the secretariat of which is held by AFNOR.

Introduction

A very large majority of microorganisms used in industry are safe and harmless. Very few of them - usually used for manufacturing vaccines or diagnostics - are potentially pathogenic to humans or animals. These pathogenic microorganisms are used in contained processes according to the level of hazard.

One of the main biosafety problems facing users of pathogenic microorganisms is to identify the hazard level of the microorganisms employed in various fields of activities in order to apply the most appropriate safety measures.

1 Scope

This CEN Report examines the existing lists of pathogens of domestic animals and gives recommendations that a classification into three classes/categories/groups be established.

Different criteria of classification are described.

Genetically modified microorganisms (GMM) have been deliberately excluded. Only wild type species are considered.

2 Examination of the various existing lists and systems of classification of animal pathogens

2.1 General

For the purpose of this CEN Report, an existing list is defined as a list issued from a consensual agreement by an Expert Committee and which has been officially published by national competent authorities of a CEN Member State, or by national or international nomenclature groups.

Three main sources were therefore considered :

- the Office International des Epizooties (OIE) ;
- the Commission of the European Communities ;
- the national publications.

The situation in different European countries is also examined.

2.2 Office International des Epizooties

The Office International des Epizooties, world organization of animal health, periodically releases lists of pathogenic microorganisms that cause diseases in animals. Two lists A and B were first established. The criteria initially used for classification of animal diseases have evolved since the 1920s. Changes were occasionally implemented and diseases were added or removed. In many cases the current classification is not based on clear-cut and generally accepted criteria.

An OIE workgroup (September 1994) (see annex A [3]) proposed a modification of the definitions of lists A and B and the experts decided to establish three lists : A, B, and C. The classification of transmissible animal diseases with measurable economical costs is carry out by means of a decision flowchart based on four criteria :

- does the disease affect multiple regions ?
- is the disease excluded or eradicated from regions ?
- are the losses caused by the disease potentially severe ?
- has the disease potential for global spread ?

This classification may also be used for setting priorities for national disease-prevention programs.

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In 1994, a new list of pathogens was published by OIE (see annex A [4]). This list was established from replies to a questionnaire on research into diagnosis and control of animal disease sent out to 200 laboratories worldwide for three years, and provides a survey of animal pathogens used in laboratories.

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2.3 Situation in Europe

2.3.1 Directive 93/88/EEC

Some animal pathogens are also human pathogens, such as *Mycobacterium bovis*, Rabies virus, Japanese Encephalitis virus. They are included in the Directive 93/88/EEC (see annex A [1]), which set up a first list of bacteria, viruses, parasites and fungi of groups 2, 3 and 4 to be included in the Directive 90/679/EEC, Annex III (see annex A [2]). All the major zoonotic microorganisms are assigned to a risk group taking into account only the risk for humans.

2.3.2 Other European lists

The European Union regularly publishes Directives and Decisions with regard to animal pathogens and animal diseases.

a) Directives and Decisions based on sanitary policies relative to trade and transport of animal between countries.

- Directive 93/54/EEC (see annex A [15]) deals with fish and aquaculture products and sets out in Annex A three lists of pathogens for aquatic animals. The lists I and II are correlated to susceptible species but the list III does not specify the target species. Prophylactic measures are different in lists I/II and in list III where it is indicated that

sale of aquatic products originating in areas contaminated by the listed diseases is forbidden.

- Directive 64/432/EEC (see annex A [16]), Annex E, and Directive 91/68 EEC, Annex B (see annex A [17]) draw up lists of highly infectious diseases for ruminants and pigs, and specify protection measures by controlling the sanitary state of animals before and after sale.

Diseases listed in the Annex E shall be declared to the competent authorities. The Commission is informed of new outbreak of these diseases, checks the application of the prophylactic measures and controls the new cases of the declared diseases. These diseases are subjected to national plans of control or eradication.

- Directive 90/539/EEC modified (see annex A [18]) deals with poultry diseases. Sanitary policies and protection measures are similar to these described for ruminant and pig diseases.

- Commission Decision 94/577/EC (see annex A [19]) establishes specific tests to check the safety of animal semen, and gives a list of animal pathogenic microorganisms to be searched. A reliable and uniform diagnosis procedure is described for animal pathogens listed in this Decision. There is a direct reference to lists A and B of OIE in order to prevent the diffusion of animal pathogens through the trade of semen or fertilised eggs which could have been contaminated.

b) Decisions of the Commission fixing the level of help to control a disease in a country.

These Decisions concern diseases which involve a major problem in a country. Most of them are zoonotic or cause major economic losses. The outbreak, if it exists, can be eliminated with major help from the Commission.

The CVMP Working party (Committee of veterinary medicinal products) (see annex A [5]) on immunological veterinary medical products proposes a list of animal pathogens that should be consulted when a new cell line is established for the production of a biological product. This list does not include a classification of pathogens.

2.4 Situation in Belgium

The Government of Brussels-Capital Region has issued an official classification of animal pathogens (see annex A [6]). Four risk groups have been defined based on the definitions published by Association Française de Normalisation (see annex A [7]).

This classification takes into account the importance of the disease and the risk of infection to healthy animals. The risk group of each microorganism (and the corresponding containment measures) are finally determined according to the virulence and the pathogenicity mechanisms, host range, epidemiological criteria and availability of an effective therapy, and on the maximal risk of contact between the pathogenic microorganism and the target

The list of animal pathogens published in the annex of the order (see annex A [6]) is based on international or national recognized lists and on scientific publications. However, it is noted that such a list is not definitive or all-inclusive.

Newly isolated microorganisms are classified into risk group 2 until the non-pathogenicity can be established.

The classification of parasites reflects only the infectious stage. The non-infectious stage is not taken into account and can be classified as a risk group 1 microorganism in many cases.

The existing list is currently under revision. A new list should be published in the near future.

2.5 Situation in The Netherlands

The Dutch government adopted a classification that divides organisms that are pathogenic to humans, animals and/or plants into three classes PG1, PG2 and PG3 (see annex A [20]). The definitions of these classes correspond more or less with those of the European risk groups (see annex A [2]).

Based on this set of definitions, the Dutch governmental advisory board on genetic modification (COGEM) set up a list of organisms (bacteria, fungi, parasites, rickettsias/mycoplasmas/chlamydias and viruses) pathogenic to human and/or animal (see annex A [21]).

2.6 Situation in France

A classification of zoopathogenic microorganisms has been established by Association Française de Normalisation (see annex A [7]) in 1990.

The classification proposed by AFNOR takes account of the following criteria :

- pathogenicity, [SIST CR 12894:1999](https://standards.iteh.ai/catalog/standards/sist/1ff5ee7-5036-4c76-a981-46b83eba64dd/sist-cr-12894-1999)
- economic aspects, <https://standards.iteh.ai/catalog/standards/sist/1ff5ee7-5036-4c76-a981-46b83eba64dd/sist-cr-12894-1999>
- spread of pathogen agent,
- prophylactics and treatments,

and differentiates three categories of hazard for the environment : class Ea1, class Ea2 and class Ea3.

Class Ea1 microorganisms which can cause disease in animals and which present in varying degrees the following characteristics : limited geographical significance, low interspecies transmissibility or none, not vectors or carriers. The economic and/or medical effect is limited. They normally require no specific containment measures. Prophylactics and/or effective treatments are generally available.

Class Ea2 microorganisms which cause serious epizootic diseases among animals. Interspecies diffusion may be on a large scale. They necessitate the imposition of health regulations applicable to species to be named by the authorities in each country concerned. Prophylaxis by medical means or health regulations is available.

Class Ea3 microorganisms which cause extremely serious panzootic or epizootic diseases with high mortality and possibly catastrophic economic consequences for the farming areas affected. In general, there is no known medical prophylactic treatment and a policy of containment, enforced compulsorily if appropriate, is the only measure it is possible to take.

An official list of animal diseases (MRLC : *Maladie Réputée Légalement Contagieuse*) was published by the French authorities (see annex A [13], [14]). General and specific sanitary policies are specified. The registration of a disease is based on clinical symptoms ; the isolation and identification of the germ in a clinical sample is not sufficient to register this disease as MRLC.

At present, no official list of animal pathogens assigned to a class is published in France ; but a list of zoopathogens established by a group of veterinary experts is being circulated.

2.7 Situation in Germany

According to the risk to humans, lists with four classes of risk assigned to each (zoo)pathogens were produced, but no specific hazard categories to animals exist.

The following sources have assigned classes of risk for certain microorganisms.

GenTSV (German safety ordinance on genetic engineering) classified microorganisms as human or animal pathogens with their appropriate risk group according to Gene Technology Regulations.

In April 1995, the BMG (Federal Health Ministry) (see annex A [9]) published a list in the *Bundesgesundheitsblatt* (federal health periodical) which supersedes the list of organisms previously included in the GenTSV as well as other lists. The classification of animal pathogens is based on the GenTSV definitions. The classification criterion for this list is the natural virulence of the organism for animals as well as human not suffering from immunosuppression.

BG-Chemie classified microorganisms as human or animal pathogens according to the current listing of BG-Chemie (see annex A [8]). Zoopathogenicity is indicated.

Both sources are mainly based on and are in agreement with the Directive 93/88/EEC (see annex A [1]).

The classification criteria include :

- biohazard criteria including pathogenicity ;
- public health/occupational safety/environmental criteria ;
- spread of pathogenic microorganisms ;
- availability of prophylactics and treatments.

2.8 Situation in the United Kingdom

The Ministry of Agriculture, Fisheries and Food (MAFF) defined an "animal pathogen" as "any collection or culture of organisms or any derivative either on its own or in recombinant

form of such collection or culture of organisms which may cause disease in animals or poultry", and distinguishes four hazard groups for animal pathogens :

- Group 1 Disease producing organisms which are enzootic and do not produce notifiable disease.
- Group 2 Disease producing organisms which are either exotic or produce notifiable disease, but have a low risk of spread from the laboratory.
- Group 3 Disease producing organisms which are either exotic or produce notifiable disease and have a moderate risk of spread from the laboratory.
- Group 4 Disease producing organisms which are either exotic or produce notifiable disease and have a high risk of spread from the laboratory.

The classification is made for the purpose of protecting animal health from escapes of organism from a laboratory and not protection of workers in that laboratory (see annex A [13]). It is used both to determine the laboratory containment conditions appropriate to a programme of work, and to specify the conditions which shall be maintained during that work. It is considered that the greatest proven risk to animal health comes from the movement of infected animals rather than escape of laboratory pathogens.

NOTE : Rabies and rabies related to virus are not included in this classification because of special accommodation.

The British Government established two main documents. These are the Importation of Animal Pathogens Order 1980 (see annex A [10]) and the Specified Animal Pathogens Order 1993 (see annex A [11]).

The Order prohibits any person from having in their possession or introducing into animals any of the organisms listed except under the authority of a license. Changes were made in 1993 when prohibition on import was removed in respect of importations from other EU Member States.

3 Conclusions

A wide consensus exists to accept three classes of animal pathogens, i.e. classes 2, 3 and 4, class 1 being defined as non-pathogenic (see table 1), except for the United Kingdom. However, in the latter case where laboratory work is concerned, the four classes were defined to make the classification much more understandable and useable in the field.

The definitions are different in some cases but they are based on the same criteria :

- biohazard ;
- pathogenicity ;
- economic aspects ;
- spread of pathogenic agent ;
- availability of prophylactics and treatments.

Table 1 : Pathogenicity classes/categories/risk groups among different classifications.

Belgium	France	Germany	The Netherlands	United Kingdom	OIE
1		1			
2	Ea1	2	PG1	1	C
3	Ea2	3	PG2	2	B
4	Ea3	4	PG3	3	A
				4	

To ensure an unique, reproducible and scientific classification of their hazardous potential, a horizontal standard on microbiological criteria for risk assessment of microorganisms should be developed, and specific risk classes for animal pathogens assigned. A decision tree on the OIE model (see 2.2) could be useful. For those microorganisms where there may be a risk to humans, this should be indicated in the appropriate animal list.

The taxonomy and the pathogenicity concept are constantly evolving. The names of bacterial species were modified when more precise methods allowed a revision of their place in the phylogenic tree. For viruses, the family components were redistributed and new ones created. New infectious agents are discovered each year ; some pathogenic effects unknown until now have been found in species previously considered to be non susceptible. At the same time, molecular biology progress enables identification of virulence factors and recognition of non virulent variants of species considered as pathogenic.

Attenuated strains are not classified in the same way as the virulent strain. This point introduces a different degree of classification for a same pathogen : some serotypes could be re-evaluated.

For these reasons, it is not possible to establish a unique, definitive and exhaustive list of animal pathogens. However a attempt to draw up a list of animal pathogens classified according to the different systems of classification (see table 1) is proposed in annex B.

4 Recommendations

At present, many classifications of animal pathogens are in use in Europe and elsewhere. They differ in their purpose (e.g. lists of pathogens used in laboratories, quarantine lists, epizooties control), definitions of classes and/or in the risk ranking of individual agents.

Apart from these differences among the classifications, a substantial number of microorganisms are assigned to more or less equivalent classes.

The use of several classifications based on different principles leads to confusion at the European level as to what is meant by a certain risk class in a given country and hinders harmonisation of regulation.

For this purpose, it can be recommended that a classification into three classes/categories/groups of animal pathogenic microorganisms be established.

Annex A (informative)**Bibliography**

- [1] Council Directive 93/88/EEC of 12 October 1993 amending Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 paragraphe 1 of Directive 89/391/EEC). OJEC 29.10.1993, n° L 268, p 71.
- [2] Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 of Directive 89/391/EEC). OJEC 31.12.1990, n° L 374, p 1.
- [3] Report on the meeting of the OIE adhoc group on categorisation of diseases. Paris, 15-17 September 1994, 8 p.
- [4] OIE: Veterinary Biotechnology Newsletter Volume 4, 1994 ISSN 1018-533X.
- [5] CVMP Working party on immunological veterinary medicinal products - Table of extraneous agents to be tested for in relation to the general and species ; specific guidelines on production and control of veterinary vaccines. Final version 7/01/94, Commission of the European communities.
- [6] Arrêté du Gouvernement de la Région de Bruxelles-Capitale relatif aux installations effectuant des opérations mettant en oeuvre des microorganismes ou des organismes, pathogènes ou génétiquement modifiés. 25.01.1994. Moniteur Belge. 1424-1483. <https://standards.iteh.ai/catalog/standards/sist/1ff5ee7-5036-4c76-a981-46b83eba64dd/sist-cr-12894-1999>
- [7] NF X-42-075 Biotechnology : Guide of good practices in microbiology analysis and research in the field of animal health
- [8] Merkblätter Sichere Biotechnologie - BG Chemie, B004 (4/91), B005 (8/91), B006 (1/92), B007 (4/91).
- [9] Liste risikobewerteter Spender- und Empfängerorganismen für gentechnische Arbeiten. Bundesgesundhbl. 38, 5 (1995) - Sonderbeilage.
- [10] The Importation of Animal Pathogens Order 1980 Statutory Instrument 1980 N° 1212 ANIMALS. Diseases of Animals. 5p.
- [11] The Specified Animal Pathogens Order 1993 Statutory Instrument 1993 N° 3250 ANIMALS. Animal Health. 1155-1155.05.
- [123] Importation and Keeping of Animal Pathogens. Ministry of Agriculture, Fisheries and Food, Scottish Office Agriculture and Fisheries Department Welsh Office Agriculture Department. 02/1994. 19p.
- [13] Code rural, art 224, 225, 226, 227.
- [14] Décret n° 95-218 du 27 février 1995 complétant et modifiant la liste des maladies des animaux réputées contagieuses.

- [15] Council Directive 93/54/EEC of 24 June 1993 amending Directive 91/67/EEC concerning the animal health conditions governing the placing on the market of aquaculture animals and products. OJEC 19.07.1993, n° L 175, p34.
- [16] Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine. OJEC 29.07.64, n° 121, p 1977.
- [17] Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals. OJEC 19.02.1991, n° L 46, p 19.
- [18] Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs. OJEC 31.10.1990, n° L 303, p 6.
- [19] Commission Decision 94/577/EC of 15 July 1994 concerning the animal health conditions and veterinary certification for the importation of bovine semen from third countries. OJEC 26.08.1994, n° L221, p 26.
- [20] Ministerial Order on the contained use of genetically modified organism, Ministry of housing, spacial planning and the environment. The Hague, Staatscourant 207, 1993. *Regeling ingeperkt gebruik genetisch gemodificeerde organismen. Ministerie van Volkshuisvesting, Ruimtelijke Ordening en Milieu, Den Haag, Straatscourant 207, 1993.*
- [21] Guidelines for the creation and use of genetically modified organisms. Commission on Genetic Modification, Utrecht, 1993. *Richtlijnen voor de vervaardiging van en de handelingen met genetisch gemodificeerde organismen. Commissie Genetische Modificatie, Utrecht, 1993.*