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# Legislation

Contents





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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other Acts are printed in bold type and preceded by an asterisk.

I

*(Acts whose publication is obligatory)*

# COUNCIL REGULATION (EC) No 1658/98

## of 17 July 1998

## on co-financing operations with European non-governmental development organisations (NGOs) in fields of interest to the developing countries

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 130w thereof,

Having regard to the proposal from the Commission [1],

Acting in accordance with the procedure laid down in Article 189c of the Treaty [2],

Whereas the Commission, in its communication to the Council of 6 October 1975, put forward guidelines on relations with non-governmental development organisations (NGOs), together with general conditions and procedures for the use of funds intended for development operations by such organisations;

Whereas the budgetary authority introduced into the 1976 budget an item for co-financing with NGOs and has since steadily increased the volume of such funding (from ECU 2,5 million in 1976 to ECU 174 million in 1995) on the basis of the Commission's annual reports on the use of these resources;

Whereas at its meeting on 28 November 1977, the Council approved the general conditions and procedures proposed by the Commission;

Whereas the European Parliament, in its Resolution of 14 May 1992 on the role of NGOs in development cooperation [3], reaffirmed the specific and irreplaceable role of NGOs and the usefulness and effectiveness of their development operations, emphasising in particular the key role of NGOs' work on behalf of marginal social groups in developing countries, the need to preserve the NGO's freedom of action, and the vital role of NGOs in promoting human rights and the development of grassroots democracy;

Whereas, in its Resolution of 27 May 1991 on cooperation with the NGOs, the Council underlined the importance of the autonomy and independence of NGOs; whereas it recognised, moreover, that the Community system of cooperation with the NGOs was necessarily complementary to similar efforts at national level and recognised the need for flexibility in procedures and their application;

Whereas, in its conclusions of 18 November 1992, the Council noted with satisfaction the criteria by the Commission when selecting development and education projects for co-financing, notably strengthening the fabric of democracy and respect for human rights in the developing countries, and particularly welcomed the fact that the Commission had made it clear that the main criterion remained the quality of the project, an approach which it backed unreservedly;

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[1] OJ No C 251, 27.09.1995, p. 18.

[2] Opinion of the European Parliament of 15 December 1995 (OJ C 17, 22.1.1996, p. 455), common position of the Council of 7 July 1997 (OJ C 307, 8.10.1997, p. 1) and Decision of the European Parliament of 18 December 1997 (OJ C 14, 19.1.1998, p. 124).

[3] OJ C 150, 15.6.1992, p. 273.

Whereas administrative procedures should be established for co-financing operations with European NGOs in fields of interest to the developing countries,

HAS ADOPTED THIS REGULATION:

*Article 1*

1. The Community shall co-finance operations in the field with European non-governmental development organisations (NGOs), as defined in Article 3, to meet the basic needs of disadvantaged people in developing countries. Priority shall be assigned to proposals for operations based on an initiative by partners in developing countries. Such operations shall be proposed by European NGOs and conducted in cooperation with their partners in the developing countries and shall be aimed at poverty alleviation as well as at enhancing the target group's quality of life and own development capacity.

2. The Community shall also co-finance with European NGOs, as defined in Article 3, public awareness and information operations in Europe about development problems in the developing countries and their relations with the industrialised world. Such operations shall be proposed by European NGOs and shall be designed to mobilise public support in Europe for development and for strategies and operations benefiting people in the developing countries.

3. The Community shall also co-finance operations designed to reinforce cooperation and coordination between NGOs from the Member States, and between NGOs from the Member States and the Community Institutions.

*Article 2*

1. The operations co-financed in the developing countries under Article 1(1) shall in particular concern local social and economic development in rural and urban areas, the development of human resources, particularly by means of training, and institutional support for local partners in the developing countries.

Within those fields of activity, though the quality of the operation is paramount, particular attention shall be given to operations connected with:

— the strengthening of civil society and participatory development, and the promotion and defence of human rights and democracy,

— the role of women in development,

— sustainable development.

Particular attention shall also be paid to:

— the protection of threatened cultures, especially endangered indigenous cultures,

— the protection and improvement of the circumstances and of the rights of children in the developing countries.

2. Public awareness and information operations in all Member States, to be implemented under Article 1(2), shall be targeted at clearly-defined groups, deal with clearly defined issues, be founded on a balanced analysis and a sound knowledge of the issues and groups targeted, and involve a European dimension.

Though the quality of operation is paramount, special attention shall be given to public awareness operations which:

— highlight the interdependence of the Member States and the developing countries,

— seek to mobilise support for more equitable North-South relations,

— encourage cooperation between NGOs,

— enable partners in the developing countries to play an active part.

3. The operations designed to reinforce coordination between NGOs from the Member States and with the Community Institutions, to be implemented under Article 1(3), shall, *inter alia*, concern the development of appropriate exchange and communication networks.

4. In determining whether a proposed operation is suitable for Community co-financing the criterion shall be its expected developmental impact in the developing country or countries concerned. Attention shall be paid to:

— the sustainable impact in project design,

— the clear definition and monitoring of objectives and indicators of achievement for all projects,

— consistency with other development actions of decentralised agents, while avoiding incompatibility with other instruments of Community cooperation.

*Article 3*

1. The agents of cooperation eligible for co-financing under this Regulation shall be NGOs satisfying the following conditions:

— they must be constituted as autonomous non-profit-making organisations in a Member State in accordance with the laws of that State,

— they must have their headquarters in a Member State and the headquarters must be the main centre for decisions relating to the co-financed operations,

— the majority of their funding must originate in Europe.

2. In determining whether an NGO is eligible for co-financing, account shall also be taken of:

— its capacity to mobilise genuine solidarity on the part of the European public for its development activities;

— the priority it accords to development and its experience in that field,

— its administrative and financial management capacities,

— where possible, its knowledge of the sector and country concerned,

— its ability to support the development operations proposed by the partners in the developing countries and the nature and scope of its links with similar organisations in the developing countries.

*Article 4*

1. Community co-financing for the operations referred to in Article 1 may cover, in foreign or local currency:

— investment spending;

— operational spending linked with investment, while ensuring that projects remain viable after external aid comes to an end;

— any spending necessary for the smooth implementation of the co-financed operations, including the administrative costs of NGOs or NGO networks.

In the specific instance in which exchange rates alter by an exceptionally large margin to the detriment of the final beneficiaries of the projects in developing countries, the Commission may, at the request of the NGO concerned, take appropriate measures to neutralise the effects of the alteration.

2. An NGO with which a co-financing contract is concluded shall notify its partners of the Community's contribution to the operation.

3. The NGO shall systematically encourage the developing-country agencies or partners ultimately benefiting from an operation to contribute in kind or financially, according to their means and the specific nature of the operation concerned.

*Article 5*

Community co-financing under this Regulation shall take the form of grants, including contributions to working capital for microcredit projects.

In the case of microcredit projects co-financed with European NGOs which provide that the local partner in developing countries fully or partly constitute and administer working capital, the amount of mini-loans reimbursed by the final beneficiaries to the working capital may be used again for further mini-loans to other final beneficiaries.

*Article 6*

1. The Commission shall appraise, decide and administer the co-financing of operations covered by this Regulation according to the budgetary and other procedures in force, and in particular those laid down in the Financial Regulation applicable to the general budget of the European Communities, taking account of the nature and specific features of NGOs, and particularly their financial contribution to the operations in question.

As a rule, the decision as to whether an operation is to be supported should be taken within six months of the date of receipt of the application. If, in examining the file, it emerges that the application is incomplete, the six-month period shall run from the date of receipt of the information required. If the decision is negative, verifiable reasons shall be given to the NGO concerned.

2. All co-financing contracts concluded under this Regulation shall provide for the Commission and the Court of Auditors to conduct on-the-spot checks according to the usual procedures laid down by the Commission under the rules in force, and in particular those of the Financial Regulation applicable to the general budget of the European Communities.

3. The Community contribution shall not, as a rule, exceed 50 % of the total cost or 75 % of total contributions, except in exceptional cases. Even in such

cases, NGOs shall make a significant contribution to projects and the Community contribution shall not exceed 85 % of the total financial contributions.

4. Decisions on the Community co-financing of projects and programmes (multiannual programmes, consortium operations, block grants) exceeding ECU 2 million shall be adopted under the procedure laid down in Article 9.

5. Every three months, the Commission shall inform the Member States of the co-financing projects and programmes approved, indicating their amounts, nature, the beneficiary country and partner. That information shall be accompanied by an Annex setting out clearly those projects or programmes which exceed ECU 1 million.

*Article 7*

1. During the second six months following each budget year the Commission shall report to the European Parliament and the Council, giving information on the NGOs benefiting from co-financing, summarising the operations financed in the course of the previous budget year, evaluating the implementation of this Regulation in that period and proposing general guidelines for the following year. Where block grants are concerned, the annual report shall contain a list of the recipient NGOs, while a list of the projects financed with these block grants shall appear in the report for the following year. The report shall set out the conclusions of any independent evaluations performed.

2. The Commission, acting in accordance with the procedure laid down in Article 10, shall adopt the decisions on the general guidelines for the following year and the revision of the general conditions.

*Article 8*

The Commission shall be assisted by a Committee composed of the representatives of the Member States and chaired by the representative of the Commission.

*Article 9*

1. Where the procedure laid down in this Article is to be followed, the Commission shall be assisted by the Committee set up under Article 8.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged, which shall apply immediately.

(b) However, if these measures are not in accordance with the opinion of the Committee, they shall be communicated by the Commission to the Council forthwith. In that event:

— the Commission shall defer application of the measures which it has decided for a period of one month as from the date of communication,

— the Council, acting by a qualified majority, may take a different decision within the time limit referred to in the first indent.

*Article 10*

1. Where the procedure laid down in this Article is to be followed, the Commission shall be assisted by the Committee set up under Article 8.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged, which shall apply immediately.

(b) However, if these measures are not in accordance with the opinion of the Committee, they shall be communicated by the Commission to the Council forthwith. In that event:

— the Commission may defer application of the measures which it has decided for a maximum period of one month from the date of such communication,

— the Council, acting by a qualified majority, may take a different decision within the time limit referred to in the first indent.

*Article 11*

The Commission shall regularly evaluate operations co-financed by the Community in order to establish whether their objectives have been attained and with a view to providing guidelines for improving the efficiency

of future operations. The Commission shall submit to the Committee referred to in Article 8 a summary of the evaluations; if necessary, the evaluations may be examined by the Committee. The evaluation reports shall be available to the Member States on request.

*Article 12*

Three years after this Regulation enters into force, the Commission shall submit to the European Parliament and the Council an overall evaluation of the operations financed by the Community under this Regulation, together with suggestions regarding the future of this Regulation and, where necessary, proposals for amending it.

*Article 13*

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 July 1998.

*For the Council*

*The President*

W. RUTTENSTORFER

# COUNCIL REGULATION (EC) No 1659/98

## of 17 July 1998

## on decentralised cooperation

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 130w thereof,

Having regard to the proposal from the Commission [1],

Acting in accordance with the procedure laid down in Article 189c of the Treaty [2],

Whereas decentralised cooperation is a new approach to development cooperation which places the agents at the focal point of implementation and hence pursues the dual aims of gearing operations to needs and making them viable;

Whereas the importance of a decentralised approach to development cooperation has been emphasised in the Fourth ACP-EC Convention, Council Regulation (EEC) No 443/92 of 25 February 1992 on financial and technical assistance to, and economic cooperation with, the developing countries in Asia and Latin America [3], and the Council Resolution of 27 May 1991 on cooperation with NGOs and in numerous European Parliament Resolutions;

Whereas the budgetary authority decided to include in the 1992 budget a heading for the promotion of this approach in all developing countries;

Whereas a financial reference amount, within the meaning of point 2 of the Declaration by the European Parliament, the Council and the Commission of 6 March 1995 on the incorporation of financial provisions into legislative acts [4] is included in this Regulation for the period 1999 to 2001, without thereby affecting the powers of the budgetary authority as they are defined by the Treaty;

Whereas decentralised cooperation is intended to help bring about a real change in the long term of the Union's development cooperation procedures;

Whereas decentralised cooperation makes an important contribution to achieving the development cooperation policy objectives of the Community as set out in Article 130u of the Treaty;

Whereas administrative procedures should be established accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

The Community shall support operations and initiatives on sustainable development undertaken by decentralised cooperation agents of the Community and the developing countries, in particular those designed to promote:

— a more participatory approach to development, responsive to the needs and initiatives of the populations in the developing countries,

— a contribution to the diversification and reinforcement of civil society and grassroots democracy in the countries concerned,

— the mobilisation of decentralised cooperation agents in the Community and the developing countries in pursuit of these objectives within the structured programmes.

All developing countries shall be eligible for operations to promote decentralised cooperation.

*Article 2*

The priority fields for operations under this Regulation shall be:

— the development of human and technical resources and local rural or urban social and economic development in the developing countries,

— information and the mobilisation of decentralised cooperation agents,

— support for strengthening the institutional capacities of such agents and their capacity for action,

— methodolical back-up and follow-up for operations.

*Article 3*

The cooperation partners eligible for financial support under this Regulation shall be decentralised cooperation

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(1) OJ C 250, 26.9.1995, p. 13.
(2) Opinion of the European Parliament delivered on 15 December 1995 (OJ C 17, 22.1.1996, p. 460). Council Common Position of 5 November 1997 (OJ C 43, 9.2.1998) and Decision of the European Parliament of 1 April 1998 (OJ C 138, 4.5.1998).
(3) OJ L 52, 27.2.1992, p. 1.
(4) OJ L 102, 4.4.1996, p. 4.

agents in the Community or the developing countries, namely: local authorities, non-governmental organisations, local traders' associations and local citizens' groups, cooperatives, trade unions, women's and youth organisations, teaching and research institutions, churches and any non-governmental associations likely to contribute to development.

*Article 4*

1. Community financing of the operations referred to in Article 1 shall cover a period of three years (1999 to 2001).

The financial reference amount for the implementation of this programme for the period 1999 to 2001 shall be ECU 18 million.

The annual appropriations shall be authorized by the budgetary authority within the limits of the financial perspective.

2. The budgetary authority shall determine the appropriations available for each financial year, taking account of the principles of sound financial management referred to in Article 2 of the Financial Regulation applicable to the general budget of the European Communities.

*Article 5*

1. The instruments to be employed in the course of the operations referred to in Article 1 shall include studies, technical assistance, training or other services, supplies and works, along with audits and evaluation and monitoring missions.

2. Community financing may cover both investment expenditure, with the exception of the purchase of buildings, and, since the project must, if possible, aim at medium-term viability, recurring expenditure (including administrative, maintenance and operating expenditure).

3. A contribution from the partners defined in Article 3 shall be sought for each cooperation operation. The contribution shall be requested according to their means and the nature of the operation concerned.

4. Opportunities may be sought for co-financing with other fund providers, and especially with Member States.

5. In order to attain the objectives of coherence and complementarity laid down in the Treaty, and with the aim of guaranteeing optimum efficiency of the totality of these operations, the Commission may take all necessary coordination measures, including in particular:

(a) the establishment of a system for the systematic exchange and analysis of information on operations financed or for which financing is envisaged by the Community and the Member States;

(b) on-the-spot coordination of these operations by means of regular meetings and exchange of information between the representatives of the Commission and Member States in the beneficiary country.

*Article 6*

Financial support under this Regulation shall be in the form of grants.

*Article 7*

1. The Commission shall appraise, decide and administer operations covered by this Regulation according to the budgetary and other procedures in force, and in particular those laid down in the Financial Regulation applicable to the general budget of the European Communities.

2. Decisions relating to grants of more than ECU 1 million for individual operations financed under this Regulation and any amendment involving an increase of more than 20 % in the amount initially approved for such an operation shall be adopted under the procedure laid down in Article 8.

3. Project and programme appraisal shall take into account the following factors:

— effectiveness and viability of operations,

— cultural and social aspects, aspects relating to equal opportunity for men and women, and the environment,

— institutional development necessary to achieve objectives of the operation,

— experience gained from operations of the same kind.

4. All financing agreements or contracts concluded under this Regulation shall provide for the Commission and the European Court of Auditors to conduct on-the-spot checks according to the usual procedures laid down by the Commission under the rules in force, and in particular those in the Financial Regulation applicable to the general budget of the European Communities.

5. Participation in invitations to tender and the award of contracts shall be open on equal terms to all natural and legal persons of the Member States and of the recipient country. It may be extended to other developing countries and, in exceptional cases which are fully justified, to other third countries.

6. Supplies shall originate in the Member States, the recipient country or other developing countries. In exceptional cases, where circumstances warrant, supplies may originate in other third countries.

*Article 8*

1. The Commission shall be assisted by the geographically determined Committee competent for development.

2. The Commission representative shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged which shall apply immediately.

(b) However, if these measures are not in accordance with the opinion of the Committee, they shall be communicated by the Commission to the Council forthwith. In that event:

— the Commission shall defer application of the measures which it has decided on for a period of one month the date of such communication;

— the Council, acting by a qualified majority, may take a different decision within the time limit referred to in the first indent.

*Article 9*

The Committee referred to in Article 8 shall meet once a year to discuss general guidelines presented by the Commission representative for operations in the year ahead.

*Article 10*

After each budget year, the Commission shall submit an annual report to the European Parliament and the Council, summarising the operations financed in the course of that year and evaluating the implementation of this Regulation in that period.

The annual report shall in particular give details on the decentralised cooperation agents with whom contracts have been concluded.

Every three months, the Commission shall inform the Member States of the operations and projects approved, stating their cost and nature, the recipient country and partners. This information shall be accompanied by an Annex clearly setting out the projects or programmes which exceed ECU 1 million.

*Article 11*

The Commission shall make regular assessments of operations financed by the Community, in order to establish whether the objectives targeted by these operations have been attained and in order to give indications to improve the effectiveness of future operations. The Commission shall submit to the Committee referred to in Article 8 a summary of assessments carried out, which the latter may examine where appropriate. The assessment reports shall be available to Member States requesting them.

*Article 12*

Before the end of 2000, the Commission shall submit to the European Parliament and the Council an overall assessment of the operations financed by the Community under this Regulation, accompanied by suggestions concerning the future of this Regulation.

*Article 13*

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Communities*.

It shall apply until 31 December 2001.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 17 July 1998.

*For the Council*

*The President*

W. RUTTENSDORFER

# DIRECTIVE 98/43/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## of 6 July 1998

## on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 57(2), Article 66 and Article 100a thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 189b of the Treaty [3],

(1) Whereas there are differences between the Member States' laws, regulations and administrative provisions on the advertising and sponsorship of tobacco products; whereas such advertising and sponsorship transcend the borders of the Member States and the differences in question are likely to give rise to barriers to the movement between Member States of the products which serve as the media for such advertising and sponsorship and to freedom to provide services in this area, as well as distort competition, thereby impeding the functioning of the internal market;

(2) Whereas those barriers should be eliminated and, to this end, the rules relating to the advertising and sponsoring of tobacco products should be approximated, whilst leaving Member States the possibility of introducing, under certain conditions, such requirements as they consider necessary in order to guarantee the protection of the health of individuals;

(3) Whereas, in accordance with Article 100a(3) of the Treaty, the Commission is obliged, in its proposals under paragraph 1 concerning health, safety, environmental protection and consumer protection, to take as a base a high level of protection;

(4) Whereas this Directive must therefore take due account of the health protection of individuals, in particular in relation to young people, for whom advertising plays an important role in tobacco promotion;

(5) Whereas in order to ensure the proper functioning of the internal market the Council adopted, on the basis of Article 100a, Directive 89/622/EEC [4] and Directive 90/239/EEC [5] concerning the labelling of tobacco products and the maximum tar yield of cigarettes, respectively;

(6) Whereas advertising relating to medicinal products for human use is covered by Directive 92/28/EEC [6]; whereas advertising relating to products intended for use in overcoming addiction to tobacco does not fall within the scope of this Directive;

(7) Whereas this Directive will not apply to communications intended exclusively for professionals in the tobacco trade, the presentation of tobacco products offered for sale and the indication of their prices, and, depending on sales structures, advertising directed at purchasers at tobacco sales outlets and the sale of third-country publications which do not satisfy the conditions laid down in this Directive, provided, however, that they comply with Community law and the Community's obligations at international level; whereas it is for the Member States, where necessary, to take appropriate measures in these areas;

(8) Whereas, given the interdependence between the various forms of advertising — oral, written,

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[1] OJ C 129, 21.5.1992, p. 5.
[2] OJ C 313, 30.11.1992, p. 27.
[3] Opinion of the European Parliament of 11 February 1992 (OJ C 67, 16.3.1992, p. 35), confirmed under the Article 189b procedure on 3 December 1993, Council Common Position of 12 February 1998 (OJ C 91, 26.3.1998, p. 34) and Decision of the European Parliament of 13 May 1998 (OJ C 167, 1.6.1998). Council Decision of 22 June 1998.
[4] OJ L 359, 8.12.1989, p. 1. Directive as amended by Directive 92/41/EEC (OJ L 158, 11.6.1992, p. 30).
[5] OJ L 137, 30.5.1990, p. 36.
[6] OJ L 113, 30.4.1992, p. 13.

printed, on radio or television or at the cinema — and in order to prevent any risk of distorting competition or circumventing rules and regulations, this Directive must cover all forms and means of advertising apart from television advertising already covered by Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities [1];

(9) Whereas all forms of indirect advertising and sponsorship, and likewise free distribution, have the same effects as direct advertising, and whereas they should, without prejudice to the fundamental principle of freedom of expression, be regulated, including indirect forms of advertising which, while not mentioning the tobacco product directly, use brand names, trade marks, emblems or other distinctive features associated with tobacco products; whereas, however, Member States may defer application of these provisions to allow time for commercial practices to be adjusted and sponsorship of tobacco products to be replaced by other suitable forms of support;

(10) Whereas, without prejudice to the regulation of the advertising of tobacco products, Member States remain free to allow the continued use, under certain conditions, for the advertising of products or services other than tobacco products, of a brand name which was already in use in good faith both for such products or services and for tobacco products before this Directive entered into force;

(11) Whereas existing sponsorship of events or activities which Member States may continue to authorise for a period of eight years after the entry into force of this Directive ending not later than 1 October 2006 and which will be subject to voluntary-restraint measures and decrease of expenditure levels during the transitional period should include all means of achieving the aims of sponsorship as defined in this Directive;

(12) Whereas Member States must take adequate and effective steps to ensure control of the implementation of national measures adopted pursuant to this Directive in compliance with their national legislation,

HAVE ADOPTED THIS DIRECTIVE:

*Article 1*

The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products.

*Article 2*

For the purposes of this Directive, the following definitions shall apply:

1. 'tobacco products': all products intended to be smoked, sniffed, sucked or chewed inasmuch as they are made, even partly, of tobacco;

2. 'advertising': any form of commercial communication with the aim or the direct or indirect effect of promoting a tobacco product, including advertising which, while not specifically mentioning the tobacco product, tries to circumvent the advertising ban by using brand names, trade marks, emblems or other distinctive features of tobacco products;

3. 'sponsorship': any public or private contribution to an event or activity with the aim or the direct or indirect effect of promoting a tobacco product;

4. 'tobacco sales outlet': any place where tobacco products are offered for sale.

*Article 3*

1. Without prejudice to Directive 89/552/EEC, all forms of advertising and sponsorship shall be banned in the Community.

2. Paragraph 1 shall not prevent the Member States from allowing a brand name already used in good faith both for tobacco products and for other goods or services traded or offered by a given undertaking or by different undertakings prior to 30 July 1998 to be used for the advertising of those other goods or services.

However, this brand name may not be used except in a manner clearly distinct from that used for the tobacco product, without any further distinguishing mark already used for a tobacco product.

3. (a) Member States shall ensure that no tobacco product bears the brand name, trade mark,

[1] OJ L 298, 17.10.1989, p. 23. Directive as last amended by Directive 97/36/EC (OJ L 202, 30.7.1997, p. 60).

emblem or other distinctive feature of any other product or service, unless the tobacco product has already been traded under that brand name, trade mark, emblem or other distinctive feature on the date referred to in Article 6(1);

(b) the ban provided for in paragraph 1 may not be circumvented, in respect of any product or service placed or offered on the market as from the date laid down in Article 6(1), by the use of brand names, trade marks, emblems and other distinguishing features already used for a tobacco product.

To this end, the brand name, trade mark, emblem and any other distinguishing feature of the product or service must be presented in a manner clearly distinct from that used for the tobacco product.

4. Any free distribution having the purpose or the direct or indirect effect of promoting a tobacco product shall be banned.

5. This Directive shall not apply to:

— communications intended exclusively for professionals in the tobacco trade,

— the presentation of tobacco products offered for sale and the indication of their prices at tobacco sales outlets,

— advertising aimed at purchasers in establishments specialising in the sale of tobacco products and on their shop-fronts or, in the case of establishments selling a variety of articles or services, at locations reserved for the sale of tobacco products, and at sales outlets which, in Greece, are subject to a special system under which licences are granted for social reasons ('periptera'),

— the sale of publications containing advertising for tobacco products which are published and printed in third countries, where those publications are not principally intended for the Community market.

*Article 4*

Member States shall ensure that adequate and effective means exist of ensuring and monitoring the implementation of national measures adopted pursuant to this Directive. These means may include provisions whereby persons or organisations with a legitimate interest under national law in the withdrawal of advertising which is incompatible with this Directive may take legal proceedings against such advertising or bring such advertising to the attention of an administrative body competent to give a ruling on complaints or to institute the appropriate legal proceedings.

*Article 5*

This Directive shall not preclude Member States from laying down, in accordance with the Treaty, such stricter requirements concerning the advertising or sponsorship of tobacco products as they deem necessary to guarantee the health protection of individuals.

*Article 6*

1. Member States shall bring into force the laws, regulations, and administrative provisions necessary to comply with this Directive not later than 30 July 2001. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of domestic law which they adopt in the field covered by this Directive.

3. Member States may defer the implementation of Article 3(1) for:

— one year in respect of the press,

— two years in respect of sponsorship.

In exceptional cases and for duly justified reasons, Member States may continue to authorise the existing sponsorship of events or activities organised at world level for a further period of three years ending not later than 1 October 2006, provided that:

— the sums devoted to such sponsorship decrease over the transitional period,

— voluntary-restraint measures are introduced in order to reduce the visibility of advertising at the events or activities concerned.

*Article 7*

The Commission shall submit to the European Parliament, the Council and the Economic and Social Committee not later than 30 July 2001, and subsequently every two years, a report on the implementation of this Directive, with particular reference to the implementation and effects of Article 3(2) and (3) and Article 6(3). Where appropriate, it shall submit proposals for the adaptation of this Directive to suit developments identified in the report. Such adaptation shall not affect the periods provided for in Article 6(3).

*Article 8*

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

*Article 9*

This Directive is addressed to the Member States.

Done at Brussels, 6 July 1998.

| *For the European Parliament* | *For the Council* |
|---|---|
| *The President* | *The President* |
| J. M. GIL-ROBLES | R. EDLINGER |

# DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## of 6 July 1998

## on the legal protection of biotechnological inventions

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 189b of the Treaty [3],

(1) Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions will certainly be of fundamental importance for the Community's industrial development;

(2) Whereas, in particular in the field of genetic engineering, research and development require a considerable amount of high-risk investment and therefore only adequate legal protection can make them profitable;

(3) Whereas effective and harmonised protection throughout the Member States is essential in order to maintain and encourage investment in the field of biotechnology;

(4) Whereas following the European Parliament's rejection of the joint text, approved by the Conciliation Committee, for a European Parliament and Council Directive on the legal protection of biotechnological inventions [4], the European Parliament and the Council have determined that the legal protection of biotechnological inventions requires clarification;

(5) Whereas differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the different Member States; whereas such differences could create barriers to trade and hence impede the proper functioning of the internal market;

(6) Whereas such differences could well become greater as Member States adopt new and different legislation and administrative practices, or whereas national case-law interpreting such legislation develops differently;

(7) Whereas uncoordinated development of national laws on the legal protection of biotechnological inventions in the Community could lead to further disincentives to trade, to the detriment of the industrial development of such inventions and of the smooth operation of the internal market;

(8) Whereas legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law; whereas the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfil the requirements for patentability;

(9) Whereas in certain cases, such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals, certain concepts

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[1] OJ C 296, 8.10.1996, p. 4 and OJ C 311, 11.10.1997, p. 12.

[2] OJ C 295, 7.10.1996, p. 11.

[3] Opinion of the European Parliament of 16 July 1997 (OJ C 286, 22.9.1997, p. 87). Council Common Position of 26 February 1998 (OJ C 110, 8.4.1998, p. 17) and Decision of the European Parliament of 12 May 1998 (OJ C 167, 1.6.1998). Council Decision of 16 June 1998.

[4] OJ C 68, 20.3.1995, p. 26.

in national laws based upon international patent and plant variety conventions have created uncertainty regarding the protection of biotechnological and certain microbiological inventions; whereas harmonisation is necessary to clarify the said uncertainty;

(10) Whereas regard should be had to the potential of the development of biotechnology for the environment and in particular the utility of this technology for the development of methods of cultivation which are less polluting and more economical in their use of ground; whereas the patent system should be used to encourage research into, and the application of, such processes;

(11) Whereas the development of biotechnology is important to developing countries, both in the field of health and combating major epidemics and endemic diseases and in that of combating hunger in the world; whereas the patent system should likewise be used to encourage research in these fields; whereas international procedures for the dissemination of such technology in the Third World and to the benefit of the population groups concerned should be promoted;

(12) Whereas the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) [1] signed by the European Community and the Member States, has entered into force and provides that patent protection must be guaranteed for products and processes in all areas of technology;

(13) Whereas the Community's legal framework for the protection of biotechnological inventions can be limited to laying down certain principles as they apply to the patentability of biological material as such, such principles being intended in particular to determine the difference between inventions and discoveries with regard to the patentability of certain elements of human origin, to the scope of protection conferred by a patent on a biotechnological invention, to the right to use a deposit mechanism in addition to written descriptions and lastly to the option of obtaining non-exclusive compulsory licences in respect of interdependence between plant varieties and inventions, and conversely;

(14) Whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes; whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards;

(15) Whereas no prohibition or exclusion exists in national or European patent law (Munich Convention) which precludes *a priori* the patentability of biological matter;

(16) Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;

(17) Whereas significant progress in the treatment of diseases has already been made thanks to the existence of medicinal products derived from elements isolated from the human body and/or otherwise produced, such medicinal products resulting from technical processes aimed at obtaining elements similar in structure to those existing naturally in the human body and whereas, consequently, research aimed at obtaining and isolating such elements valuable to medicinal production should be encouraged by means of the patent system;

(18) Whereas, since the patent system provides insufficient incentive for encouraging research into and production of biotechnological medicines which are needed to combat rare or 'orphan' diseases, the Community and the Member States have a duty to respond adequately to this problem;

[1] OJ L 336, 23.12.1994, p. 213.

(19) Whereas account has been taken of Opinion No 8 of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission;

(20) Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment;

(21) Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself;

(22) Whereas the discussion on the patentability of sequences or partial sequences of genes is controversial; whereas, according to this Directive, the granting of a patent for inventions which concern such sequences or partial sequences should be subject to the same criteria of patentability as in all other areas of technology: novelty, inventive step and industrial application; whereas the industrial application of a sequence or partial sequence must be disclosed in the patent application as filed;

(23) Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;

(24) Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs;

(25) Whereas, for the purposes of interpreting rights conferred by a patent, when sequences overlap only in parts which are not essential to the invention, each sequence will be considered as an independent sequence in patent law terms;

(26) Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law;

(27) Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents;

(28) Whereas this Directive does not in any way affect the basis of current patent law, according to which a patent may be granted for any new application of a patented product;

(29) Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety;

(30) Whereas the concept 'plant variety' is defined by the legislation protecting new varieties, pursuant to which a variety is defined by its whole genome and therefore possesses individuality and is clearly distinguishable from other varieties;

(31) Whereas a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants;

(32) Whereas, however, if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process;

(33) Whereas it is necessary to define for the purposes of this Directive when a process for the breeding of plants and animals is essentially biological;

(34) Whereas this Directive shall be without prejudice to concepts of invention and discovery, as developed by national, European or international patent law;

(35) Whereas this Directive shall be without prejudice to the provisions of national patent law whereby processes for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded from patentability;

(36) Whereas the TRIPs Agreement provides for the possibility that members of the World Trade Organisation may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law;

(37) Whereas the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against *ordre public* or morality must also be stressed in this Directive;

(38) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to *ordre public* and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability;

(39) Whereas *ordre public* and morality correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention;

(40) Whereas there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offends against *ordre public* and morality; whereas it is therefore important to exclude unequivocally from patentability processes for modifying the germ line genetic identity of human beings and processes for cloning human beings;

(41) Whereas a process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being;

(42) Whereas, moreover, uses of human embryos for industrial or commercial purposes must also be excluded from patentability; whereas in any case such exclusion does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it;

(43) Whereas pursuant to Article F(2) of the Treaty on European Union, the Union is to respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to the Member States, as general principles of Community law;

(44) Whereas the Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology; whereas it should be pointed out in this connection that that Group may be consulted only where biotechnology is to be evaluated at the level of basic ethical principles, including where it is consulted on patent law;

(45) Whereas processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit in terms of research, prevention, diagnosis or therapy to man or animal, and also animals resulting from such processes, must be excluded from patentability;

(46) Whereas, in view of the fact that the function of a patent is to reward the inventor for his creative efforts by granting an exclusive but time-bound right, and thereby encourage inventive activities,

the holder of the patent should be entitled to prohibit the use of patented self-reproducing material in situations analogous to those where it would be permitted to prohibit the use of patented, non-self-reproducing products, that is to say the production of the patented product itself;

(47) Whereas it is necessary to provide for a first derogation from the rights of the holder of the patent when the propagating material incorporating the protected invention is sold to a farmer for farming purposes by the holder of the patent or with his consent; whereas that initial derogation must authorise the farmer to use the product of his harvest for further multiplication or propagation on his own farm; whereas the extent and the conditions of that derogation must be limited in accordance with the extent and conditions set out in Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights [1];

(48) Whereas only the fee envisaged under Community law relating to plant variety rights as a condition for applying the derogation from Community plant variety rights can be required of the farmer;

(49) Whereas, however, the holder of the patent may defend his rights against a farmer abusing the derogation or against a breeder who has developed a plant variety incorporating the protected invention if the latter fails to adhere to his commitments;

(50) Whereas a second derogation from the rights of the holder of the patent must authorise the farmer to use protected livestock for agricultural purposes;

(51) Whereas the extent and the conditions of that second derogation must be determined by national laws, regulations and practices, since there is no Community legislation on animal variety rights;

(52) Whereas, in the field of exploitation of new plant characteristics resulting from genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where, in relation to the genus or species concerned, the plant variety represents significant technical progress of considerable economic interest compared to the invention claimed in the patent;

(53) Whereas, in the field of the use of new plant characteristics resulting from new plant varieties in genetic engineering, guaranteed access must, on payment of a fee, be granted in the form of a compulsory licence where the invention represents significant technical progress of considerable economic interest;

(54) Whereas Article 34 of the TRIPs Agreement contains detailed provisions on the burden of proof which is binding on all Member States; whereas, therefore, a provision in this Directive is not necessary;

(55) Whereas following Decision 93/626/EEC [2] the Community is party to the Convention on Biological Diversity of 5 June 1992; whereas, in this regard, Member States must give particular weight to Article 3 and Article 8(j), the second sentence of Article 16(2) and Article 16(5) of the Convention when bringing into force the laws, regulations and administrative provisions necessary to comply with this Directive;

(56) Whereas the Third Conference of the Parties to the Biodiversity Convention, which took place in November 1996, noted in Decision III/17 that 'further work is required to help develop a common appreciation of the relationship between intellectual property rights and the relevant provisions of the TRIPs Agreement and the Convention on Biological Diversity, in particular on issues relating to technology transfer and conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising out of the use of genetic resources, including the protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity',

[1] OJ L 227, 1.9.1994, p. 1. Regulation as amended by Regulation (EC) No 2506/95 (OJ L 258, 28.10.1995, p. 3).

[2] OJ L 309, 31.12.1993, p. 1.

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

**Patentability**

*Article 1*

1. Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.

2. This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.

*Article 2*

1. For the purposes of this Directive,

(a) 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;

(b) 'microbiological process' means any process involving or performed upon or resulting in microbiological material.

2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

3. The concept of 'plant variety' is defined by Article 5 of Regulation (EC) No 2100/94.

*Article 3*

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

*Article 4*

1. The following shall not be patentable:

(a) plant and animal varieties;

(b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

*Article 5*

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

*Article 6*

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

*Article 7*

The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.

CHAPTER II

**Scope of protection**

*Article 8*

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

*Article 9*

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product in incorporated and in which the genetic information is contained and performs its function.

*Article 10*

The protection referred to in Articles 8 and 9 shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market in the territory of a Member State by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

*Article 11*

1. By way of derogation from Articles 8 and 9, the sale or other form of commercialisation of plant propagating material to a farmer by the holder of the patent or with his consent for agricultural use implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm, the extent and conditions of this derogation corresponding to those under Article 14 of Regulation (EC) No 2100/94.

2. By way of derogation from Articles 8 and 9, the sale or any other form of commercialisation of breeding stock or other animal reproductive material to a farmer by the holder of the patent or with his consent implies authorisation for the farmer to use the protected livestock for an agricultural purpose. This includes making the animal or other animal reproductive material available for the purposes of pursuing his agricultural activity but not sale within the framework or for the purpose of a commercial reproduction activity.

3. The extent and the conditions of the derogation provided for in paragraph 2 shall be determined by national laws, regulations and practices.

CHAPTER III

**Compulsory cross-licensing**

*Article 12*

1. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

2. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Member States shall provide that, where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

3. Applicants for the licences referred to in paragraphs 1 and 2 must demonstrate that:

(a) they have applied unsuccessfully to the holder of the patent or of the plant variety right to obtain a contractual licence;

(b) the plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

4. Each Member State shall designate the authority or authorities responsible for granting the licence. Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Regulation (EC) No 2100/94 shall apply.

## CHAPTER IV

## Deposit, access and re-deposit of a biological material

### *Article 13*

1. Where an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate for the purposes of patent law unless:

(a) the biological material has been deposited no later than the date on which the patent application was filed with a recognised depositary institution. At least the international depositary authorities which acquired this status by virtue of Article 7 of the Budapest Treaty of 28 April 1977 on the international recognition of the deposit of micro-organisms for the purposes of patent procedure, hereinafter referred to as the 'Budapest Treaty', shall be recognised;

(b) the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited;

(c) the patent application states the name of the depository institution and the accession number.

2. Access to the deposited biological material shall be provided through the supply of a sample:

(a) up to the first publication of the patent application, only to those persons who are authorised under national patent law;

(b) between the first publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;

(c) after the patent has been granted, and notwithstanding revocation or cancellation of the patent, to anyone requesting it.

3. The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force:

(a) not to make it or any material derived from it available to third parties; and

(b) not to use it or any material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, as applicable, expressly waives such an undertaking.

4. At the applicant's request, where an application is refused or withdrawn, access to the deposited material shall be limited to an independent expert for 20 years from the date on which the patent application was filed. In that case, paragraph 3 shall apply.

5. The applicant's requests referred to in point (b) of paragraph 2 and in paragraph 4 may only be made up to the date on which the technical preparations for publishing the patent application are deemed to have been completed.

### *Article 14*

1. If the biological material deposited in accordance with Article 13 ceases to be available from the recognised depositary institution, a new deposit of the material shall be permitted on the same terms as those laid down in the Budapest Treaty.

2. Any new deposit shall be accompanied by a statement signed by the depositor certifying that the newly deposited biological material is the same as that originally deposited.

## CHAPTER V

## Final provisions

### *Article 15*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

*Article 16*

The Commission shall send the European Parliament and the Council:

(a) every five years as from the date specified in Article 15(1) a report on any problems encountered with regard to the relationship between this Directive and international agreements on the protection of human rights to which the Member States have acceded;

(b) within two years of entry into force of this Directive, a report assessing the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable;

(c) annually as from the date specified in Article 15(1), a report on the development and implications of patent law in the field of biotechnology and genetic engineering.

*Article 17*

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

*Article 18*

This Directive is addressed to the Member States.

Done at Brussels, 6 July 1998.

| *For the European Parliament* | *For the Council* |
|---|---|
| *The President* | *The President* |
| J. M. GIL-ROBLES | R. EDLINGER |