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Legislation

Contents

I Acts whose publication is obligatory

- ★ Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights 1
- ★ Council Directive 94/43/EC of 27 July 1994 establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market 31

I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EC) No 2100/94

of 27 July 1994

on Community plant variety rights

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 235 thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas plant varieties pose specific problems as regards the industrial property régime which may be applicable;

Whereas industrial property regimes for plant varieties have not been harmonized at Community level and therefore continue to be regulated by the legislation of the Member States, the content of which is not uniform;

Whereas in such circumstances it is appropriate to create a Community regime which, although co-existing with national regimes, allows for the grant of industrial property rights valid throughout the Community;

Whereas it is appropriate that the implementation and application of this Community regime should not be carried out by the authorities of the Member States but by a Community Office with legal personality, the 'Community Plant Variety Office';

Whereas the system must also have regard to developments in plant breeding techniques including biotechnology; whereas in order to stimulate the breeding and development of new varieties, there should be improved protection compared with the present situation for all plant breeders without, however, unjustifiably

impairing access to protection generally or in the case of certain breeding techniques;

Whereas varieties of all botanical genera and species should be protectable;

Whereas protectable varieties must comply with internationally recognized requirements, i.e. distinctness, uniformity, stability and novelty, and also be designated by a prescribed variety denomination;

Whereas it is important to provide for a definition of a plant variety, in order to ensure the proper functioning of the system;

Whereas this definition is not intended to alter definitions which may have been established in the field of intellectual property rights, especially the patent field, nor to interfere with or exclude from application laws governing the protectability of products, including plants and plant material, or processes under such other industrial property rights;

Whereas it is however highly desirable to have a common definition in both fields; whereas therefore appropriate efforts at international level should be supported to reach such a common definition;

Whereas for the grant of Community plant variety rights an assessment of important characteristics relating to the variety is necessary; whereas, however, these characteristics need not necessarily relate to their economic importance;

Whereas the system must also clarify to whom the right to Community plant variety protection pertains; whereas in some cases it would be to several persons in common, not just to one; whereas the formal entitlement to make applications must be regulated;

Whereas the system must also define the term 'holder' used in this Regulation; whereas that term 'holder' without further specification is used in this Regulation including in its Article 29 (5), it is intended to be within the meaning of Article 13 (1) thereof;

⁽¹⁾ OJ No C 244, 28. 9. 1990, p. 1 and
OJ No C 113, 23. 4. 1993, p. 7.

⁽²⁾ OJ No C 305, 23. 11. 1992, p. 55 and
OJ No C 67, 16. 3. 1992, p. 148.

⁽³⁾ OJ No C 60, 8. 3. 1991, p. 45.

Whereas, since the effect of a Community plant variety right should be uniform throughout the Community, commercial transactions subject to the holder's agreement must be precisely delimited; whereas the scope of protection should be extended, compared with most national systems, to certain material of the variety to take account of trade via countries outside the Community without protection; whereas, however, the introduction of the principle of exhaustion of rights must ensure that the protection is not excessive;

Whereas in order to stimulate plant breeding, the system basically confirms the internationally accepted rule of free access to protected varieties for the development therefrom, and exploitation, of new varieties;

Whereas in certain cases where the new variety, although distinct, is essentially derived from the initial variety, a certain form of dependency from the holder of the latter one should be created;

Whereas, the exercise of Community plant variety rights must be subjected to restrictions laid down in provisions adopted in the public interest;

Whereas this includes safeguarding agricultural production; whereas that purpose requires an authorization for farmers to use the product of the harvest for propagation under certain conditions;

Whereas it must be ensured that the conditions are laid down at Community level;

Whereas compulsory licensing should also be provided for under certain circumstances in the public interest, which may include the need to supply the market with material offering specified features, or to maintain the incentive for continued breeding of improved varieties;

Whereas the use of prescribed variety denominations should be made obligatory;

Whereas the Community plant variety right should in principle have a life of at least 25 years and in the case of vine and tree species, at least 30 years; whereas other grounds for termination must be specified;

Whereas a Community plant variety right is an object of the holder's property and its role in relation to the non-harmonized legal provisions of the Member States, particularly of civil law, must therefore be clarified; whereas this applies also to the settlement of

infringements and the enforcement of entitlement to Community plant variety rights;

Whereas, it is necessary to ensure that the full application of the principles of the Community plant variety rights system is not impaired by the effects of other systems; whereas for this purpose certain rules, in conformity with Member States' existing international commitments, are required concerning the relationship to other industrial property rights;

Whereas it is indispensable to examine whether and to what extent the conditions for the protection accorded in other industrial property systems, such as patents, should be adapted or otherwise modified for consistency with the Community plant variety rights system; whereas this, where necessary, should be laid down in balanced rules by additional Community law;

Whereas the duties and powers of the Community Plant Variety Office, including its Boards of Appeal, relating to the grant, termination or verification of Community plant variety rights and publications are as far as possible to be modelled on rules developed for other systems, as are also the Office's structure and Rules of Procedure, the collaboration with the Commission and Member States particularly through an Administrative Council, the involvement of Examination Offices in technical examination and moreover the necessary budgetary measures;

Whereas the Office should be advised and supervised by the aforementioned Administrative Council, composed of representatives of Member States and the Commission;

Whereas the Treaty does not provide, for the adoption of this Regulation, powers other than those of Article 235;

Whereas this Regulation takes into account existing international conventions such as the International Convention for the Protection of New Varieties of Plants (UPOV Convention), the Convention of the Grant of European Patents (European Patent Convention) or the Agreement on trade-related aspects of intellectual property rights, including trade in counterfeit goods; whereas it consequently implements the ban on patenting plant varieties only to the extent that the European Patent Convention so requires, i.e. to plant varieties as such;

Whereas this Regulation should be re-examined for amendment as necessary in the light of future developments in the aforementioned Conventions,

HAS ADOPTED THIS REGULATION:

PART ONE

GENERAL PROVISIONS

Article 1

Community plant variety rights

A system of Community plant variety rights is hereby established as the sole and exclusive form of Community industrial property rights for plant varieties.

Article 2

Uniform effect of Community plant variety rights

Community plant variety rights shall have uniform effect within the territory of the Community and may not be granted, transferred or terminated in respect of the abovementioned territory otherwise than on a uniform basis.

Article 3

National property rights for plant varieties

This Regulation shall be without prejudice to the right of the Member States to grant national property rights for plant varieties, subject to the provisions of Article 92 (1).

Article 4

Community Office

For the purpose of the implementation of this Regulation a Community Plant Variety Office, hereinafter referred to as 'the Office', is hereby established.

PART TWO

SUBSTANTIVE LAW

CHAPTER I

CONDITIONS GOVERNING THE GRANT OF
COMMUNITY PLANT VARIETY RIGHTS

Article 5

Object of Community plant variety rights

1. Varieties of all botanical genera and species, including, *inter alia*, hybrids between genera or species, may form the object of Community plant variety rights.

2. For the purpose of this Regulation, 'variety' shall be taken to mean a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

- defined by the expression of the characteristics that results from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics, and

— considered as a unit with regard to its suitability for being propagated unchanged.

3. A plant grouping consists of entire plants or parts of plants as far as such parts are capable of producing entire plants, both referred to hereinafter as 'variety constituents'.

4. The expression of the characteristics referred to in paragraph 2, first indent, may be either invariable or variable between variety constituents of the same kind provided that also the level of variation results from the genotype or combination of genotypes.

Article 6

Protectable varieties

Community plant variety rights shall be granted for varieties that are:

- (a) distinct;
- (b) uniform;
- (c) stable; and
- (d) new.

Moreover, the variety must be designated by a denomination in accordance with the provisions of Article 63.

Article 7

Distinctness

1. A variety shall be deemed to be distinct if it is clearly distinguishable by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety whose existence is a matter of common knowledge on the date of application determined pursuant to Article 51.

2. The existence of another variety shall in particular be deemed to be a matter of common knowledge if on the date of application determined pursuant to Article 51:

- (a) it was the object of a plant variety right or entered in an official register of plant varieties, in the Community or any State, or in any intergovernmental organization with relevant competence;
- (b) an application for the granting of a plant variety right in its respect or for its entering in such an official register was filed, provided the application has led to the granting or entering in the meantime.

The implementing rules pursuant to Article 114 may specify further cases as examples which shall be deemed to be a matter of common knowledge.

Article 8

Uniformity

A variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness, as well as any others used for the variety description.

Article 9

Stability

A variety shall be deemed to be stable if the expression of the characteristics which are included in the examination for distinctness as well as any others used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle.

Article 10

Novelty

1. A variety shall be deemed to be new if, at the date of application determined pursuant to Article 51, variety constituents or harvested material of the variety have not been sold or otherwise disposed of to others, by or with

the consent of the breeder within the meaning of Article 11, for purposes of exploitation of the variety:

- (a) earlier than one year before the abovementioned date, within the territory of the Community;
- (b) earlier than four years or, in the case of trees or of vines, earlier than six years before the said date, outside the territory of the Community.

2. The disposal of variety constituents to an official body for statutory purposes, or to others on the basis of a contractual or other legal relationship solely for production, reproduction, multiplication, conditioning or storage, shall not be deemed to be a disposal to others within the meaning of paragraph 1, provided that the breeder preserves the exclusive right of disposal of these and other variety constituents, and no further disposal is made. However, such disposal of variety constituents shall be deemed to be a disposal in terms of paragraph 1 if these constituents are repeatedly used in the production of a hybrid variety and if there is disposal of variety constituents or harvested material of the hybrid variety.

Likewise, the disposal of variety constituents by one company or firm within the meaning of the second paragraph of Article 58 of the Treaty to another of such companies or firms shall not be deemed to be a disposal to others, if one of them belongs entirely to the other or if both belong entirely to a third such company or firm, provided no further disposal is made. This provision shall not apply in respect of cooperative societies.

3. The disposal of variety constituents or harvested material of the variety, which have been produced from plants grown for the purposes specified in Article 15 (b) and (c) and which are not used for further reproduction or multiplication, shall not be deemed to be exploitation of the variety, unless reference is made to the variety for purposes of that disposal.

Likewise, no account shall be taken of any disposal to others, if it either was due to, or in consequence of the fact that the breeder had displayed the variety at an official or officially recognized exhibition within the meaning of the Convention on International Exhibitions, or at an exhibition in a Member State which was officially recognized as equivalent by that Member State.

CHAPTER II

PERSONS ENTITLED

Article 11

Entitlement to Community plant variety rights

1. The person who bred, or discovered and developed the variety, or his successor in title, both — the person and his successor — referred to hereinafter as 'the

breeder', shall be entitled to the Community plant variety right.

2. If two or more persons bred, or discovered and developed the variety jointly, entitlement shall be vested jointly in them or their respective successors in title. This provision shall also apply to two or more persons in cases where one or more of them discovered the variety and the other or the others developed it.

3. Entitlement shall also be invested jointly in the breeder and any other person or persons, if the breeder and the other person or persons have agreed to joint entitlement by written declaration.

4. If the breeder is an employee, the entitlement to the Community plant variety right shall be determined in accordance with the national law applicable to the employment relationship in the context of which the variety was bred, or discovered and developed.

5. Where entitlement to a Community plant variety right is vested jointly in two or more persons pursuant to paragraphs 2 to 4, one or more of them may empower the others by written declaration to such effect to claim entitlement thereto.

Article 12

Entitlement to file an application for a Community plant variety right

1. An application for a Community plant variety right may be filed by any natural or legal person, or any body ranking as a legal person under the law applicable to that body, provided they are:

- (a) nationals of one of the Member States or nationals of a member of the Union for the Protection of New Varieties of Plants within the meaning of Article 1 (xi) of the Act of 1991 of the International Convention for the Protection of New Varieties of Plants, or are domiciled or have their seat or an establishment in such a State;
- (b) nationals of any other State who do not meet the requirements laid down in (a) in respect of domicile, seat or establishment, in so far as the Commission, after obtaining the opinion of the Administrative Council referred to in Article 36, has so decided. Such a decision may be made dependent on the other State affording protection for varieties of the same botanical taxon to nationals of all the Member States, which corresponds to the protection afforded pursuant to this Regulation; the Commission shall establish whether this condition is met.

2. An application may be filed jointly by two or more such persons.

CHAPTER III

EFFECTS OF COMMUNITY PLANT VARIETY RIGHTS

Article 13

Rights of the holder of a Community plant variety right and prohibited acts

1. A Community plant variety right shall have the effect that the holder or holders of the Community plant variety right, hereinafter referred to as 'the holder', shall be entitled to effect the acts set out in paragraph 2.

2. Without prejudice to the provisions of Articles 15 and 16, the following acts in respect of variety constituents, or harvested material of the protected variety, both referred to hereinafter as 'material', shall require the authorization of the holder:

- (a) production or reproduction (multiplication);
- (b) conditioning for the purpose of propagation;
- (c) offering for sale;
- (d) selling or other marketing;
- (e) exporting from the Community;
- (f) importing to the Community;
- (g) stocking for any of the purposes mentioned in (a) to (f).

The holder may make his authorization subject to conditions and limitations.

3. The provisions of paragraph 2 shall apply in respect of harvested material only if this was obtained through the unauthorized use of variety constituents of the protected variety, and unless the holder has had reasonable opportunity to exercise his right in relation to the said variety constituents.

4. In the implementing rules pursuant to Article 114, it may be provided that in specific cases the provisions of paragraph 2 of this Article shall also apply in respect of products obtained directly from material of the protected variety. They may apply only if such products were obtained through the unauthorized use of material of the protected variety, and unless the holder has had reasonable opportunity to exercise his right in relation to the said material. To the extent that the provisions of paragraph 2 apply to products directly obtained, they shall also be considered to be 'material'.

5. The provisions of paragraphs 1 to 4 shall also apply in relation to:

- (a) varieties which are essentially derived from the variety in respect of which the Community plant variety right has been granted, where this variety is not itself an essentially derived variety;

(b) varieties which are not distinct in accordance with the provisions of Article 7 from the protected variety; and

(c) varieties whose production requires the repeated use of the protected variety.

6. For the purposes of paragraph 5 (a), a variety shall be deemed to be essentially derived from another variety, referred to hereinafter as 'the initial variety' when:

(a) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety;

(b) it is distinct in accordance with the provisions of Article 7 from the initial variety; and

(c) except for the differences which result from the act of derivation, it conforms essentially to the initial variety in the expression of the characteristics that results from the genotype or combination of genotypes of the initial variety.

7. The implementing rules pursuant to Article 114 may specify possible acts of derivation which come at least under the provisions of paragraph 6.

8. Without prejudice to Article 14 and 29, the exercise of the rights conferred by Community plant variety rights may not violate any provisions adopted on the grounds of public morality, public policy or public security, the protection of health and life of humans, animals or plants, the protection of the environment, the protection of industrial or commercial property, or the safeguarding of competition, of trade or of agricultural production.

Article 14

Derogation from Community plant variety right

1. Notwithstanding Article 13 (2), and for the purposes of safeguarding agricultural production, farmers are authorized to use for propagating purposes in the field, on their own holding the product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than a hybrid or synthetic variety, which is covered by a Community plant variety right.

2. The provisions of paragraph 1 shall only apply to agricultural plant species of:

(a) Fodder plants:

Cicer arietinum L. — Chickpea milkvetch

Lupinus luteus L. — Yellow lupin

Medicago sativa L. — Lucerne

Pisum sativum L. (partim) — Field pea

Trifolium alexandrinum L. — Berseem/Egyptian clover

Trifolium resupinatum L. — Persian clover

Vicia faba — Field bean

Vicia sativa L. — Common vetch

and, in the case of Portugal, *Lolium multiflorum* Lam — Italian rye-grass

(b) Cereals:

Avena sativa — Oats

Hordeum vulgare L. — Barley

Oryza sativa L. — Rice

Phalaris canariensis L. — Canary grass

Secale cereale L. — Rye

X *Triticosecale* Wittm. — Triticale

Triticum aestivum L. emend. Fiori et Paol. — Wheat

Triticum durum Desf. — Durum wheat

Triticum spelta L. — Spelt wheat

(c) Potatoes:

Solanum tuberosum — Potatoes

(d) Oil and fibre plants:

Brassica napus L. (partim) — Swede rape

Brassica rapa L. (partim) — Turnip rape

Linum usitatissimum — linseed with the exclusion of flax.

3. Conditions to give effect to the derogation provided for in paragraph 1 and to safeguard the legitimate interests of the breeder and of the farmer, shall be established, before the entry into force of this Regulation, in implementing rules pursuant to Article 114, on the basis of the following criteria:

— there shall be no quantitative restriction of the level of the farmer's holding to the extent necessary for the requirements of the holding,

— the product of the harvest may be processed for planting, either by the farmer himself or through services supplied to him, without prejudice to certain restrictions which Member States may establish regarding the organization of the processing of the said product of the harvest, in particular in order to ensure identity of the product entered for processing with that resulting from processing,

— small farmers shall not be required to pay any remuneration to the holder; small farmers shall be considered to be:

— in the case of those of the plant species referred to in paragraph 2 of this Article to which Council Regulation (EEC) No 1765/92 of 30 June 1992 establishing a support system for producers of certain arable crops⁽¹⁾ applies, farmers who do not grow plants on an area bigger than the area which would be needed to produce 92 tonnes of cereals; for the calculation of the area, Article 8 (2) of the aforesaid Regulation shall apply,

⁽¹⁾ OJ No L 181, 1. 7. 1992, p. 12. Regulation as last amended by Regulation (EEC) No 1552/93 (OJ No L 154, 25. 6. 1993, p. 19).

- in the case of other plant species referred to in paragraph 2 of this Article, farmers who meet comparable appropriate criteria,
- other farmers shall be required to pay an equitable remuneration to the holder, which shall be sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area; the actual level of this equitable remuneration may be subject to variation over time, taking into account the extent to which use will be made of the derogation provided for in paragraph 1 in respect of the variety concerned,
- monitoring compliance with the provisions of this Article or the provisions adopted pursuant to this Article shall be a matter of exclusive responsibility of holders; in organizing that monitoring, they may not provide for assistance from official bodies,
- relevant information shall be provided to the holders on their request, by farmers and by suppliers of processing services; relevant information may equally be provided by official bodies involved in the monitoring of agricultural production, if such information has been obtained through ordinary performance of their tasks, without additional burden or costs. These provisions are without prejudice, in respect of personal data, to Community and national legislation on the protection of individuals with regard to the processing and free movement of personal data.

Article 15

Limitation of the effects of Community plant variety rights

The Community plant variety rights shall not extend to:

- (a) acts done privately and for non-commercial purposes;
- (b) acts done for experimental purposes;
- (c) acts done for the purpose of breeding, or discovering and developing other varieties;
- (d) acts referred to in Article 13 (2) to (4), in respect of such other varieties, except where the provisions of Article 13 (5) apply, or where the other variety or the material of this variety comes under the protection of a property right which does not contain a comparable provision; and
- (e) acts whose prohibition would violate the provisions laid down in Articles 13 (8), 14 or 29.

Article 16

Exhaustion of Community plant variety rights

The Community plant variety right shall not extend to acts concerning any material of the protected variety, or of a variety covered by the provisions of Article 13 (5), which has been disposed of to others by the holder or with his consent, in any part of the Community, or any material derived from the said material, unless such acts:

- (a) involve further propagation of the variety in question, except where such propagation was intended when the material was disposed of; or
- (b) involve an export of variety constituents into a third country which does not protect varieties of the plant genus or species to which the variety belongs, except where the exported materials is for final consumption purposes.

Article 17

Use of variety denominations

1. Any person who, within the territory of the Community, offers or disposes of to others for commercial purposes variety constituents of a protected variety, or a variety covered by the provisions of Article 13 (5), must use the variety denomination designated pursuant to Article 63; where it is used in writing, the variety denomination shall be readily distinguishable and clearly legible. If a trade mark, trade name or similar indication is associated with the designated denomination, this denomination must be easily recognizable as such.

2. Any person effecting such acts in respect of any other material of the variety, must inform of that denomination in accordance with other provisions in law or if a request is made by an authority, by the purchaser or by any other person having a legitimate interest.

3. Paragraphs 1 and 2 shall apply even after the termination of the Community plant variety right.

Article 18

Limitation of the use of variety denominations

1. The holder may not use any right granted in respect of a designation that is identical with the variety denomination to hamper the free use of that denomination in connection with the variety, even after the termination of the Community plant variety right.

2. A third party may use a right granted in respect of a designation that is identical with the variety denomination

to hamper the free use of that denomination only if that right was granted before the variety denomination was designated pursuant to Article 63.

3. Where a variety is protected by a Community plant variety right or, in a Member State or in a Member of the International Union for the Protection of New Varieties of Plants by a national property right, neither its designated denomination or any designation which might be confused with it can be used, within the territory of the Community, in connection with another variety of the same botanical species or a species regarded as related pursuant to the publication made in accordance with Article 63 (5), or for material of such variety.

CHAPTER IV

DURATION AND TERMINATION OF COMMUNITY PLANT VARIETY RIGHTS

Article 19

Duration of Community plant variety rights

1. The term of the Community plant variety right shall run until the end of the 25th calendar year or, in the case of varieties of vine and tree species, until the end of the 30th calendar year, following the year of grant.

2. The Council, acting by qualified majority on proposal from the Commission, may, in respect of specific genera or species, provide for an extension of these terms up to a further five years.

3. A Community plant variety right shall lapse before the expiry of the terms laid down in paragraph 1 or pursuant to paragraph 2, if the holder surrenders it by sending a written declaration to such effect to the Office, and with effect from the day following the day on which the declaration is received by the Office.

Article 20

Nullity of Community plant variety rights

1. The Office shall declare the Community plant variety right null and void if it is established:

- (a) that the conditions laid down in Articles 7 or 10 were not complied with at the time of the Community plant variety right; or
- (b) that where the grant of the Community plant variety right has been essentially based upon information and documents furnished by the applicant, the conditions laid down in Articles 8 and 9 were not

complied with at the time of the grant of the right; or

- (c) that the right has been granted to a person who is not entitled to it, unless it is transferred to the person who is so entitled.

2. Where the Community plant variety right is declared null and void, it shall be deemed not to have had, as from the outset, the effects specified in this Regulation.

Article 21

Cancellation of Community plant variety rights

1. The Office shall cancel the Community plant variety right with effect in futurum if it is established that the conditions laid down in Article 8 or 9 are no longer complied with. If it is established that these conditions were already no longer complied with from a point in time prior to cancellation, cancellation may be made effective as from that juncture.

2. The Office may cancel a Community plant variety right with effect in futurum if the holder, after being requested to do so, and within a time limit specified by the Office:

- (a) has not fulfilled an obligation pursuant to Article 64 (3); or
- (b) in the case referred to in Article 66, does not propose another suitable variety denomination; or
- (c) fails to pay such fees as may be payable to keep the Community plant variety right in force; or
- (d) either as the initial holder or as a successor in title as a result of a transfer pursuant to Article 23, no longer satisfies the conditions laid down in Articles 12 and 82.

CHAPTER V

COMMUNITY PLANT VARIETY RIGHTS AS OBJECTS OF PROPERTY

Article 22

Assimilation with national laws

1. Save where otherwise provided in Articles 23 to 29, a Community plant variety right as an object of property shall be regarded in all respects, and for the entire territory of the Community, as a corresponding property right in the Member State in which:

- (a) according to the entry in the Register of Community Plant Variety Rights, the holder was domiciled or had his seat or an establishment on the relevant date; or

(b) if the conditions laid down in subparagraph (a) are not fulfilled, the first-mentioned procedural representative of the holder, as indicated in the said Register, was domiciled or had his seat or an establishment on the date of registration.

2. Where the conditions laid down in paragraph 1 are not fulfilled, the Member State referred to in paragraph 1 shall be the Member State in which the seat of the Office is located.

3. Where domiciles, seats or establishments in two or more Member States are entered in respect of the holder or the procedural representatives in the Register referred to in paragraph 1, the first-mentioned domicile or seat shall apply for the purposes of paragraph 1.

4. Where two or more persons are entered in the Register referred to in paragraph 1 as joint holders, the relevant holder for the purposes of applying paragraph 1 (a) shall be the first joint holder taken in order of entry in the Register who fulfils the conditions. Where none of the joint holders fulfils the conditions laid down in paragraph 1 (a), paragraph 2 shall be applicable.

Article 23

Transfer

1. A Community plant variety right may be the object of a transfer to one or more successors in title.

2. Transfer of a Community plant variety right by assignment can be made only to successors who comply with the conditions laid down in Article 12 and 82. It shall be made in writing and shall require the signature of the parties to the contract, except when it is a result of a judgement or of any other acts terminating court proceedings. Otherwise it shall be void.

3. Save as otherwise provided in Article 100, a transfer shall have no bearing on the rights acquired by third parties before the date of transfer.

4. A transfer shall not take effect for the Office and may not be cited *vis-à-vis* third parties unless documentary evidence thereof as provided for in the implementing rules is provided and until it has been entered in the Register of Community Plant Variety Rights. A transfer that has not yet been entered in the Register may, however, be cited *vis-à-vis* third parties who have acquired rights after the date of transfer but who knew of the transfer at the date on which they acquired those rights.

Article 24

Levy of execution

A Community plant variety right may be levied in execution and be the subject of provisional, including protective, measures within the meaning of Article 24 of the Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters, signed in Lugano on 16 September 1988, hereinafter referred to as the 'Lugano Convention'.

Article 25

Bankruptcy or like proceedings

Until such time as common rules for the Member States in this field enter into force, the only Member State in which a Community plant variety right may be involved in bankruptcy or like proceedings shall be that in which such proceedings are first brought within the meaning of national law or of conventions applicable in this field.

Article 26

The application for a Community plant variety right as an object of property

Articles 22 to 25 shall apply to applications for Community plant variety rights. Concerning such applications, the references made in those Articles to the Register of Community Plant Variety Rights shall be regarded as references to the Register of Application for Community Plant Variety Rights.

Article 27

Contractual exploitation rights

1. Community plant variety rights may form in full or in part the subject of contractually granted exploitation rights. Exploitation rights may be exclusive or non-exclusive.

2. The holder may invoke the rights conferred by the Community plant variety right against a person enjoying the right of exploitation who contravenes any of the conditions or limitations attached to his exploitation right pursuant to paragraph 1.

Article 28

Joint holdership

Articles 22 to 27 shall apply *mutatis mutandis* in the event of joint holdership of a Community plant variety right in proportion to the respective share held, where such shares have been determined.

*Article 29***Compulsory exploitation right**

1. Compulsory exploitation rights shall be granted to one or more persons by the Office, on application by that person or those persons, but only on grounds of public interest and after consulting the Administrative Council referred to in Article 36.

2. On application by a Member State, by the Commission or by an organization set up at Community level and registered by the Commission, a compulsory exploitation right may be granted, either to a category of persons satisfying specific requirements, or to anyone in one or more Member States or throughout the Community. It may be granted only on grounds of public interest and with the approval of the Administrative Council.

3. The Office shall, when granting the compulsory exploitation right, stipulate the type of acts covered and specify the reasonable conditions pertaining thereto as well as the specific requirements referred to in paragraph 2. The reasonable conditions shall take into account the interests of any holder of plant variety rights who would be affected by the grant of the compulsory exploitation right. The reasonable conditions may include a possible time limitation, the payment of an appropriate

royalty as equitable remuneration to the holder, and may impose certain obligations on the holder, the fulfilment of which are necessary to make use of the compulsory exploitation right.

4. On the expiry of each one-year period after the grant of the compulsory exploitation right and within the aforementioned possible time limitation, any of the parties to proceedings may request that the decision on the grant of the compulsory exploitation right be cancelled or amended. The sole grounds for such a request shall be that the circumstances determining the decision taken have in the meantime undergone change.

5. On application, the compulsory exploitation right shall be granted to the holder in respect of an essentially derived variety if the criteria set out in paragraph 1 are met. The reasonable conditions referred to in paragraph 3 shall include the payment of an appropriate royalty as equitable remuneration to the holder of the initial variety.

6. The implementing rules pursuant to Article 114 may specify certain cases as examples of public interest referred to in paragraph 1 and moreover lay down details for the implementation of the provisions of the above paragraphs.

7. Compulsory exploitation rights may not be granted by Member States in respect of a Community plant variety right.

PART THREE**THE COMMUNITY PLANT VARIETY OFFICE****CHAPTER I****GENERAL PROVISIONS***Article 30***Legal status, sub-offices**

1. The Office shall be a body of the Community. It shall have legal personality.

2. In each of the Member States, the Office shall enjoy the most extensive legal capacity accorded to legal persons under their laws. It may, in particular, acquire or dispose of movable and immovable property and may be a party to legal proceedings.

3. The Office shall be represented by its President.

4. With the consent of the Administrative Council referred to in Article 36, the Office may entrust national agencies with the exercise of specific administrative functions of the Office or establish its own sub-offices for that purpose in the Member States, subject to their consent.

*Article 31***Staff**

1. The Staff Regulations of Officials of the European Communities, the Conditions of Employment of Other Servants of the European Communities and the rules adopted jointly by the institutions of the European Communities for purposes of the application of those Staff Regulations and Conditions of Employment shall apply to the staff of the Office, without prejudice to the application of Article 47 to the members of the Board of Appeal.

2. Without prejudice to Article 43, the powers conferred on the appointing authority by the Staff Regulations, and by the Conditions of Employment of Other Servants, shall be exercised by the Office in respect of its own staff.

*Article 32***Privileges and immunities**

The Protocol on the Privileges and Immunities of the European Communities shall apply to the Office.

*Article 33***Liability**

1. The contractual liability of the Office shall be governed by the law applicable to the contract in question.
2. The Court of Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Office.
3. In the case of non-contractual liability, the Office shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its departments or by its servants in the performance of their duties.
4. The Court of Justice shall have jurisdiction in disputes relating to compensation for the damage referred to in paragraph 3.
5. The personal liability of its servants towards the Office shall be governed by the provisions laid down in the Staff Regulations or Conditions of Employment applicable to them.

*Article 34***Languages**

1. The provisions laid down in Regulation No 1 of 15 April 1958 determining the languages to be used in the European Economic Community ⁽¹⁾, shall apply regarding the Office.
2. Applications to the Office, the documents required to process such applications and all other papers submitted shall be filed in one of the official languages of the European Communities.
3. Parties to proceedings before the Office as specified in the implementing rules pursuant to Article 114, shall be entitled, to conduct written and oral proceedings in any official language of the European Communities with translation and, in the case of hearings, simultaneous interpretation, at least into any other of the official languages of the European Communities chosen by any other party to proceedings. The exercise of these rights does not imply specific charges for the parties to proceedings.
4. The translation services required for the functioning of the Office are in principle provided by the Translation Centre of the Bodies of the Union.

⁽¹⁾ OJ No 17, 6. 10. 1958, p. 385/58. Regulation as last amended by the 1985 Act of Accession.

*Article 35***Decisions of the Office**

1. Decisions of the Office shall, provided they do not have to be made by the Board of Appeal pursuant to Article 72, be taken by or under the authority of the President of the Office.
2. Subject to paragraph 1, decisions pursuant to Articles 20, 21, 29, 59, 61, 62, 63, 66 or 100 (2) shall be taken by a Committee of three members of the Office's staff. The qualifications of the members of such Committee, the powers of individual members in the preparatory phase of the decisions, the voting conditions and the role of the President in respect of such Committee shall be determined in the implementing rules pursuant to Article 114. Otherwise, the members of such Committee, in making their decisions, shall not be bound by any instructions.
3. Decisions of the President, other than those specified in paragraph 2, if not taken by the President, may be taken by a member of the Office's staff to whom the power to do so has been delegated pursuant to Article 42 (2) (h).

CHAPTER II

THE ADMINISTRATIVE COUNCIL

*Article 36***Creation and powers**

1. An Administrative Council is hereby set up, attached to the Office. In addition to the powers assigned to the Administrative Council by other provisions of this Regulation, or by the provisions referred to in Articles 113 and 114, it shall have the powers in relation to the Office defined below:
 - (a) It shall advise on matters for which the Office is responsible, or issue general guidelines in this respect.
 - (b) It shall examine the management report of the President, and shall moreover monitor the Office's activities, on the basis of that examination and any other information obtained.
 - (c) It shall, on a proposal from the Office, either determine the number of Committees referred to in Article 35, the work allocation and the duration of their respective function, or issue general guidelines in this respect.
 - (d) It may establish rules on working methods of the Office.
 - (e) It may issue test guidelines pursuant to Article 56 (2).

2. Moreover the Administrative Council:

- may deliver opinions to, and require information from the Office or the Commission, where it considers that this is necessary,
- may forward to the Commission, with or without amendments, the drafts placed before it pursuant to Article 42 (2) (g), or its own draft amendments to this Regulation, to the provisions referred to in Articles 113 and 114 or to any other rules relating to Community plant variety rights,
- shall be consulted pursuant to Articles 113 (4) and 114 (2),
- shall carry out its functions relating the Office's budget pursuant to Articles 109, 111 and 112.

Article 37

Composition

1. The Administrative Council shall be composed of one representative of each Member State and one representative of the Commission and their alternates.
2. The members of the Administrative Council may, subject to the provisions of its rules of procedure, be assisted by advisers or experts.

Article 38

Chairmanship

1. The Administrative Council shall elect a Chairman and a Deputy Chairman from among its members. The Deputy Chairman shall *ex officio* replace the Chairman in the event of him being prevented from attending to his duties.
2. The terms of office of the Chairman or Deputy Chairman shall expire when their respective membership of the Administrative Council ceases. Without prejudice to this provision, the duration of the terms of office of the Chairman or Deputy Chairman shall be three years, unless another Chairman or Deputy Chairman have been elected before the end of this period. The terms of office shall be renewable.

Article 39

Meetings

1. Meetings of the Administrative Council shall be convened by its Chairman.
2. The President of the Office shall take part in the deliberations, unless the Administrative Council decides otherwise. He shall not have the right to vote.

3. The Administrative Council shall hold an ordinary meeting once a year; in addition, it shall meet on the initiative of its Chairman or at the request of the Commission or of one-third of the Member States.

4. It shall adopt rules of procedure, and may set up, in accordance with these rules, Committees placed under its authority.

5. The Administrative Council may invite observers to attend its meetings.

6. The secretariat for the Administrative Council shall be provided by the Office.

Article 40

Place of meetings

The Administrative Council shall meet at the seat of the Commission, or at the location of the Office or of an Examination Office. The details shall be determined in the rules of procedure.

Article 41

Voting

1. The Administrative Council shall take its decisions, other than those referred to in paragraph 2, by a simple majority of the representatives of the Member States.
2. The majority of three quarters of the representatives of the Member States shall be required for the decisions which the Administrative Council is empowered to take under Articles 12 (1) (b), 29, 36 (1) (a), (b), (d) and (e), 43, 47, 109 (3) and 112.
3. Each Member State shall have one vote.
4. The decisions of the Administrative Council shall have no binding force within the meaning of Article 189 of the Treaty.

CHAPTER III

MANAGEMENT OF THE OFFICE

Article 42

Functions and powers of the President

1. The Office shall be managed by the President.
2. To this end, the President shall have, in particular, the following functions and powers:
 - (a) The President shall take all necessary steps, including the adoption of internal administrative instructions and the publications of notices, to ensure the functioning of the Office in accordance with the provisions of this Regulation, with those referred to in Articles 113 and 114, or with the rules established, or guidelines issued, by the Administrative Council pursuant to Article 36 (1).

- (b) He shall submit a management report to the Commission and Administrative Council each year.
- (c) He shall exercise in respect of the staff the powers laid down in Article 31 (2).
- (d) He shall submit proposals as referred to in Article 36 (1) (c) and 47 (2).
- (e) He shall draw up estimates of the revenue and expenditure of the Office pursuant to Article 109 (1), and shall implement the budget pursuant to Article 110.
- (f) He shall supply information as required by the Administrative Council pursuant to Article 36 (2), first indent.
- (g) He may place before the Administrative Council draft amendments to this Regulation, to the provisions referred to in Articles 113 and 114 or to any other rules relating to Community plant variety rights.
- (h) He may delegate his powers to other members of the Office's staff, and subject to the provisions referred to in Articles 113 and 114.

3. The President shall be assisted by one or more Vice-Presidents. If the President is absent or indisposed, the Vice-President or one of the Vice-Presidents shall take his place in accordance with the procedure laid down in the rules established, or the guidelines issued, by the Administrative Council pursuant to Article 36 (1).

Article 43

Appointment of senior officials

- 1. The President of the Office shall be appointed by the Council from a list of candidates which shall be proposed by the Commission after obtaining the opinion of the Administrative Council. Power to dismiss the President shall lie with the Council, acting on a proposal from the Commission after obtaining the opinion of the Administrative Council.
- 2. The term of office of the President shall not exceed five years. This term of office shall be renewable.
- 3. The Vice-President or Vice-Presidents of the Office shall be appointed or dismissed as in paragraphs 1 and 2, after consultation of the President.
- 4. The Council shall exercise disciplinary authority over the officials referred to in paragraphs 1 and 3.

Article 44

Control of legality

- 1. The Commission shall control the legality of those acts of the President in respect of which Community law

does not provide for any control on legality by another body, and of the acts of the Administrative Council relating to the Office's budget.

- 2. The Commission shall require that any unlawful act referred to in paragraph 1 be altered or annulled.

3. Member States, any member of the Administrative Council or any other persons directly and personally involved may refer to the Commission any act referred to in paragraph 1, whether express or implied, to examine the legality of that act. Referral shall be made to the Commission within two months of the day on which the party concerned became aware of the act in question. The Commission shall take and communicate a decision within two months.

CHAPTER IV

THE BOARDS OF APPEAL

Article 45

Establishment and powers

- 1. There shall be established within the Office one or more Boards of Appeal.
- 2. The Board or Boards of Appeal shall be responsible for deciding on appeals from the decisions referred to in Article 67.
- 3. The Board or Boards of Appeal shall be convened as necessary. The number of Boards of Appeal and the work allocation shall be determined in the implementing rules pursuant to Article 114.

Article 46

Composition of the Boards of Appeal

- 1. A Board of Appeal shall consist of a Chairman and two other members.
- 2. The Chairman shall select for each case the other members and their respective alternates from the list of qualified members established pursuant to Article 47 (2).
- 3. Where the Board of Appeal considers that the nature of the appeal so requires, it may call up to two further members from the aforesaid list for that case.
- 4. The qualifications required for the members of each Board of Appeal, the powers of individual members in the preparatory phase of the decisions and the voting

conditions shall be determined in the implementing rules pursuant to Article 114.

Article 47

Independence of the members of the Boards of Appeal

1. The Chairmen of the Boards of Appeal and their respective alternates shall be appointed by the Council from a list of candidates for each chairman and each alternate which shall be proposed by the Commission after obtaining the opinion of the Administrative Council. The term of office shall be five years. It shall be renewable.

2. The other members of the Boards of Appeal shall be those selected pursuant to Article 46 (2), from a list of qualified members established on a proposal from the Office, for a term of five years, by the Administrative Council. The list shall be established for a term of five years. This shall be renewable for whole or part of the list.

3. The members of the Board of Appeal shall be independent. In making their decisions they shall not be bound by any instructions.

4. The members of the Boards of Appeal may not be members of the Committees referred to in Article 35 nor perform any other duties in the Office. The function of the members of the Boards of Appeal may be a part-time function.

5. The members of the Boards of Appeal may not be removed from office nor from the list respectively, during the respective term, unless there are serious grounds for

such removal and the Court of Justice of the European Communities, on application by the Commission after obtaining the opinion of the Administrative Council takes a decision to this effect.

Article 48

Exclusion and objection

1. Members of the Boards of Appeal may not take part in any appeal proceedings if they have any personal interest therein, or if they have previously been involved as representatives of one of the parties to proceedings, or if they participated in the decision under appeal.

2. If, for one of the reasons mentioned in paragraph 1 or for any other reason, a member of a Board of Appeal considers that he should not take part in any appeal proceedings, he shall inform the Board of Appeal accordingly.

3. Members of the Boards of Appeal may be objected to by any party to the appeal proceedings for one of the reasons mentioned in paragraph 1, or if suspected of partiality. An objection shall not be admissible if, while being aware of a reason for objecting, the party to the appeal proceedings has taken a procedural step. No objection may be based on the nationality of members.

4. The Boards of Appeal shall decide as to the action to be taken in the cases specified in paragraphs 2 and 3 without the participation of the member concerned. For the purposes of taking this decision, the member who withdraws or has been objected to shall be replaced in the Board of Appeal by his alternate.

PART FOUR

PROCEEDINGS BEFORE THE OFFICE

CHAPTER I

APPLICATIONS

Article 49

Filing of applications

1. An application for a Community plant variety right shall be filed at the choice of the applicant:

- (a) at the Office directly; or
- (b) at one of the sub-offices or national agencies, established or entrusted, pursuant to Article 30 (4), subject to the applicant forwarding an information

on this filing to the Office directly within two weeks after filing.

Details on the manner in which the information referred to in (b) above must be forwarded, may be laid down in the implementing rules pursuant to Article 114. The omission of forwarding information on an application to the Office pursuant to (b) above, does not affect the validity of the application if the application has reached the Office within one month after filing at the sub-office or national agency.

2. Where the application is filed at one of the national agencies referred to in paragraph 1 (b), the national agency shall take all steps to forward the application to the Office within two weeks after filing. National agencies may charge the applicant a fee which shall not exceed the administrative costs of receiving and forwarding the application.

*Article 50***Conditions governing applications**

1. The application for a Community plant variety right must contain at least the following:

- (a) a request for the grant of a Community plant variety right;
- (b) identification of the botanical taxon;
- (c) information identifying the applicant or, where appropriate, the joint applicants;
- (d) the name of the breeder and an assurance that, to the best of the applicants knowledge, no further persons have been involved in the breeding, or discovery and development, of the variety; if the applicant is not the breeder, or not the only breeder, he shall provide the relevant documentary evidence as to how the entitlement to the Community plant variety right came into his possession;
- (e) a provisional designation for the variety;
- (f) a technical description of the variety;
- (g) the geographic origin of the variety;
- (h) the credentials of any procedural representative;
- (i) details of any previous commercialization of the variety;
- (j) details of any other application made in respect of the variety.

2. Details of the conditions referred to in paragraph 1, including the provision of further information, may be laid down in the implementing rules pursuant to Article 114.

3. An application shall propose a variety denomination which may accompany the application.

*Article 51***Date of application**

The date of application for a Community plant variety right shall be the date on which a valid application was received by the Office pursuant to Article 49 (1) (a) or by a sub-office or national agency pursuant to Article 49 (1) (b), provided it complies with Article 50 (1) and subject to payment of the fees due pursuant to Article 83 within a time limit specified by the Office.

*Article 52***The right of priority**

1. The right of priority of an application shall be determined by the date of receipt of the application. Where applications have the same date of application, the

priorities thereof shall be determined according to the order in which they were received, if this can be established. Otherwise they shall have the same priority.

2. If the applicant or his predecessor in title has already applied for a property right for the variety in a Member State or in a Member of the International Union for the Protection of New Varieties of Plants, and the date of application is within 12 months of the filing of the earlier application, the applicant shall enjoy a right of priority for the earlier application as regards the application for the Community plant variety right, provided the earlier application still exists on the date of application.

3. The right of priority shall have the effect that the date on which the earlier application was filed shall count as the date of application for the Community plant variety right for the purposes of Articles 7, 10 and 11.

4. Paragraphs 2 and 3 shall also apply in respect of earlier applications that were filed in another Member State, provided the conditions set out in Article 12 (1) (b), second sentence, is met regarding this State on the date of application for the Community plant variety right.

5. Any claim for a right of priority earlier than that provided for in paragraph 2 shall lapse if the applicant does not submit to the Office within three months of the date of application copies of the earlier application that have been certified by the authorities responsible for such application. If the earlier application has not been made in one of the official languages of the European Communities, the Office may require, in addition, a translation of the earlier application in one of these languages.

CHAPTER II**EXAMINATION***Article 53***Formal examination of application**

1. The Office shall examine whether:

- (a) the application has effectively been filed pursuant to Article 49;
- (b) the application complies with the conditions laid down in Article 50 and the conditions laid down in the implementing rules pursuant to that Article;
- (c) where appropriate, a claim for priority complies with the provision laid down in Article 52 (2), (4) and (5); and
- (d) the fees due pursuant to Article 83 have been paid within a time limit specified by the Office.

2. If the application, although complying with the conditions referred to in Article 51, does not comply with

other conditions laid down in Article 50, the Office shall give the applicant an opportunity to correct any deficiencies that may have been identified.

3. If the application does not comply with the conditions referred to in Article 51, the Office shall inform the applicant thereof, or, where this is not possible, publish the information pursuant to Article 89.

Article 54

Substantive examination

1. The Office shall examine whether the variety may be the object of a Community plant variety right pursuant to Article 5, whether the variety is new pursuant to Article 10, whether the applicant is entitled to file an application pursuant to Article 12 and whether the conditions laid down in Article 82 are complied with. The Office shall also examine whether the proposed variety denomination is suitable pursuant to Article 63. For such purposes, it may avail itself of the services of other bodies.

2. The first applicant shall be deemed to be entitled to the Community plant variety right pursuant to Article 11. This shall not apply if, before a decision on the application is taken, the Office is aware, or it is shown by a final judgment delivered with regard to a claim for entitlement pursuant to Article 98 (4), that entitlement is not or is not solely vested in the first applicant. Where the identity of the sole or other person entitled has been determined, the person or persons may enter the proceedings as applicant or applicants.

Article 55

Technical examination

1. Where the Office has not discovered any impediment to the grant of a Community plant variety right on the basis of the examination pursuant to Articles 53 and 54, it shall arrange for the technical examination relating to compliance with the conditions laid down in Articles 7, 8 and 9 to be carried out by the competent office or offices in at least one of the Member States entrusted with responsibility for the technical examination of varieties of the species concerned by the Administrative Council, hereafter referred to as the 'Examination Office or Offices'.

2. Where no Examination Office is available, the Office may, with the consent of the Administrative Council, entrust other appropriate agencies with responsibility therefore or establish its own sub-offices for the same purposes. For the purpose of the provisions of this Chapter, such agencies or sub-offices shall be considered as Examination Offices. They may avail themselves of facilities made available by the applicant.

3. The Office shall forward to the Examination Offices copies of the application as required under the implementing rules pursuant to Article 114.

4. The Office shall determine, through general rules or through requests in individual cases, when, where and in what quantities and qualities the material for the technical examination and reference samples are to be submitted.

5. Where the applicant makes a claim for priority pursuant to Article 52 (2) or (4), he shall submit the necessary material and any further documents required within two years of the date of application pursuant to Article 51. If the earlier application is withdrawn or refused before the expiry of two years, the Office may require the applicant to submit the material or any further documents within a specified time limit.

Article 56

The conduct of technical examinations

1. Unless a different manner of technical examination relating to compliance with the conditions laid down in Articles 7 to 9 has been arranged, the Examination Offices shall, for the purposes of the technical examination, grow the variety or undertake any other investigations required.

2. The conduct of any technical examinations shall be in accordance with test guidelines issued by the Administrative Council and any instructions given by the Office.

3. For the purposes of the technical examination, the Examination Offices may, with the approval of the Office, avail themselves of the services of other technically qualified bodies and take into account the available findings of such bodies.

4. Each Examination Office shall begin the technical examination, unless the Office has otherwise provided, no later than on the date on which a technical examination would have begun on the basis of an application for a national property right filed on the date on which the application sent by the Office was received by the Examination Office.

5. In the case of Article 55 (5), each Examination Office shall begin the technical examination, unless the Office has otherwise provided, no later than on the date on which an examination would have begun on the basis of an application for a national property right, provided the necessary material and any further documents required were submitted at that date.

6. The Administrative Council may determine that the technical examination for varieties of vine and tree species may begin at a later date.

Article 57

Examination reports

1. The Examination Office shall, at the request of the Office or if it deems the results of the technical

examination to be adequate to evaluate the variety, send the Office an examination report, and, where it considers that the conditions laid down in Articles 7 to 9 are complied with, a description of the variety.

2. The Office shall communicate the results of the technical examinations and the variety description to the applicant and shall give him an opportunity to comment thereon.

3. Where the Office does not consider the examination report to constitute a sufficient basis for decision, it may provide of its own motion, after consultation of the applicant, or on request of the applicant for complementary examination. For the purposes of assessment of the results, any complementary examination carried out until a decision taken pursuant to Articles 61 and 62 becomes final shall be considered to be part of the examination referred to in Article 56 (1).

4. The results of the technical examination shall be subject to the exclusive rights of disposal of the Office and may only otherwise be used by the Examination Offices in so far as this is approved by the Office.

Article 58

Costs of technical examinations

The Office shall pay the Examination Offices a fee in accordance with the implementing rules pursuant to Article 114.

Article 59

Objections to grant of right

1. Any person may lodge with the Office a written objection to the grant of a Community plant variety right.

2. Objectors shall be party to the proceedings for grant of the Community plant variety right in addition to the applicant. Without prejudice to Article 88, objectors shall have access to the documents, including the results of the technical examination and the variety description as referred to in Article 57 (2).

3. Objections may be based only on the contention that:

- (a) the conditions laid down in Articles 7 to 11 are not complied with;
- (b) there is an impediment under Article 63 (3) or (4) to a proposed variety denomination.

4. Objections may be lodged:

- (a) at any time after the application and prior to a decision pursuant to Articles 61 or 62, in the case of paragraph 3 (a) hereof;

- (b) within three months of the publication of the proposed variety denomination pursuant to Article 89, in the case of objections under paragraph 3 (b) hereof.

5. The decisions on objections may be taken together with the decisions pursuant to Articles 61, 62 or 63.

Article 60

Priority of a new application in the case of objections

Where an objection on the grounds that the conditions laid down in Article 11 are not met leads to the withdrawal or refusal of the application for a Community plant variety right and if the objector files an application for a Community plant variety right within one month following the withdrawal or within one month of the date on which the refusal becomes final in respect of the same variety, he may require that the date of the withdrawn or refused application be deemed to be the date of his application.

CHAPTER III

DECISIONS

Article 61

Refusal

1. The Office shall refuse applications for a Community plant variety right if and as soon as it establishes that the applicant:

- (a) has not remedied any deficiencies within the meaning of Article 53 which he was given an opportunity to correct within the time limit notified to him;
- (b) has not complied with a rule or request pursuant to Article 55 (4) or (5) within the time limit laid down, unless the Office has consented to non-submission; or
- (c) has not proposed a variety denomination which is suitable pursuant to Article 63.

2. The Office shall also refuse applications for a Community plant variety right if:

- (a) it establishes that the conditions it is required to verify pursuant to Article 54 have not been fulfilled; or
- (b) it reaches the opinion on the basis of the examination reports pursuant to Article 57, that the conditions laid down in Articles 7, 8 and 9 have not been fulfilled.

Article 62

Grant

If the Office is of the opinion that the findings of the examination are sufficient to decide on the application

and there are no impediments pursuant to Articles 59 and 61, it shall grant the Community plant variety right. The decision shall include an official description of the variety.

Article 63

Variety denomination

1. Where a Community plant variety right is granted, the Office shall approve, for the variety in question, the variety denomination proposed by the applicant pursuant to Article 50 (3), if it considers, on the basis of the examination made pursuant to the second sentence of Article 54 (1), that this denomination is suitable.

2. A variety denomination is suitable, if there is no impediment pursuant to paragraphs 3 or 4 of this Article.

3. There is an impediment for the designation of a variety denomination where:

- (a) its use in the territory of the Community is precluded by the prior right of a third party;
- (b) it may commonly cause its users difficulties as regards recognition or reproduction;
- (c) it is identical or may be confused with a variety denomination under which another variety of the same or of a closely related species is entered in an official register of plant varieties or under which material of another variety has been marketed in a Member State or in a Member of the International Union for the Protection of New Varieties of Plants, unless the other variety no longer remains in existence and its denomination has acquired no special significance;
- (d) it is identical or may be confused with other designations which are commonly used for the marketing of goods or which have to be kept free under other legislation;
- (e) it is liable to give offence in one of the Member States or is contrary to public policy;
- (f) it is liable to mislead or to cause confusion concerning the characteristics, the value or the identity of the variety, or the identity of the breeder or any other party to proceedings.

4. There is another impediment where, in the case of a variety which has already been entered:

- (a) in one of the Member States; or
- (b) in a Member of the International Union for the Protection of New Varieties of Plants; or

- (c) in another State for which it has been established in a Community act that varieties are evaluated there under rules which are equivalent to those laid down in the Directives on common catalogues;

in an official register of plant varieties or material thereof and has been marketed there for commercial purposes, and the proposed variety denomination differs from that which has been registered or used there, unless the latter one is the object of an impediment pursuant to paragraph 3.

5. The Office shall publish the species which it considers 'closely related' within the meaning of paragraph 3 (c).

CHAPTER IV

THE MAINTENANCE OF COMMUNITY PLANT VARIETY RIGHTS

Article 64

Technical verification

1. The Office shall verify the continuing existence unaltered of the protected varieties.

2. For this purpose, a technical verification shall be carried out pursuant to Articles 55 and 56.

3. The holder shall be required to provide all the information necessary to assess the continuing existence unaltered of the variety to the Office and to the Examination Offices to which technical verification of the variety has been entrusted. He shall be required, in accordance with the instructions given by the Office, to submit material of the variety and to permit to verify whether appropriate measures have been taken to ensure the continuing existence unaltered of the variety.

Article 65

Report on the technical verification

1. At the request of the Office, or if it establishes that the variety is not uniform or stable, the Examination Office entrusted with the technical verification shall send the Office a report on its findings.

2. If any deficiencies pursuant to paragraph 1 have been found during the technical verification, the Office shall inform the holder of the results of the technical verification and shall give him an opportunity to comment thereon.

Article 66

Amendment of the variety denomination

1. The Office shall amend a variety denomination designated pursuant to Article 63 if it establishes that the

denomination does not satisfy, or no longer satisfies, the conditions laid down in Article 63 and in the event of a prior conflicting right of a third party, if the holder agrees to the amendment or the holder or any other person required to use the variety denomination has been prohibited, by a final judgment, for this reason from using the variety denomination.

2. The Office shall give the holder an opportunity to propose an amended variety denomination and shall proceed in accordance with Article 63.

3. Objections may be lodged against the proposed amended variety denomination in accordance with Article 59 (3) (b).

CHAPTER V

APPEALS

Article 67

Decisions subject to appeal

1. An appeal shall lie from decisions of the Office which have been taken pursuant to Articles 20, 21, 59, 61, 62, 63 and 66, as well as on decisions related to fees pursuant to Article 83, to costs pursuant to Article 85, to the entering or deletion of information in the Register pursuant to Article 87 and to the public inspection pursuant to Article 88.

2. An appeal lodged pursuant to paragraph 1 shall have suspensory effect. The Office may, however, if it considers that circumstances so require, order that the contested decision not be suspended.

3. An appeal may lie from decisions of the Office pursuant to Articles 29 and 100 (2), unless a direct appeal is lodged pursuant to Article 74. The appeal shall not have suspensory effect.

4. An appeal against a decision which does not terminate proceedings as regards one of the parties may only be made in conjunction with an appeal against the final decision, unless the decision provides for separate appeal.

Article 68

Persons entitled to appeal and to be parties to appeal proceedings

Any natural or legal person may appeal, subject to Article 82, against a decision, addressed to that person, or against a decision which, although in the form of a decision addressed to another person, is of direct and individual concern to the former. The parties to proceedings may, and the Office shall, be party to the appeal proceedings.

Article 69

Time limit and form

Notice of appeal shall be filed in writing at the Office within two months of the service of the decision where addressed to the appealing person, or, in the absence thereof, within two months of the publication of the decision, and a written statement setting out the grounds of appeal shall be filed within four months after the aforesaid service or publication.

Article 70

Interlocutory revision

1. If the body of the Office which has prepared the decision considers the appeal to be admissible and well founded, the Office shall rectify the decision. This shall not apply where the appellant is opposed by another party to the appeal proceedings.

2. If the decision is not rectified within one month after receipt of the statement of grounds, for the appeal, the Office shall forthwith:

- decide whether it will take an action pursuant to Article 67 (2), second sentence, and
- remit the appeal to the Board of Appeal.

Article 71

Examination of appeals

1. If the appeal is admissible, the Board of Appeal shall examine whether the appeal is well-founded.

2. When examining the appeal, the Board of Appeal shall as often as necessary invite the parties to the appeal proceedings to file observations on notifications issued by itself or on communications from the other parties to the appeal proceedings within specified time limits. Parties to the appeal proceedings shall be entitled to make oral representations.

Article 72

Decision on appeal

The Board of Appeal shall decide on the appeal on the basis of the examination carried out pursuant to Article 71. The Board of Appeal may exercise any power which lies within the competence of the Office, or it may remit the case to the competent body of the Office for further action. The latter one shall, in so far as the facts are the same, be bound by the *ratio decidendi* of the Board of Appeal.

*Article 73***Further appeal**

1. A further appeal to the Court of Justice of the European Communities shall lie from decisions of the Board of Appeal.
2. The further appeal may be lodged on grounds of lack of competence, infringement of an essential procedural requirement, infringement of the Treaty, of this Regulation, or of any rule of law relating to their application or misuse of power.
3. The further appeal may be made by any party to the appeal proceedings who is adversely affected by its decision, or by the Commission or the Office.
4. The further appeal shall be lodged with the Court of Justice within two months of service of the decision of the Board of Appeal.
5. If the Court of Justice remits the case for further action to the Board of Appeal, the Board shall, in so far as the facts are the same, be bound by the *ratio decidendi* of the Court of Justice.

*Article 74***Direct appeal**

1. A direct appeal to the Court of Justice of the European Communities may lie from decisions of the Office pursuant to Articles 29 and 100 (2).
2. The provisions laid down in Article 73 shall apply *mutatis mutandis*.

CHAPTER VI

MISCELLANEOUS CONDITIONS GOVERNING PROCEEDINGS

*Article 75***Statement of grounds on which decisions are based, right of audience**

Decisions of the Office shall be accompanied by statements of the grounds on which they are based. They shall be based only on grounds or evidence on which the parties to proceedings have had an opportunity to present their comments orally or in writing.

*Article 76***Examination of the facts by the Office of its own motion**

In proceedings before it the Office shall make investigations on the facts of its own motion, to the

extent that they come under the examination pursuant to Articles 54 and 55. It shall disregard facts or items of evidence which have not been submitted within the time limit set by the Office.

*Article 77***Oral proceedings**

1. Oral proceedings shall be held either on the initiative of the Office itself or at the request of any of the parties to proceedings.
2. Without prejudice to paragraph 3, oral proceedings before the Office shall not be public.
3. Oral proceedings before the Board of Appeal including delivery of the decision, shall be public in so far as the Board of Appeal before which the proceedings are taking place does not decide otherwise in circumstances where serious and unwarranted disadvantages could arise from admitting the public, particularly for any of the parties to the appeal proceedings.

*Article 78***Taking of evidence**

1. In any proceedings before the Office, the means of giving or obtaining evidence may include the following:
 - (a) hearing the parties to proceedings;
 - (b) requests for information;
 - (c) the production of documents or other evidence;
 - (d) hearing the witnesses;
 - (e) opinions by experts;
 - (f) inspection;
 - (g) sworn affidavits.
2. Where the Office decides through a collective body, that body may commission one of its members to examine the evidence adduced.
3. If the Office considers it necessary that a party to proceedings, witness or expert give evidence orally, it shall either:
 - (a) issue a summons requiring the relevant person to appear before it; or
 - (b) request the competent judicial or other authority in the country of domicile of the relevant person to take the evidence as provided for in Article 91 (2).
4. A party to proceedings, witness or expert who is summoned before the Office may request it to allow his

evidence to be heard by the competent judicial or other authority in his country of domicile. On receipt of such a request or in the case that no reaction was given to the summons, the Office may, in accordance with Article 91 (2), request the competent judicial or other authority to hear the evidence of that person.

5. If a party to proceedings, witness or expert gives evidence before the Office, the Office may, if it considers it advisable that the evidence be given under oath or otherwise in binding form, request the competent judicial or other authority in the country of domicile of the relevant person to hear his evidence under the requisite conditions.

6. When the Office requests a competent judicial or other authority to take evidence, it may request it to take the evidence in binding form and to permit a member of the Office to attend the hearing and question the party to proceedings, witness or expert either through that judicial or other authority or directly.

Article 79

Service

The Office shall of its own motion effect service of all decisions and summonses, and of notifications and communications, from which a time limit is reckoned, or which are required to be served either in pursuance of other provisions of this Regulation or by provisions adopted pursuant to this Regulation or by order of the President of the Office. Service may be effected through the competent variety offices of the Member States.

Article 80

Restitutio in integrum

1. Where, in spite of having taken all due care in the particular circumstances, the applicant for a Community plant variety right or the holder or any other party to proceedings before the Office has been unable to observe a time limit *vis-à-vis* the Office, his rights shall, upon application, be restored if his failure to respect the time limit has resulted directly, by virtue of this Regulation, in the loss of any right or means of redress.

2. Applications shall be filed in writing within two months after the cause of non-compliance when the time limit has ceased to operate. The act omitted shall be completed within this period. Applications shall be admissible only within the period of one year following the expiry of the time limit which has not been observed.

3. An application shall be accompanied by a statement of the grounds on which it is based and the facts on which it relies.

4. The provisions of this Article shall not apply to the time limits referred to in paragraph 2 nor to the time limits specified in Article 52 (2), (4) and (5).

5. Any person who, in a Member State, has in good faith used or made effective and genuine arrangements to use a variety which is the subject of a published application for grant of a Community plant variety right, or of a Community plant variety right that has been granted, in the course of a period between the loss of rights pursuant to paragraph 1 in respect of the application or of a Community plant variety right that has been granted and the restoration of those rights, may without payment continue such use in the course of his business or for the needs thereof.

Article 81

General principles

1. In the absence of procedural provisions in this Regulation or in provisions adopted pursuant to this Regulation, the Office shall apply the principles of procedural law which are generally recognized in the Member States.

2. Article 48 shall apply *mutatis mutandis* to the staff of the Office in so far as it is involved in decisions of the kind referred to in Article 67, and to the staff of the Examination Offices, in so far as it participates in measures for the preparation of such decisions.

Article 82

Procedural representative

Persons who are not domiciled or do not have a seat or an establishment within the territory of the Community may participate as party to proceedings before the Office only if they have designated a procedural representative who is domiciled or has his seat or an establishment within the territory of the Community.

CHAPTER VII

FEES, SETTLEMENT OF COSTS

Article 83

Fees

1. The Office shall charge fees for its official acts provided for under this Regulation as well as for each year of the duration of a Community plant variety right, pursuant to the fees regulations adopted in accordance with Article 113.

2. If fees due in respect of the official acts set out in Article 113 (2) or of other official acts referred to in the

fees regulations, which are only to be carried out on application, are not paid, the application shall be deemed not to have been filled or the appeal not to have been lodged if the acts necessary for the payment of the fees have not been effected within one month of the date on which the Office served a new request for payment of fees and indicated in so doing these consequences of failure to pay.

3. If certain information provided by the applicant for grant of a Community plant variety right can only be verified by a technical examination which goes beyond the framework established for the technical examination of varieties of the taxon concerned, the fees for the technical examination may be increased, after having heard the person liable to pay the fees, up to the amount of the expenditure actually incurred.

4. In the case of a successful appeal, the appeal fees or, in case of a partial success, the corresponding part of the appeal fees, shall be refunded. However, the refund can be fully or partly refused if the success of the appeal is based on facts which were not available at the time of the original decision.

Article 84

Termination of financial obligations

1. The Office's right to require payment of fees shall lapse after four years from the end of the calendar year in which the fees became due for payment.

2. Rights against the Office for the refunding of fees or of sums overcharged by the Office shall lapse after four years from the end of the calendar year in which the rights arose.

3. A request for payment of a fee shall have the effect of interrupting the time limit specified in paragraph 1, and a written and reasoned claim for refund shall have the effect of interrupting the time limit specified in paragraph 2. After interruption the time limit shall begin to run again immediately and shall terminate at the latest six years after the end of the calendar year in which it originally commenced, unless judicial proceedings to enforce the right have been instituted in the meantime; in that case the time limit shall end not earlier than one year after the judgment has acquired the authority of a final decision.

Article 85

Apportionment of costs

1. The losing party to proceedings for revocation or cancellation of a Community plant variety right, or to appeal proceedings shall bear the costs incurred by the other party to proceedings as well as all costs incurred by

him essential to the proceedings, including travel and subsistence and the remuneration of an agent, adviser or advocate, within the limits of the scales set for each category of costs under the conditions laid down in the implementing rules pursuant to Article 114.

2. However, where each party to proceedings succeeds on some and fails on other heads, or if reasons of equity so dictate, the Office or Board of Appeal shall decide a different apportionment of costs.

3. The party to proceedings who terminates the proceedings by withdrawing the application for a Community plant variety right, the application for revocation or cancellation of rights, or the appeal, or by surrendering the Community plant variety rights, shall bear the costs incurred by the other party to proceedings as stipulated in paragraphs 1 and 2.

4. Where the parties to proceedings conclude before the Office, or Board of Appeal a settlement of costs differing from that provided for in the preceding paragraphs, note shall be taken of that agreement.

5. On request, the Office or Board of Appeal shall determine the amount of the costs to be paid pursuant to the preceding paragraphs.

Article 86

Enforcement of decisions which determine the amount of costs

1. Final decisions of the Office which determine the amount of costs shall be enforceable.

2. Enforcement shall be governed by the rules of civil procedure applicable in the Member State in which it takes place. Subject only to verification that the relevant document is authentic, the enforcement clause or endorsement shall be appended by the national authority appointed for that purpose by the Government of each Member State; the Governments shall inform the Office and the Court of Justice of the European Communities of the identity of each such national authority.

3. When, upon application by the party seeking enforcement, these formalities have been completed, it shall be entitled to proceed to endorsement under national law by bringing the matter directly before the competent body.

4. Enforcement shall not be suspended except by decision of the Court of Justice of the European Communities. Control as to the regularity of enforcement measures shall, however, reside with the national courts.

CHAPTER VIII

REGISTERS

*Article 87***Establishment of the Registers**

1. The Office shall keep a Register of Applications for Community Plant Variety Rights which shall contain the following particulars:

- (a) applications for a Community plant variety right together with a statement of the taxon and the provisional designation of the variety, the date of application and the name and address of the applicant, of the breeder and of any procedural representative concerned;
- (b) any cases of termination of proceedings concerning applications for a Community plant variety right together with the information set out in subparagraph (a);
- (c) proposals for variety denominations;
- (d) changes in the identity of the applicant or his procedural representative;
- (e) on request, any levy of execution as referred to in Articles 24 and 26.

2. The Office shall keep a Register of Community Plant Variety Rights wherein, after grant of a Community plant variety right, the following particulars shall be entered:

- (a) the species and variety denomination of the variety;
- (b) the official description of the variety or a reference to documents in the Office's possession in which the official description of the variety is contained as integrating part of the Register;
- (c) in the case of varieties for which material with specific components has to be used repeatedly for the production of material, a reference to such components;
- (d) the name and address of the holder, of the breeder and of any procedural representative concerned;
- (e) the date on which the Community plant variety right begins and ends, together with the reasons for the termination of right;
- (f) on request, any contractual exclusive exploitation right or compulsory exploitation right, including the name and address of the person enjoying the right of exploitation;
- (g) on request, any levy of execution as referred to in Article 24;
- (h) where the holder of an initial variety and the breeder of a variety essentially derived from the initial variety both so request, the identification of the varieties as initial and essentially derived including the variety

denominations and the names of the parties concerned. A request from one of the parties concerned only shall suffice if he has obtained either a non-contentious acknowledgement by the other party pursuant to Article 99 or a final decision or a final judgment pursuant to the provisions of this Regulation which contain an identification of the varieties concerned as initial and essentially derived.

3. Any other particular or any condition for the entering in both Registers may be specified in the implementing rules pursuant to Article 114.

4. The Office may of its own motion and upon consultation with the holder adapt the official variety description in respect of the number and type of characteristics or of the specified expressions of those characteristics, when necessary, in the light of the current principles governing the description of varieties of the taxon concerned, in order to render the description of the variety comparable with the descriptions of other varieties of the taxon concerned.

*Article 88***Public inspection**

1. The Registers mentioned in Article 87 shall be open to public inspection.

2. In case of a legitimate interest, the following shall be open to public inspection, in accordance with the conditions set up in the implementing rules pursuant to Article 114:

- (a) documents relating to applications for grant of a Community plant variety right;
- (b) documents relating to Community plant variety rights already granted;
- (c) the growing of varieties for the purposes of their technical examination;
- (d) the growing of varieties for the purpose of verifying their continuing existence.

3. In the case of varieties for which material with specific components has to be used repeatedly for the production of material, at the request of the applicant for a Community plant variety right, all data relating to components, including their cultivation, shall be withheld from inspection. Such a request for withholding from inspection may not be filed once the decision on the application for grant of a Community plant variety right has been taken.

4. Materials submitted or obtained in connection with examinations under Articles 55 (4), 56 and 64 may not be given to other parties by the competent authorities under this Regulation unless the person entitled gives his consent or such transfer is required in connection with the cooperation covered by this Regulation for the purposes of the examination or by virtue of legal provisions.

*Article 89***Periodical publications**

The Office shall at least every two months, issue a publication containing the information entered into the Registers pursuant to Article 87 (1) and (2) (a), (d), (e), (f), (g) and (h), and not yet published. The Office shall also publish an annual report, containing information which the Office regards as expedient, but at least a list of valid Community plant variety rights, their holders, the dates of grant and expiry and the approved variety denominations. Details of these publications shall be specified by the Administrative Council.

*Article 90***Exchange of information and of publications**

1. The Office and the competent variety offices of the Member States shall, on request and without prejudice to the conditions set up for the sending of results of technical examinations, dispatch to each other for their own use, free of charge, one or more copies of their respective publications and any other useful information relating to property rights applied for or granted.

2. The data referred to in Article 88 (3) shall be excluded from information, unless:

(a) the information is necessary for the conduct of the examinations pursuant to Articles 55 and 64; or

(b) the applicant for a Community plant variety right or the holder gives his consent.

*Article 91***Administrative and legal cooperation**

1. Unless otherwise provided in this Regulation or in national law, the Office, Examination Offices referred to in Article 55 (1) and the courts or authorities of the Member States shall on request give assistance to each other by communicating information or opening files related to the variety, and samples or growing thereof for inspection. Where the Office and the Examination Offices lay files, samples or growing thereof open to inspection by courts or public prosecutors' offices, the inspection shall not be subject to the restrictions laid down in Article 88, and the inspection given by the Examination Offices shall not be subject to a decision of the Office pursuant to that Article.

2. Upon receipt of letters rogatory from the Office, the courts or other competent authorities of the Member States shall undertake on behalf of that Office and within the limits of their jurisdiction, any necessary enquiries or other related measures.

PART FIVE**IMPACT ON OTHER LAWS***Article 92***Cumulative protection prohibited**

1. Any variety which is the subject matter of a Community plant variety right shall not be the subject of a national plant variety right or any patent for that variety. Any rights granted contrary to the first sentence shall be ineffective.

2. Where the holder has been granted another right as referred to in paragraph 1 for the same variety prior to grant of the Community plant variety right, he shall be unable to invoke the rights conferred by such protection for the variety for as long as the Community plant variety right remains effective.

*Article 93***Application of national law**

Claims under Community plant variety rights shall be subject to limitations imposed by the law of the Member States only as expressly referred to in this Regulation.

PART SIX

CIVIL LAW CLAIMS, INFRINGEMENTS, JURISDICTION

*Article 94***Infringement**

1. Whosoever:
 - (a) effects one of the acts set out in Article 13 (2) without being entitled to do so, in respect of a variety for which a Community plant variety right has been granted; or
 - (b) omits the correct usage of a variety denomination as referred to in Article 17 (1) or omits the relevant information as referred to in Article 17 (2); or
 - (c) contrary to Article 18 (3) uses the variety denomination of a variety for which a Community plant variety right has been granted or a designation that may be confused with it;

may be sued by the holder to enjoin such infringement or to pay reasonable compensation or both.

2. Whosoever acts intentionally or negligently shall moreover be liable to compensate the holder for any further damage resulting from the act in question. In cases of slight negligence, such claims may be reduced according to the degree of such slight negligence, but not however to the extent that they are less than the advantage derived therefrom by the person who committed the infringement.

*Article 95***Acts prior to grant of Community plant variety rights**

The holder may require reasonable compensation from any person who has, in the time between publication of the application for a Community plant variety right and grant thereof, effected an act that he would be prohibited from performing subsequent thereto.

*Article 96***Prescription**

Claims pursuant to Articles 94 and 95 shall be time barred after three years from the time at which the Community plant variety right has finally been granted and the holder has knowledge of the act and of the identity of the party liable or, in the absence of such knowledge, after 30 years from the termination of the act concerned.

*Article 97***Supplementary application of national law regarding infringement**

1. Where the party liable pursuant to Article 94 has, by virtue of the infringement, made any gain at the expense of the holder or of a person entitled to exploitation rights, the courts competent pursuant to Articles 101 or 102 shall apply their national law, including their private international law, as regards restitution.
2. Paragraph 1 shall also apply as regards other claims that may arise in respect of the performance or omission of acts pursuant to Article 95 in the time between publication of the application for grant of a Community plant variety right and the disposal of the request.
3. In all other respects the effects of Community plant variety rights shall be determined solely in accordance with this Regulation.

*Article 98***Claiming entitlement to a Community plant variety right**

1. If a Community plant variety right has been granted to a person who is not entitled to it under Article 11, the person entitled to it may, without prejudice to any other remedy which may be open to him under the laws of the Member States, claim to have the Community plant variety right transferred to him.
2. Where a person is entitled to only part of a Community plant variety right, that person may, in accordance with paragraph 1, claim to be made a joint holder.
3. Claims pursuant to paragraphs 1 and 2 may be invoked only within a period of up to five years of publication of the grant of the Community plant variety right. This provision shall not apply if the holder knew, at the time it was granted to or acquired by him, that he was not entitled to such rights or that entitlement thereto was not vested solely in him.
4. The person entitled shall be eligible *mutatis mutandis* to pursue claims pursuant to paragraphs 1 and 2 in respect of an application for grant of a Community plant variety right filed by a person who was not entitled to it or whom the entitlement was not vested solely.

*Article 99***Obtaining identification of a variety**

The holder of an initial variety and the breeder of a variety essentially derived from the initial variety shall be

entitled to obtain an acknowledgement of the identification of the varieties concerned as initial and essentially derived.

Article 100

Consequences of a change in holdership of a Community plant variety right

1. In the event of a complete change in the holdership of a Community plant variety right in consequence of a final judgment delivered pursuant to Articles 101 or 102 for the purposes of claiming entitlement under Article 98 (1), any exploitation or other rights shall lapse with the entry of the person entitled in the Register of Community Plant Variety Rights.

2. Where the holder or a person enjoying the right of exploitation has effected one of the acts set out in Article 13 (2) or has made effective and genuine arrangements to do so prior to the commencement of the proceedings pursuant to Articles 101 or 102, he may continue or perform such acts provided he requests a non-exclusive exploitation right from the new holder entered in the Register of Community Plant Variety Rights. Such requests must be made within the time limit laid down in the implementing rules. The exploitation right may be granted by the Office in the absence of an agreement between the parties. Article 29 (3) to (7) shall apply *mutatis mutandis*.

3. Paragraph 2 shall not apply where the holder or persons enjoying the right of exploitation acted in bad faith when they effected the acts or began to make the arrangements.

Article 101

Jurisdiction and procedure in legal actions relating to civil law claims

1. The Lugano Convention as well as the complementary provisions of this Article and of Articles 102 to 106 of this Regulation shall apply to proceedings relating to actions in respect of the claims referred to in Articles 94 to 100.

2. Proceedings of the type referred to in paragraph 1 shall be brought in the courts:

- (a) of the Member State or another Contracting Party to the Lugano Convention in which the defendant is domiciled or has his seat or, in the absence of such, has an establishment; or
- (b) if this condition is not met in any of the Member States or Contracting Parties, of the Member State in which the plaintiff is domiciled or has his seat or, in the absence of such, has an establishment; or
- (c) if this condition is also not met in any of the Member States, of the Member States in which the seat of the Office is located.

The competent courts shall have jurisdiction in respect of infringements alleged to have been committed in any of the Member States.

3. Proceedings relating to actions in respect of claims for infringement may also be brought in the courts for the place where the harmful event occurred. In such cases, the court shall have jurisdiction only in respect of infringements alleged to have been committed in the territory of the Member State to which it belongs.

4. The legal processes and the competent courts shall be those that operate under the laws of the State determined pursuant to paragraphs 2 or 3.

Article 102

Supplementary provisions

1. Actions for claiming entitlement pursuant to Article 98 of this Regulation shall not be considered to fall under the provisions of Article 5 (3) and (4) of the Lugano Convention.

2. Notwithstanding Article 101 of this Regulation, Articles 5 (1), 17 and 18 of the Lugano Convention shall apply.

3. For the purposes of applying Articles 101 and 102 of this Regulation, the domicile or seat of a party shall be determined pursuant to Articles 52 and 53 of the Lugano Convention.

Article 103

Rules of procedure applicable

Where jurisdiction lies with national courts pursuant to Articles 101 and 102, the rules of procedure of the relevant State governing the same type of action relating to corresponding national property rights shall apply without prejudice to Articles 104 and 105.

Article 104

Entitlement to bring an action for infringement

1. Actions for infringement may be brought by the holder. Persons enjoying exploitation rights may bring such actions unless that has been expressly excluded by agreement with the holder in the case of an exclusive exploitation right or by the Office pursuant to Articles 29 or 100 (2).

2. Any person enjoying exploitation rights shall, for the purpose of obtaining compensation for damage suffered by him, be entitled to intervene in an infringement action brought by the holder.

Article 105

Obligation of national courts or other bodies

A national court or other body hearing an action relating to a Community plant variety right shall treat the Community plant variety right as valid.

*Article 106***Stay of proceedings**

1. Where an action relates to claims pursuant to Article 98 (4) and the decision depends upon the protectability of the variety pursuant to Article 6, this decision may not be given before the Office has decided on the application for a Community plant variety right.

2. Where an action relates to a Community plant variety right that has been granted and in respect of which proceedings for revocation or cancellation pursuant to Articles 20 or 21 have been initiated, the proceedings may be stayed in so far as the decision

depends upon the validity of the Community plant variety right.

*Article 107***Penalties for infringement of Community plant variety rights**

Member States shall take all appropriate measures to ensure that the same provisions are made applicable to penalize infringements of Community plant variety rights as apply in the matter of infringements of corresponding national rights.

PART SEVEN**BUDGET, FINANCIAL CONTROL, COMMUNITY IMPLEMENTING RULES***Article 108***Budget**

1. Estimates of all the Office's revenue and expenditure shall be prepared for each financial year and shall be shown in the Office's budget, and each financial year shall correspond with the calendar year.

2. The revenue and expenditure shown in the budget shall be in balance.

3. Revenue shall comprise, without prejudice to other types of income, total fees payable pursuant to Article 83 under the fees regulations referred to in Article 113, and, to the extent necessary, a subsidy from the general budget of the European Communities.

4. Expenditure shall comprise, without prejudice to other types of expenditure, the fixed costs of the Office and the costs arising from the Office's normal functioning, including sums payable to the Examination Offices.

immediately forward the estimate to the Commission, together with the list of posts and the explanatory statement, and may attach its opinion. The Commission shall forward them to the budget authority of the Communities and may attach an opinion along with an alternative estimate.

3. The Administrative Council shall adopt the budget, which shall include the Office's list of posts. Should the estimate contain a subsidy referred to in Article 108 (3), the budget shall, if necessary, be adjusted to the appropriations in the general budget of the European Communities.

*Article 110***Implementation of the budget**

The President shall implement the Office's budget.

*Article 111***Control**

1. Control of commitment and payment of all expenditure and control of the existence and recovery of all revenue of the Office shall be carried out by the financial controller appointed by the Administrative Council.

2. Not later than 31 March each year the President shall transmit to the Commission, the Administrative Council and the Court of Auditors of the European Communities accounts of the Office's total revenue and expenditure for the preceding financial year. The Court of Auditors shall examine them in accordance with relevant provisions applicable to the general budget of the European Communities.

*Article 109***Preparation of the budget**

1. The President shall draw up each year an estimate of the Office's revenue and expenditure for the following year and shall transmit it to the Administrative Council not later than 31 March each year, together with a list of posts and, where the estimate provides for a subsidy referred to in Article 108 (3), prefaced by an explanatory statement.

2. Should the estimate provide for a subsidy referred to in Article 108 (3), the Administrative Council shall

3. The Administrative Council shall give a discharge to the President of the Office in respect of the implementation of the budget.

Article 112

Financial provisions

The Administrative Council shall, after consulting the Court of Auditors, adopt internal financial provisions specifying, in particular, the procedure for establishing and implementing the Office's budget. The financial provisions must, as far as possible, correspond to the provisions of the Financial Regulation applicable to the general budget of the European Communities and depart from them only when the specific requirements of the individual operation of the Office so dictate.

Article 113

Fees regulations

1. The fees regulations shall determine in particular the matters for which fees pursuant to Article 83 (1) are due, the amounts of the fees and the way in which they are to be paid.

2. Fees shall be charged for at least in respect of the following matters for:

(a) the processing of applications for grant of a Community plant variety right; this fee shall cover:

- the formal examination, (Article 53),
- the substantive examination (Article 54),
- the examination of the variety denomination (Article 63),
- the decision (Articles 61, 62)
- the related publishing (Article 89);

(b) the arranging and carrying out of the technical examination;

(c) the processing of an appeal including the decision;

(d) each year of the duration of a Community plant variety right.

3. (a) Without prejudice to (b) and (c), the amounts of the fees shall be fixed at such a level as to ensure that the revenue in respect thereof is in principle sufficient for the budget of the Office to be balanced.

(b) However, the subsidy referred to in Article 108 (3) may cover, for a transitional period ending on 31 December of the fourth year from the date laid down in Article 118 (2), the expenditure relating to the initial running phase of the Office. In accordance with the procedure laid down in

Article 115, this period may be extended, if necessary, for no more than one year.

(c) Moreover, during the abovementioned transitional period only, the subsidy referred to in Article 108 (3) may also cover certain expenditure of the Office relating to certain activities other than the processing of applications, the arranging and carrying out of the technical examinations and the processing of appeals. These activities shall be specified, at the latest one year after the adoption of this Regulation, in implementing rules pursuant to Article 114.

4. The fees regulations shall be adopted in accordance with the procedure laid down in Article 115, after consultation of the Administrative Council on the draft of the measures to be taken.

Article 114

Other implementing rules

1. Detailed implementing rules shall be adopted for the purpose of applying this Regulation. They shall in particular include provisions:

- defining the relationship between the Office and the Examination Offices, agencies or its own sub-offices referred to in Articles 30 (4) and 55 (1) and (2),
- on matters referred to in Articles 36 (1) and 42 (2),
- on the procedure of the Boards of Appeal.

2. Without prejudice to Articles 112 and 113, all the implementing rules referred to in this Regulation shall be adopted in accordance with the procedure laid down in Article 115, after consultation of the Administrative Council on the draft of the measures to be taken.

Article 115

Procedure

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

2. Where the procedure laid down in this Article is to be followed, 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 if they are in accordance with the opinion of the committee.
- (b) If the measures envisaged are not in accordance with the opinion of the committee, or if no

opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

PART EIGHT

TRANSITIONAL AND FINAL PROVISIONS

Article 116

Derogations

1. Notwithstanding Article 10 (1) (a) and without prejudice to the provisions of Article 10 (2) and (3), a variety shall be deemed to be new also in cases where variety constituents or harvested material thereof have not been sold or otherwise disposed of to others, by or with the consent of the breeder, within the territory of the Community for purposes of exploitation of the variety, earlier than four years, in the case of trees or of vines earlier than six years, before the entry into force of this Regulation, if the date of application is within one year of that date.

2. The provision of paragraph 1 shall apply to such varieties also in cases where a national plant variety right was granted in one or more Member States before the entry into force of this Regulation.

3. Notwithstanding Articles 55 and 56, the technical examination of these varieties shall be carried out to the extent possible by the Office on the basis of the available findings resulting from any proceedings for the grant of a national plant variety right, in agreement with the authority before which these proceedings were held.

4. In the case of a Community plant variety right granted pursuant to paragraphs 1 or 2:

- Article 13 (5) (a) shall not apply in relation to essentially derived varieties, the existence of which was a matter of common knowledge in the Community before the date of entry into force of this Regulation.
- Article 14 (3), fourth indent shall not apply to farmers who continue to use an established variety in accordance with the authorization of Article 14 (1) if, before the entry into force of this Regulation, they have already used the variety for the purposes described in Article 14 (1) without payment of a remuneration; this provision shall apply until 30 June of the seventh year following that of the entry into force of this Regulation. Before that date the Commission shall submit a report on the situation of the established varieties dealing with each variety

individually. That period may be extended, in the implementing provisions adopted pursuant to Article 114, in so far as the Commission's report justifies it.

- without prejudice to the rights conferred by national protection, the provisions of Article 16 shall apply *mutatis mutandis* to acts concerning material disposed of to others by the breeder or with his consent prior to the date of entry into force of this Regulation, and effected by person who, prior to that date, have already effected such acts or have made effective and genuine arrangements to do so.

If such earlier acts have involved further propagation which was intended within the meaning of Article 16 (a), the authorization of the holder shall be required for any further propagation after the expiry of the second year, in the case of varieties of vine and tree species after the expiry of the fourth year, following the date of entry into force of this Regulation.

- Notwithstanding Article 19, the duration of the Community plant variety right shall be reduced by the longest period:
 - during which variety constituents or harvested material thereof have been sold or otherwise disposed of to others, by or with the consent of the breeder, within the territory of the Community for purposes of exploitation of the variety, as established in the findings resulting from the procedure for the grant of the Community plant variety right, in the case of paragraph 1,
 - during which any national plant variety right or rights have been effective, in the case of paragraph 2,

but not more than by five years.

Article 117

Transitional provisions

The Office shall be set up in good time to assume fully the tasks incumbent upon it pursuant to this Regulation as from 27 April 1995.

Article 118

Entry into force

1. This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Communities*.
2. Articles 1, 2, 3, 5 to 29 and 49 to 106 shall apply from 27 April 1995.

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

Done at Brussels, 27 July 1994.

For the Council
The President
Th. WAIGEL

COUNCIL DIRECTIVE 94/43/EC

of 27 July 1994

establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market⁽¹⁾, and in particular Article 18 (1) thereof,

Having regard to the proposal from the Commission,

Whereas Annex VI to Directive 91/414/EEC lays down uniform principles aiming to ensure that the Member States, in deciding on authorizations for plant protection products, apply the requirements of Article 4 (1) (b), (c), (d) and (e) of the Directive in an equivalent manner and at the high level of protection of human and animal health and the environment sought by the Directive;

Whereas it is therefore necessary to lay down detailed principles concerning the evaluation of information on plant protection products supplied by applicants and the decision to be made on authorization on the basis of the results of that evaluation;

Whereas such principles have to be laid down for each of the different requirements provided for in Article 4 (1) (b), (c), (d) and (e);

Whereas, initially, it is desirable to lay down uniform principles for chemical plant protection products only; whereas it therefore remains for the uniform principles for products containing micro-organisms to be laid down in accordance with the same procedure as provided for in Article 18 (1) of the Directive 91/414/EEC;

Whereas the provisions of this Directive on the protection of water are without prejudice to Member States' obligations under the Directives concerning the

protection of water, and in particular Directives 75/440/EEC⁽²⁾, 80/68/EEC⁽³⁾ and 80/778/EEC⁽⁴⁾;

Whereas a review of the abovementioned Directives is necessary and this should be carried out as soon as possible;

Whereas, pending such review, the provisions of this Directive concerning the protection of water are transitional in nature;

Whereas it is important to evaluate the impact of the use of plant protection products on groundwater, but whereas the models currently available do not enable a precise estimate to be made of the foreseeable concentration in such water; whereas it is therefore necessary to re-examine the provisions of Part C, point 2.5.1.2 (b) of Annex VI to Directive 91/414/EEC as soon as models validated at Community level enable such concentration to be estimated precisely,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex VI to Directive 91/414/EEC is hereby established as set out in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than one year after its entry into force.

⁽¹⁾ OJ No L 230, 19. 8. 1991, p. 1. Directive as amended by Commission Directive 93/71/EEC (OJ No L 221, 31. 8. 1993, p. 27).

⁽²⁾ Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States (OJ No L 194, 25. 7. 1975, p. 26. Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

⁽³⁾ Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances (OJ No L 20, 26. 1. 1980, p. 43). Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

⁽⁴⁾ Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption (OJ No L 229, 30. 8. 1980, p. 11). Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

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 the Member States.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 27 July 1994.

For the Council,
The President
Th. WAIGEL

ANNEX

ANNEX VI

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORIZATION OF PLANT PROTECTION PRODUCTS

CONTENTS

A. INTRODUCTION

B. EVALUATION

1. General principles

2. Specific principles

- 2.1. *Efficacy*
- 2.2. *Absence of unacceptable effects on plants or plant products*
- 2.3. *Impact on vertebrates to be controlled*
- 2.4. *Impact on human or animal health*
 - 2.4.1. arising from the plant protection product
 - 2.4.2. arising from residues
- 2.5. *Influence on the environment*
 - 2.5.1. Fate and distribution in the environment
 - 2.5.2. Impact on non-target species
- 2.6. *Analytical methods*
- 2.7. *Physical and chemical properties*

C. DECISION-MAKING

1. General principles

2. Specific principles

- 2.1. *Efficacy*
- 2.2. *Absence of unacceptable effects on plants or plant products*
- 2.3. *Impact on vertebrates to be controlled*
- 2.4. *Impact on human or animal health*
 - 2.4.1. arising from the plant protection product
 - 2.4.2. arising from residues
- 2.5. *Influence on the environment*
 - 2.5.1. Fate and distribution in the environment
 - 2.5.2. Impact on non-target species
- 2.6. *Analytical methods*
- 2.7. *Physical and chemical properties*

A. INTRODUCTION

1. The principles developed in this Annex aim to ensure that evaluations and decisions with regard to authorization of plant protection products, provided they are chemical preparations, result in the implementation of the requirements of Article 4 (1) (b), (c), (d) and (e) of this Directive by all the Member States at the high level of protection of human and animal health and the environment.
2. In evaluating applications and granting authorizations Member States shall:
 - (a) — ensure that the dossier supplied is in accordance with the requirements of Annex III, at the latest at the time of finalization of the evaluation for the purpose of decision-making without prejudice, where relevant, to the provisions of Article 13 (1) (a), (4) and (6) of this Directive,
— ensure that the data submitted are acceptable in terms of quantity, quality, consistency and reliability and sufficient to permit a proper evaluation of the dossier,
— evaluate, where relevant, justifications submitted by the applicant for not supplying certain data;
 - (b) take into account the Annex II data concerning the active substance in the plant protection product, submitted for the purpose of inclusion of the active substance concerned in Annex I, and the results of the evaluation of those data, without prejudice, where relevant, to the provisions of Article 13 (1) (b), (2), (3) and (6) of this Directive;
 - (c) take into consideration other relevant technical or scientific information they can reasonably possess with regard to the performance of the plant protection product or to the potentially adverse effects of the plant protection product, its components or its residues.
3. Where in the specific principles on evaluation reference is made to Annex II data, this shall be understood as being the data referred to in point 2 (b).
4. Where the data and information provided are sufficient to permit completion of the evaluation for one of the proposed uses, applications must be evaluated and a decision made for the proposed use.

Taking account of justifications provided and with the benefit of any subsequent clarifications, Member States shall reject applications for which the data gaps are such that it is not possible to finalize the evaluation and to make a reliable decision for at least one of the proposed uses.

5. During the process of evaluation and decision-making, Member States shall cooperate with the applicants in order to resolve any questions on the dossier quickly or to identify at an early stage any additional studies necessary for a proper evaluation of the dossier, or to amend any proposed conditions for the use of the plant protection product or to modify its nature or its composition in order to ensure full satisfaction of the requirements of this Annex or of this Directive.

Member States shall normally come to a reasoned decision within 12 months of receiving a technically complete dossier. A technically complete dossier is one that satisfies all the requirements of Annex III.

6. The judgments made by the competent authorities of the Member States during the evaluation and decision-making process must be based on scientific principles, preferably recognized at international level (for example, by the EPPO), and be made with the benefit of expert advice.

B. EVALUATION

1. General principles

1. Having regard to current scientific and technical knowledge, Member States shall evaluate the information referred to in Part A, point 2, and in particular:
 - (a) assess the performance in terms of efficacy and phytotoxicity of the plant protection product for each use for which authorization is sought; and

- (b) identify the hazards arising, assess their significance and make a judgment as to the likely risks to humans, animals or the environment.
2. In accordance with the terms of Article 4 of this Directive, which *inter alia* specifies that Member States shall have regard to all normal conditions under which the plant protection product may be used, and to the consequences of its use, Member States shall ensure that evaluations carried out have regard to the proposed practical conditions of use and in particular to the purpose of use, the dose, the manner, frequency and timing of applications, and the nature and composition of the preparation. Whenever possible Member States shall also take into account the principles of integrated control.
3. In the evaluation of applications submitted, Member States shall have regard to the agricultural, plant health or environmental (including climatic) conditions in the areas of use.
4. In interpreting the results of evaluations, Member States shall take into consideration possible elements of uncertainty in the information obtained during the evaluation, in order to ensure that the chances of failing to detect adverse effects or of under-estimating their importance are reduced to a minimum. The decision-making process shall be examined to identify critical decision points or items of data for which uncertainties could lead to a false classification of risk.

The first evaluation made shall be based on the best available data or estimates reflecting the realistic conditions of use of the plant protection product.

This should be followed by a repeat evaluation, taking account of potential uncertainties in the critical data and of a range of use conditions that are likely to occur and resulting in a realistic worst-case approach, to determine whether it is possible that the initial evaluation could have been significantly different.

5. Where specific principles of Section 2 provide for the use of calculation models in the evaluation of a plant protection product, those models shall:
- make a best possible estimation of all relevant processes involved taking into account realistic parameters and assumptions,
 - be submitted to an analysis as referred to in B, point 1.4,
 - be reliably validated with measurements carried out under circumstances relevant for the use of the model,
 - be relevant to the conditions in the area of use.
6. Where metabolites, degradation or reaction products are referred to in the specific principles, only those that are relevant for the proposed criterion shall be taken into consideration.

2. Specific principles

Member States shall, for the evaluation of the data and information submitted in support of applications, and without prejudice to the general principles of Section 1, implement the following principles.

2.1. *Efficacy*

- 2.1.1. Where the proposed use concerns the control of or protection against an organism, Member States shall evaluate the possibility that this organism could be harmful under the agricultural, plant health and environmental (including climatic) conditions in the area of the proposed use.
- 2.1.2. Where the proposed use concerns an effect other than the control of or protection against an organism, Member States shall evaluate whether significant damage, loss or inconvenience could occur under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use if the plant protection product were not used.
- 2.1.3. Member States shall evaluate the efficacy data on the plant protection product as provided for in Annex III having regard to the degree of control or the extent of the effect desired and having regard to the relevant experimental conditions such as:

- the choice of the crop or cultivar,
- the agricultural and environmental (including climatic) conditions,
- the presence and density of the harmful organism,
- the development stage of crop and organism,
- the amount of the plant protection product used,
- if required on the label, the amount of adjuvant added,
- the frequency and timing of the applications,
- the type of application equipment.

2.1.4. Member States shall evaluate the performance of the plant protection product in a range of agricultural, plant health and environmental (including climatic) conditions likely to be encountered in practice in the area of proposed use and in particular:

- (i) the level, consistency and duration of the effect sought in relation to the dose in comparison with a suitable reference product or products and an untreated control,
- (ii) where relevant, effect on yield or reduction of loss in storage, in terms of quantity and/or quality, in comparison with a suitable reference product or products and an untreated control.

Where no suitable reference product exists, Member States shall evaluate the performance of the plant protection product to determine whether there is a consistent and defined benefit under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.1.5. Where the product label includes requirements for use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix, Member States shall make the evaluations referred to in points 2.1.1 to 2.1.4 in relation to the information supplied for the tank mix.

Where the product label includes recommendations for use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix, Member States shall evaluate the appropriateness of the mix and of its conditions of use.

2.2. *Absence of unacceptable effects on plants or plant products*

2.2.1. Member States shall evaluate the degree of adverse effects on the treated crop after use of the plant protection product according to the proposed conditions of use in comparison, where relevant, with suitable reference product or products, where they exist, and/or an untreated control.

(a) This evaluation will take into consideration the following information:

- (i) the efficacy data provided for in Annex III;
- (ii) other relevant information on the plant protection product such as nature of the preparation, dose, method of application, number and timing of applications;
- (iii) all relevant information on the active substance as provided for in Annex II, including mode of action, vapour pressure, volatility and water solubility.

(b) This evaluation will include:

- (i) the nature, frequency, level and duration of observed phytotoxic effects and the agricultural, plant health and environmental (including climatic) conditions that affect these;
- (ii) the differences between main cultivars with regard to their sensitivity to phytotoxic effects;
- (iii) the part of the treated crop or plant products where phytotoxic effects are observed;
- (iv) the adverse impact on the yield of the treated crop or plant products in terms of quantity and/or quality;
- (v) the adverse impact on treated plants or plant products to be used for propagation, in terms of viability, germination, sprouting, rooting and establishment;

(vi) where volatile products are concerned, the adverse impact on adjacent crops.

2.2.2. Where the available data indicate that the active substance or significant metabolites, degradation and reaction products persist in soils and/or in or on plant substances in significant quantities after use of the plant protection product according to the proposed conditions of use, Member States shall evaluate the degree of adverse effects on subsequent crops. This evaluation will be carried out as specified in point 2.2.1.

2.2.3. Where the product label includes requirements for use of the plant protection product with other plant protection products or with adjuvants as a tank mix, the evaluation as specified in point 2.2.1 will be carried out in relation to the information supplied for the tank mix.

2.3. *Impact on vertebrates to be controlled*

Where the proposed use of the plant protection product aims to have an effect on vertebrates, Member States shall evaluate the mechanism by which this effect is obtained and the observed effects on the behaviour and health of the target animals; when the intended effect is to kill the target animal they shall evaluate the time necessary to obtain the death of the animal and the conditions under which death occurs.

This evaluation will take into consideration the following information:

- (i) all relevant information as provided for in Annex II and the results of the evaluation thereof, including the toxicological and metabolism studies;
- (ii) all relevant information on the plant protection product as provided for in Annex III, including toxicological studies and efficacy data.

2.4. *Impact on human or animal health*

2.4.1. *Arising from the plant protection product*

2.4.1.1. Member States shall evaluate operator exposure to active substance and/or to toxicologically relevant compounds in the plant protection product likely to occur under the proposed conditions of use (including in particular dose, application method and climatic conditions) using by preference realistic data on exposure and, if such data are not available, as suitable, validated calculation model.

(a) This evaluation will take into consideration the following information:

- (i) the toxicological and metabolism studies as provided for in Annex II and the results of the evaluation thereof including the acceptable operator exposure level (AOEL). The acceptable operator exposure level is the maximum amount of active substance to which the operator may be exposed without any adverse health effects. The AOEL is expressed as milligrams of the chemical per kilogram body weight of the operator. The AOEL is based on the highest level at which no adverse effect is observed in tests in the most sensitive relevant animal species or, if appropriate data are available, in humans;
- (ii) other relevant information on the active substances such as physical and chemical properties;
- (iii) the toxicological studies provided for in Annex III, including where appropriate dermal absorption studies;
- (iv) other relevant information as provided for in Annex III such as:
 - composition of the preparation,
 - nature of the preparation,
 - size, design and type of packaging,
 - field of use and nature of crop or target,
 - method of application including handling, loading and mixing of product,
 - exposure reduction measures recommended,
 - protective clothing recommendations,
 - maximum application rate,
 - minimum spray application volume stated on the label,
 - number and timing of applications.

- (b) This evaluation shall be made for each type of application method and application equipment proposed for use of the plant protection product as well as for the different types and sizes of containers to be used, taking account of mixing, loading operations, application of the plant protection product and cleaning and routine maintenance of application equipment.

2.4.1.2. Member States shall examine information relating to the nature and characteristics of the packaging proposed with particular reference to the following aspects:

- the type of packaging,
- its dimensions and capacity,
- the size of the opening,
- the type of closure,
- its strength, leakproofness and resistance to normal transport and handling,
- its resistance to and compatibility with the contents.

2.4.1.3. Member States shall examine the nature and characteristics of the protective clothing and equipment proposed with particular reference to the following aspects:

- obtainability and suitability,
- ease of wearing taking into account physical stress and climatic conditions.

2.4.1.4. Member States shall evaluate the possibility of exposure of other humans (bystanders or workers exposed after the application of the plant protection product) or animals to the active substance and/or to other toxicologically relevant compounds in the plant protection product under the proposed conditions of use.

This evaluation will take into consideration the following information:

- (i) the toxicological and metabolism studies on the active substance as provided for in Annex II and the results of the evaluation thereof, including the acceptable operator exposure level,
- (ii) the toxicological studies provided for in Annex III, including where appropriate dermal absorption studies,
- (iii) other relevant information on the plant protection product as provided for in Annex III such as:
 - re-entry periods, necessary waiting periods or other precautions to protect humans and animals,
 - method of application, in particular spraying,
 - maximum application rate,
 - maximum spray application volume,
 - composition of the preparation,
 - excess remaining on plants and plant products after treatment,
 - further activities whereby workers are exposed.

2.4.2. Arising from residues

2.4.2.1. Member States shall evaluate the specific information on toxicology as provided for in Annex II and in particular:

- the determination of an acceptable daily intake (ADI),
- the identification of metabolites, degradation and reaction products in treated plants or plant products,
- behaviour of residues of the active substance and its metabolites from the time of application until harvest, or in the case of post-harvest uses, until outloading of stored plant products.

2.4.2.2. Prior to evaluating the residue levels in the reported trials or in products of animal origin Member States shall examine the following information:

- data on the proposed good agricultural practice, including data on application as provided for in Annex III and proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in case of post-harvest uses,

- nature of preparation,
 - analytical methods and the residue definition.
- 2.4.2.3. On the basis of suitable statistical models Member States shall evaluate the residue levels observed in the reported trials. This evaluation shall be made for each proposed use and shall take into consideration:
- (i) the proposed conditions of use of the plant protection product;
 - (ii) the specific information on residues in or on treated plants, plant products, food and feed as provided for in Annex III and the distribution of residues between edible and non-edible parts;
 - (iii) the specific information on residues in or on treated plants, plant products, food and feed as provided for in Annex II and the results of the evaluation thereof;
 - (iv) the realistic possibilities of extrapolating data from one crop to another.
- 2.4.2.4. Member States shall evaluate the residue levels observed in products of animal origin, taking into consideration the information provided for in Annex III, Part A, point 8.4 and residues resulting from other uses.
- 2.4.2.5. Member States shall estimate the potential exposure of consumers through diet and, where relevant, other ways of exposure, using as suitable calculation model. This evaluation will take account, where relevant, of other sources of information such as other authorized uses of plant protection products containing the same active substance or which give rise to the same residues.
- 2.4.2.6. Member States shall, where relevant, estimate the exposure of animals, taking into account residue levels observed in treated plants or plant products intended to be fed to animals.

2.5. *Influence on the environment*

2.5.1. Fate and distribution in the environment

In the evaluation of the fate and distribution of the plant protection product in the environment, Member States shall have regard to all aspects of the environment, including biota, and in particular to the following:

- 2.5.1.1. Member States shall evaluate the possibility of the plant protection product reaching the soil under the proposed conditions of use; if this possibility exists they shall estimate the rate and the route of degradation in the soil, the mobility in the soil and the change in the total concentration (extractable and non-extractable (*)) of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the soil in the area of envisaged use after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

- (i) the specific information on fate and behaviour in soil as provided for in Annex II and the results of the evaluation thereof;
- (ii) other relevant information on the active substance such as:
 - molecular weight,
 - solubility in water,
 - octanol/water partition coefficient,
 - vapour pressure,
 - volatilization rate,
 - dissociation constant,
 - photodegradation rate and identity of breakdown products,
 - hydrolysis rate in relation to pH and identity of breakdown products;

(*) Non-extractable residues (sometimes referred to as 'bound' or 'non-extracted' residues) in plants and soils are defined as chemical species originating from pesticides used according to good agricultural practice that cannot be extracted by methods which do not significantly change the chemical nature of these residues. These non-extractable residues are not considered to include fragments through metabolic pathways leading to natural products.

- (iii) all information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in soil;
- (iv) where relevant, other authorized uses of plant protection products in the area of proposed use containing the same active substance or which give rise to the same residues.

2.5.1.2. Member States shall evaluate the possibility of the plant protection product reaching the groundwater intended to produce drinking water under the proposed conditions of use; if this possibility exists, they shall estimate, using a suitable calculation model validated at Community level, the concentration of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the groundwater in the area of envisaged use after use of the plant protection product according to the proposed conditions of use.

If there is no validated Community calculation model, Member States shall base their evaluation especially on the results of mobility and persistence in soil studies as provided for in Annexes II and III.

This evaluation will also take into consideration the following information:

- (i) the specific information on fate and behaviour in soil and water as provided for in Annex II and the results of the evaluation thereof;
- (ii) other relevant information on the active substance such as:
 - molecular weight,
 - solubility in water,
 - octanol/water partition coefficient,
 - vapour pressure,
 - volatilization rate,
 - hydrolysis rate in relation to pH and identity of breakdown products,
 - dissociation constant;
- (iii) all information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in soil and water;
- (iv) where relevant, other authorized uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues;
- (v) where relevant, data on dissipation including transformation and sorption in the saturated zone;
- (vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use;
- (vii) where relevant, monitoring data on the presence or absence of the active substance in groundwater as a result of previous use of plant protection products containing the same active substance or which give rise to the same residues.

2.5.1.3. Member States shall evaluate the possibility of the plant protection product reaching surface water under the proposed conditions of use; if this possibility exists they shall estimate, using a suitable calculation model validated at Community level, the short-term and long-term predicted concentration of the active substance and of metabolites, degradation and reaction products that could be expected in the surface water in the area of envisaged use after use of the plant protection product according to the proposed conditions of use.

If there is no validated Community calculation model, Member States shall base their evaluation especially on the results of mobility and persistence in soil studies and the information on run-off and drift as provided for in Annexes II and III. This evaluation will also take into consideration the following information:

- (i) the specific information on fate and behaviour in soil and water as provided for in Annex II and the results of the evaluation thereof;
- (ii) other relevant information on the active substance such as:
 - molecular weight,
 - solubility in water,
 - octanol/water partition coefficient,

- vapour pressure,
- volatilization rate,
- hydrolysis rate in relation to pH and identity of breakdown products,
- dissociation constant;
- (iii) all relevant information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in soil and water;
- (iv) possible routes of exposure:
 - drift,
 - run-off,
 - overspray,
 - discharge via drains,
 - leaching,
 - deposit in the atmosphere;
- (v) where relevant, other authorized uses of plant protection products in the area of envisaged use containing the same active substance or which give rise to the same residues;
- (vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use.

2.5.1.4. Member States shall evaluate the possibility of the plant protection product being dissipated in the air under the proposed conditions of use; if this possibility exists they shall make the best possible estimation, using where appropriate a suitable, validated calculation model, of the concentration of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the air after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

- (i) the specific information on fate and behaviour in soil, water and air as provided for in Annex II and the results of the evaluation thereof;
- (ii) other relevant information on the active substance such as:
 - vapour pressure,
 - solubility in water,
 - hydrolysis rate in relation to pH and identity of breakdown products,
 - photochemical degradation in water and air and identity of breakdown products,
 - octanol/water partition coefficient;
- (iii) all relevant information on the plant protection product as provided for in Annex III, including the information on distribution and dissipation in air.

2.5.1.5. Member States shall evaluate the procedures for destruction or decontamination of the plant protection product and its packaging.

2.5.2. Impact on non-target species

When calculating toxicity/exposure ratios Member States shall take into consideration toxicity to the most sensitive relevant organism used in the tests.

2.5.2.1. Member States shall evaluate the possibility of exposure of birds and other terrestrial vertebrates to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the extent of the short-term and long-term risk to be expected for these organisms, including their reproduction, after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation will take into consideration the following information:

- (i) the specific information relating to toxicological studies on mammals and to the effects on birds and other non-target terrestrial vertebrates, including effects on reproduction, and other relevant information concerning the active substance as provided for in Annex II and the results of the evaluation thereof;

- (ii) all relevant information on the plant protection product as provided for in Annex III, including the information on effects on birds and other non-target terrestrial vertebrates;
 - (iii) where relevant, other authorized uses of plant protection products in the area of envisaged use containing the same active substance or which give rise in the same residues.
- (b) This evaluation will include:
- (i) the fate and distribution, including persistence and biocondition, of the active substance and of relevant metabolites, breakdown and reaction products in the various parts of the environment after application of the plant protection product;
 - (ii) the estimated exposure of the species likely to be exposed at the time of application or during the period that residues are present, taking into account all relevant routes of exposure such as ingestion of the formulated product or treated food, predation on invertebrates, feeding on vertebrate prey, contact by overspraying or with treated vegetation;
 - (iii) a calculation of the acute, short-term and, where necessary, long-term toxicity/exposure ratio. The toxicity/exposure ratios are defined as respectively the quotient of LD_{50} , LC_{50} or NOEC expressed on an active substance basis and the estimated exposure expressed in mg/kg body weight.
- 2.5.2.2. Member States shall evaluate the possibility of exposure of aquatic organisms to the plant protection product under the proposed conditions of use; if this possibility exists that shall evaluate the degree of short-term and long-term risk to be expected for aquatic organisms after use of the plant protection product according to the proposed conditions of use.

- (a) This evaluation will take into consideration the following information:
- (i) the specific information relating to the effects on aquatic organisms as provided for in Annex II and the results of the evaluation thereof;
 - (ii) other relevant information on the active substance such as:
 - solubility in water,
 - octanol/water partition coefficient,
 - vapour pressure,
 - volatilization rate,
 - KOC,
 - biodegradation in aquatic systems and in particular the ready biodegradability,
 - photodegradation rate and identity of breakdown products,
 - hydrolysis rate in relation to pH and identity of breakdown products;
 - (iii) all relevant information on the plant protection product as provided for in Annex III and in particular the effects on aquatic organisms;
 - (iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues.
- (b) This evaluation will include:
- (i) the fate and distribution of residues of the active substance and of relevant metabolites, breakdown and reaction products in water, sediment or fish;
 - (ii) a calculation of the acute toxicity/exposure ratio for fish and Daphnia. This ratio is defined as the quotient of respectively acute LC_{50} or EC_{50} and the predicted short-term environmental concentration;
 - (iii) a calculation of the algal growth inhibition/exposure ratio for algae. This ratio is defined as the quotient of the EC_{50} and the predicted short-term environmental concentration;
 - (iv) a calculation of the long-term toxicity/exposure ratio for fish and Daphnia. The long-term toxicity/exposure ratio is defined as the quotient of the NOEC and the predicted long-term environmental concentration;
 - (v) where relevant, the bioconcentration in fish and possible exposure of predators of fish, including humans;

- (vi) if the plant protection product is to be applied directly to surface water, the effect on the change of surface water quality, such as pH or dissolved oxygen content.

2.5.2.3. Member States shall evaluate the possibility of exposure of honeybees to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the short-term and long-term risk to be expected for honeybees after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation will take into consideration the following information:

- (i) the specific information on toxicity to honeybees as provided for in Annex II and the results of the evaluation thereof;
- (ii) other relevant information on the active substance such as:
 - solubility in water,
 - octanol/water partition coefficient,
 - vapour pressure,
 - photodegradation rate and identity of breakdown products,
 - mode of action (e.g. insect growth regulating activity);
- (iii) all relevant information on the plant protection product as provided for in Annex III, including the toxicity to honeybees;
- (iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues.

(b) This evaluation will include:

- (i) the ratio between the maximum application rate expressed in grammes of active substance per hectare and the contact and oral LD₅₀ expressed in μg of active substance per bee (hazard quotients) and where necessary the persistence of residues on or, where relevant, in the treated plants;
- (ii) where relevant, the effects of honeybee larvae, honeybee behaviour, colony survival and development after use of the plant protection product according to the proposed conditions of use.

2.5.2.4. Member States shall evaluate the possibility of exposure of beneficial arthropods other than honeybees to the plant protection product under the proposed conditions of use; if this possibility exists they will assess the lethal and sublethal effects on these organisms to be expected and the reduction in their activity after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

- (i) the specific information on toxicity to honeybees and other beneficial arthropods as provided for in Annex II and the results of the evaluation thereof;
- (ii) other relevant information on the active substance such as:
 - solubility in water,
 - octanol/water partition coefficient,
 - vapour pressure,
 - photodegradation rate and identity of breakdown products,
 - mode of action (e.g. insect growth regulating activity);
- (iii) all relevant information on the plant protection product as provided for in Annex III such as:
 - effects on beneficial arthropods other than bees,
 - toxicity to honeybees,
 - available data from biological primary screening,
 - maximum application rate,
 - maximum number and timetable of applications.
- (iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues.

2.5.2.5. Member States shall evaluate the possibility of exposure of earthworms and other non-target soil macro-organisms to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the degree of short-term and long-term risk to be expected to these organisms after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation will take into consideration the following information:

- (i) the specific information relating to the toxicity of the active substance to earthworms and to other non-target soil macro-organisms as provided for in Annex II and the results of the evaluation thereof;
- (ii) other relevant information on the active substance such as:
 - solubility in water,
 - octanol/water partition coefficient,
 - K_d for adsorption,
 - vapour pressure,
 - hydrolysis rate in relation to pH and identity of breakdown products,
 - photodegradation rate and identity of breakdown products,
 - DT_{50} and DT_{90} for degradation in the soil;
- (iii) all relevant information on the plant protection product as provided for in Annex III, including the effects on earthworms and other non-target soil macro-organisms;
- (iv) where relevant, other authorized uses of plant protection product in the area of envisaged use, containing the same active substance or which give rise to the same residues.

(b) This evaluation will include:

- (i) the lethal and sublethal effects;
- (ii) the predicted initial and long-term environmental concentration;
- (iii) a calculation of the acute toxicity/exposure ratio (defined as the quotient of LC_{50} and predicted initial environmental concentration) and of the long-term toxicity/exposure ratio (defined as the quotient of the NOEC and predicted long-term environmental concentration);
- (iv) where relevant, the bioconcentration and persistence of residues in earthworms.

2.5.2.6. Member States shall, where the evaluation carried out under Part B, point 2.5.1.1, does not exclude the possibility of the plant protection product reaching the soil under the proposed conditions of use, evaluate the impact on microbial activity such as the impact on nitrogen and carbon mineralization processes in the soil after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

- (i) all relevant information on the active substance, including the specific information relating to the effects on non-target soil micro-organisms as provided for in Annex II and the results of the evaluation thereof;
- (ii) all relevant information on the plant protection product as provided for in Annex III, including the effects on non-target soil micro-organisms;
- (iii) where relevant, other authorized uses of plant protection products in the area of proposed use, containing the same active substance or which give rise to the same residues;
- (iv) all available information from biological primary screening.

2.6. *Analytical methods*

Member States shall evaluate the analytical methods proposed for post-registration control and monitoring purposes, to determine:

2.6.1. for formulation analysis:

the nature and quantity of the active substance(s) in the plant protection product and, where appropriate, any toxicologically, ecotoxicologically or environmentally significant impurities and co-formulants.

This evaluation will take into consideration the following information:

- (i) the data on analytical methods as provided for in Annex II and the results of the evaluation thereof;
- (ii) the data on analytical methods as provided for in Annex III and in particular:
 - the specificity and linearity of the proposed methods,
 - the importance of interferences,
 - the precision of the proposed methods (intra-laboratory repeatability and inter-laboratory reproducibility);
- (iii) the limit of detection and determination of the proposed methods for impurities;

2.6.2. for residue analysis:

the residues of the active substance, metabolites, breakdown or reaction products resulting from authorized uses of the plant protection product and which are of toxicological, ecotoxicological or environmental significance.

This evaluation will take into consideration the following information:

- (i) the data on analytical methods as provided for in Annex II and the results of the evaluation thereof;
- (ii) the data on analytical methods as provided for in Annex III and in particular:
 - the specificity of the proposed methods,
 - the precision of the proposed methods (intra-laboratory repeatability and inter-laboratory reproducibility),
 - the recovery rate of the proposed methods at appropriate concentrations;
- (iii) the limit of detection of the proposed methods;
- (iv) the limit of determination of the proposed methods.

2.7. *Physical and chemical properties*

2.7.1. Member States shall evaluate the actual active substance content of the plant protection product and its stability during storage.

2.7.2. Member States shall evaluate the physical and chemical properties of the plant protection product and in particular:

- where a suitable FAO specification exists, the physical and chemical properties addressed in that specification,
- where no suitable FAO specification exists, all the relevant physical and chemical properties for the formulation as referred to in the 'Manual on the development and use of FAO specifications for plant protection products'.

This evaluation will take into consideration the following information:

- (i) the data on the physical and chemical properties of the active substance as provided for in Annex II and the results of the evaluation thereof;
- (ii) the data on the physical and chemical properties of the plant protection product as provided for in Annex III.

2.7.3. Where proposed label claims include requirements or recommendations for use of the plant protection product with other plant protection products or adjuvants as a tank mix, the physical and chemical compatibility of the products in the mixture must be evaluated.

C. DECISION-MAKING

1. General principles

1. Where appropriate, Member States shall impose conditions or restrictions with the authorizations they grant. The nature and severity of these measures must be selected on the basis of, and be appropriate to, the nature and extent of the expected advantages and the risks likely to arise.
2. Member States shall ensure that, where necessary, decisions taken with respect to the granting of authorizations take account of the agricultural, plant health or environmental (including climatic) conditions in the areas of envisaged use. Such considerations may result in specific conditions and

restrictions of use, and, where necessary, in authorization being granted for some but not other areas within the Member State in question.

3. Member States shall ensure that the authorized amounts, in terms of rates and number of applications, are the minimum necessary to achieve the desired effect even where higher amounts would not result in unacceptable risks to human or animal health or to the environment. The authorized amounts must be differentiated according to, and be appropriate to the agricultural, plant health or environmental (including climatic) conditions in the various areas for which an authorization is granted. However, the rates and the number of applications may not give rise to undesirable effects such as the development of resistance.
4. Member States shall ensure that decisions respect the principles of integrated control if the product is intended to be used in conditions where these principles are relied on.
5. Since the evaluation is to be based on data concerning a limited number of representative species, Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species.
6. Before issuing an authorization, Member States shall ensure that the label of the product:
 - fulfils the requirements of Article 16 of this Directive,
 - also contains the information on protection of users required by Community legislation on worker protection,
 - specifies in particular the conditions or restrictions under which the plant protection product may or may not be used as referred to in points 1, 2, 3, 4 and 5.

The authorization shall mention the particulars indicated in Article 6 (2) (g) and (h), (3) and (4) of Council Directive 78/631/EEC of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides) ⁽¹⁾ and in Article 16 (g) and (h) of Directive 91/414/EEC.

7. Before issuing authorizations, Member States shall:
 - (a) ensure that the proposed packaging is in accordance with the provisions of Directive 78/631/EEC;
 - (b) ensure that:
 - the procedures for destruction of the plant protection product,
 - the procedures for neutralization of the adverse effects of the product if it is accidentally dispersed,
 - the procedures for the decontamination and destruction of the packagings,are in accordance with the relevant regulatory provisions.
8. No authorization shall be granted unless all the requirements referred to in Section 2 are satisfied. However:
 - (a) when one or more of the specific decision-making requirements referred to in Part C, points 2.1, 2.2, 2.3 or 2.7, are not fully satisfied, authorizations shall be granted only when the advantages of the use of the plant protection product under the proposed conditions of use outweigh the possible adverse effects of its use. Any restrictions on use of the product relating to non-compliance with some of the aforementioned requirements must be mentioned on the label, and non-compliance with the requirements referred to in point 2.7 must not compromise proper use of the product. These advantages can be in terms of:
 - advantages for and compatibility with integrated control measures or organic farming,
 - facilitating strategies to minimize the risk of development of resistance,

⁽¹⁾ OJ No L 206, 29. 7. 1978, p. 13. Directive as last amended by Directive 92/32/EEC (OJ No L 154, 5. 6. 1992, p. 1).

- the need for a greater diversity of types of active substances or biochemical modes of action, e.g. for use in strategies to avoid accelerated breakdown in the soil,
 - reduced risk for operators and consumers,
 - reduced contamination of the environment and reduced impact on non-target species;
- (b) where the criteria referred to in Part C, point 2.6, are not fully satisfied because of limitations in current analytical science and technology, authorization shall be granted for a limited period if the methods submitted prove adequate for the purposes intended. In this case the applicant shall be given a time limit in which to develop and submit analytical methods that are in accordance with the criteria referred to above. The authorization will be reviewed on expiry of the time limit accorded to the applicant;
- (c) where the reproducibility of the submitted analytical methods referred to in Part C, point 2.6, has only been verified in two laboratories, an authorization shall be granted for one year to permit the applicant to demonstrate the reproducibility of those methods in accordance with agreed criteria.
9. Where an authorization has been granted according to the requirements provided for in this Annex, Member States may, by virtue of Article 4 (6):
- (a) define, where possible, preferably in close cooperation with the applicant, measures to improve the performance of the plant protection product; and/or
- (b) define, where possible, in close cooperation with the applicant, measures to reduce further the exposure that could occur during and after use of the plant protection product.

Member States shall inform the applicants of any measures identified under (a) or (b) and shall invite applicants to provide any supplementary data and information necessary to demonstrate performance or potential risks arising under the changed conditions.

2. Specific principles

The specific principles shall apply without prejudice to the general principles referred to in Section 1.

2.1. *Efficacy*

- 2.1.1. Where the proposed uses include recommendations for the control of or protection against organisms which are not considered to be harmful on the basis of experience acquired or scientific evidence under normal agricultural, plant health and environmental (including climatic) conditions in the areas of proposed use or where the other intended effects are not considered to be beneficial under those conditions, no authorization shall be granted for those uses.
- 2.1.2. The level, consistency and duration of control or protection or other intended effects must be similar to those resulting from the use of suitable reference products. If no suitable reference product exists, the plant protection product must be shown to give a defined benefit in terms of the level, consistency and duration of control or protection or other intended effects under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.
- 2.1.3. Where relevant, yield response when the product is used and reduction of loss in storage must be quantitatively and/or qualitatively similar to those resulting from the use of suitable reference products. If no suitable reference product exists, the plant protection product must be shown to give a consistent and defined quantitative and/or qualitative benefit in terms of yield response and reduction of loss in storage under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.
- 2.1.4. Conclusions as to the performance of the preparation must be valid for all areas of the Member State in which it is to be authorized, and must hold for all conditions under which its use is proposed, except where the proposed label specifies that the preparation is intended for use in certain specified circumstances (e.g. light infestations, particular soil types or particular growing conditions).
- 2.1.5. Where proposed label claims include requirements for use of the preparation with other specified plant protection products or adjuvants as a tank mix, the mixture must achieve the desired effect and comply with the principles referred to in points 2.1.1 and 2.1.4.

Where proposed label claims include recommendations for use of the preparation with other specified plant protection products or adjuvants as a tankmix, Member States shall not accept the recommendations unless they are justified.

2.2. *Absence of unacceptable effects on plants or plant products*

- 2.2.1. There must be no relevant phytotoxic effects on treated plants or plant products except where the proposed label indicates appropriate limitations of use.
- 2.2.2. There must be no reduction of yield at harvest due to phytotoxic effects below that which could be obtained without the use of the plant protection product, unless this reduction is compensated for by other advantages such as an enhancement of the quality of the treated plants or plant products.
- 2.2.3. There must be no unacceptable adverse effects on the quality of treated plants or plant products, except in the case of adverse effects on processing where proposed label claims specify that the preparation should not be applied to crops to be used for processing purposes.
- 2.2.4. There must be no unacceptable adverse effects on treated plants or plant products used for propagation or reproduction, such as effects on viability, germination, sprouting, rooting and establishment, except where proposed label claims specify that the preparation should not be applied to plants or plant products to be used for propagation or reproduction.
- 2.2.5. There must be no unacceptable impact on succeeding crops, except where proposed label claims specify that particular crops, which would be affected, should not be grown following the treated crop.
- 2.2.6. There must be no unacceptable impact on adjacent crops, except where proposed label claims specify that the preparation should not be applied when particular sensitive adjacent crops are present.
- 2.2.7. Where proposed label claims include requirements for use of the preparation with other plant protection product or adjuvants, as a tank mix, the mixture must comply with the principles referred to in points 2.2.1 to 2.2.6.
- 2.2.8. The proposed instructions for cleaning the application equipment must be both practical and effective so that they can be applied with ease so as to ensure the removal of residual traces of the plant protection product which could subsequently cause damage.

2.3. *Impact on vertebrates to be controlled*

An authorization for a plant protection product intended to eliminate vertebrates shall be granted only when:

- death is synchronous with the extinction of consciousness, or
- death occurs immediately, or
- vital functions are reduced gradually without signs of obvious suffering.

For repellant products, the intended effect shall be obtained without unnecessary suffering and pain for the target animals.

2.4. *Impact on human or animal health*

2.4.1. *Arising from the plant protection product*

- 2.4.1.1. No authorization shall be granted if the extent of operator exposure in handling and using the plant protection product under the proposed conditions of use, including dose and application method, exceeds the acceptable operator exposure level (AOEL).

Moreover, the conditions of the authorization shall be in compliance with the limit value established for the active substance and/or toxicologically relevant compound(s) of the product in accordance with Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work ⁽¹⁾ and in accordance with Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work ⁽²⁾.

- 2.4.1.2. Where the proposed conditions of use require use of items of protective clothing and equipment, no authorization shall be granted unless those items are effective and in accordance with the relevant Community provisions and are readily obtainable by the user and unless it is feasible to use them under the circumstances of use of the plant protection product, taking into account climatic conditions in particular.
- 2.4.1.3. Plant protection products which because of particular properties or if mishandled or misused could lead to a high degree of risk must be subject to particular restrictions such as restrictions on the size of packaging, formulation type, distribution, use or manner of use. Moreover, plant protection products which are classified as very toxic may not be authorized for use by non-professional users.
- 2.4.1.4. Waiting and re-entry safety periods or other precautions must be such that the exposure of bystanders or workers exposed after the application of the plant protection product does not exceed the AOEL levels established for the active substance or toxicologically relevant compound(s) in the plant protection product nor any limit values established for those compounds in accordance with the Community provisions referred to in point 2.4.1.1.
- 2.4.1.5. Waiting and re-entry safety periods or other precautions must be established in such a way that no adverse impact on animals occurs.
- 2.4.1.6. Waiting and re-entry periods or other precautions to ensure that the AOEL levels and limit values are respected must be realistic; if necessary special precautionary measures must be prescribed.
- 2.4.2. Arising from residues
- 2.4.2.1. Authorizations must ensure that residues occurring reflect the minimum quantities of the plant protection product necessary to achieve adequate control corresponding to good agricultural practice, applied in such a manner (including pre-harvest intervals or withholding periods or storage periods) that the residues at harvest, slaughter or after storage, as appropriate, are reduced to a minimum.
- 2.4.2.2. Where no Community MRL ^(*) or provisional MRL (at national or at Community level) exists, Member States shall establish a provisional MRL in accordance with Article 4 (1) (f) of this

⁽¹⁾ OJ No L 327, 3. 12. 1980, p. 8. Directive as last amended by Directive 88/642/EEC (OJ No L 356, 24. 12. 1988, p. 74).

⁽²⁾ OJ No L 196, 26. 7. 1990, p. 1.

^(*) A Community MRL will mean an MRL established pursuant to Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables ⁽¹⁾, Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals ⁽²⁾, Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin ⁽³⁾, Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin ⁽⁴⁾, Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables ⁽⁵⁾ or Council Directive 91/132/EEC of 4 March 1991 amending Directive 74/63/EEC on undesirable substances and products in feedingstuffs ⁽⁶⁾.

⁽¹⁾ OJ No L 340, 9. 12. 1976, p. 26. Directive as last amended by Directive 93/58/EEC (OJ No L 211, 23. 8. 1993, p. 6).

⁽²⁾ OJ No L 221, 7. 8. 1986, p. 37. Directive as last amended by Directive 93/57/EEC (OJ No L 211, 23. 8. 1993, p. 1).

⁽³⁾ OJ No L 221, 7. 8. 1986, p. 43. Directive as last amended by Directive 93/57/EEC (OJ No L 211, 23. 8. 1993, p. 1).

⁽⁴⁾ OJ No L 224, 18. 8. 1990, p. 1. Regulation as last amended by Commission Regulation (EEC) No 955/94 (OJ No L 108, 29. 4. 1994, p. 8).

⁽⁵⁾ OJ No L 350, 14. 12. 1990, p. 71. Directive as last amended by Directive 93/58/EEC (OJ No L 211, 23. 8. 1993, p. 6).

⁽⁶⁾ OJ No L 66, 13. 3. 1991, p. 16.

Directive; conclusions as to the levels fixed must be valid for all circumstances which could influence the residue levels in the crop such as timing of application, application rate and frequency or manner of use.

- 2.4.2.3. Where the new circumstances under which the plant protection product is to be used do not correspond to those under which a provisional MRL (at national or at Community level) was established previously, Member States shall not grant an authorization for the plant protection product unless the applicant can provide evidence that its recommended use will not exceed that MRL or unless a new provisional MRL has been established by the Member State or the Commission in accordance with Article 4 (1) (f) of this Directive.
- 2.4.2.4. Where a Community MRL exists Member States shall not grant an authorization for the plant protection product unless the applicant can provide evidence that its recommended use will not exceed that MRL, or unless a new Community MRL has been established in accordance with the procedures provided for in the relevant Community legislation.
- 2.4.2.5. In the cases referred to in points 2.4.2.2 and 2.4.2.3, each application for an authorization must be accompanied by a risk assessment taking into account worst-case potential exposure of consumers in the Member State concerned on the basis of good agricultural practice.

Taking into account all registered uses, the proposed use cannot be authorized if the best possible estimate of dietary exposure exceeds the acceptable daily intake (ADI).

- 2.4.2.6. Where the nature of residues is affected during processing, a separate risk assessment may need to be carried out under the conditions provided for in point 2.4.2.5.
- 2.4.2.7. Where the treated plants or plant products are intended to be fed to animals, residues occurring shall not have an adverse effect on animal health.

2.5. *Influence on the environment*

2.5.1. Fate and distribution in the environment

- 2.5.1.1. No authorization shall be granted if the active substance and, where they are of significance from the toxicological, ecotoxicological or environmental point of view, metabolites and breakdown or reaction products, after use of the plant protection product under the proposed conditions of use:

- during tests in the field, persist in soil for more than one year (i.e. $DT_{90} > 1$ year and $DT_{50} > 3$ months), or
- during laboratory tests, form not extractable residues in amounts exceeding 70 % of the initial dose after 100 days with a mineralization rate of less than 5 % in 100 days,

unless it is scientifically demonstrated that under field conditions there is no accumulation in soil at such levels that unacceptable residues in succeeding crops occur and/or that unacceptable phytotoxic effects on succeeding crops occur and/or that there is an unacceptable impact on the environment, according to the relevant requirements provided for in points 2.5.1.2, 2.5.1.3, 2.5.1.4 and 2.5.2.

- 2.5.1.2. (a) An authorization shall be granted only in the following cases:

- (1) where adequate monitoring data relevant to the proposed conditions of use of the plant protection product are not available and on the basis of the evaluation it appears that, after use of the plant protection product under the conditions proposed, the foreseeable concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water does not exceed the lower of the following concentrations:

- (i) the maximum permissible concentration laid down by Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption ⁽¹⁾;

or

⁽¹⁾ OJ No L 229, 30. 8. 1980, p. 11. Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

- (ii) the maximum concentration laid down by the Commission when including the active substance in Annex I, on the basis of appropriate data, in particular toxicological data, or, where that concentration has not been laid down, the concentration corresponding to one tenth of the ADI laid down when the active substance was included in Annex I;
 - (2) where adequate monitoring data relevant to the proposed conditions of use of the plant protection product are available and support the conclusion that in practice, after use of the plant protection product under the conditions proposed, the concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water has not exceeded or no longer exceeds and is not in danger of exceeding the appropriate maximum concentration as referred to in (1) above.
- (b) Irrespective of the provisions in (a) above, where the concentration referred to in (a) (1) (ii) is greater than that referred to in (a) (1) (i), a conditional authorization, which is not an authorization within the meaning of Article 10 (1) of this Directive and which is for a limited period of not more than five years, may be issued only in those cases in which the conditions specified in (1) or (2) below are fulfilled:
- (1) where adequate monitoring data relevant to the proposed conditions of use of the plant protection product are not available, every conditional authorization issued shall be subject to the following requirements:
 - (i) it appearing on the basis of the evaluation that, after use of the plant protection product under the conditions proposed, the foreseeable concentration of the active substance of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water does not exceed the maximum concentration referred to in (a) (1) (ii) above; and
 - (ii) it being ensured that an adequate monitoring programme covering areas liable to be contaminated is introduced or continued in the Member State, using suitable methods of sampling and analysis, so that it can be estimated whether the maximum concentration referred to in (a) (1) (i) above will be exceeded; it is for the Member States to decide who is to bear the cost of that monitoring programme;
 - (iii) where appropriate, attaching to the authorization of the conditions for or restrictions on the use of the product concerned, to appear on the label, having regard to agricultural plant health, and environmental (including climatic) conditions in the envisaged area of use;
 - (iv) if necessary, amendment or withdrawal of the conditional authorization, in accordance with Article 4 (5) and (6), where monitoring results show that, despite the imposing of the conditions or restrictions referred to in (iii) above, after use of the plant protection product under the conditions proposed, the concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water will exceed the concentration referred to in (a) (1) (i) above;
 - (2) where adequate monitoring data relevant to the conditions of use of the plant protection product are available and support the conclusion that in practice, after use of the plant protection product under the conditions proposed, there is no risk that the concentration of the active substance or of relevant metabolites or breakdown or reaction products in groundwater intended for the production of drinking water will exceed the maximum concentration referred to in (a) (1) (ii) above, every conditional authorization issued shall be subject to the following requirements:
 - (i) prior investigation of the significance of the risk of the maximum concentration referred to in (a) (1) (i) being exceeded and of the factors involved;
 - (ii) it being ensured that an adequate programme, consisting of measures referred to in (b) (1) (ii), (iii) and (iv) above, is introduced or continued in the Member State

so as to make sure that in practice the concentration does not exceed the maximum permissible concentration referred to in (a) (1) (i) above.

- (c) If, upon expiry of the conditional authorization, monitoring results show that in practice the concentration of the active substance or of relevant metabolites or breakdown or reaction products, as a result of the use of the plant protection product under the proposed conditions of use, in groundwater intended for the production of drinking water has been reduced to a level approaching the maximum permissible concentration referred to in (a) (1) (i) above and if other amendments to the proposed conditions of use could be expected to ensure that the foreseeable concentration will be reduced below that maximum concentration, a further conditional authorization including those new amendments may be issued for a single period of not more than five years.
 - (d) A Member State may at any time introduce appropriate conditions for or restrictions on the product's use, having regard to local agricultural, plant health and environmental (including climatic) conditions, in order to comply with the concentration referred to in (a) (1) (i) above in water intended for human consumption, in accordance with Directive 80/778/EEC.
- 2.5.1.3. No authorization shall be granted if the concentration of the active substance or of relevant metabolites, breakdown or reaction products to be expected after use of the plant protection product under proposed conditions of use in surface water:
- exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, the values fixed by Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States ⁽¹⁾, or
 - has an impact deemed unacceptable on non-target species, including animals, according to the relevant requirements provided for in point 2.5.2.
- The proposed instructions for use of the plant protection product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of surface water is reduced to a minimum.
- 2.5.1.4. No authorization shall be granted if the airborne concentration of the active substance under the proposed conditions of use is such that either the AOEL or the limit values for operators, bystanders or workers as referred to in Part C, point 2.4.1, are exceeded.

2.5.2. Impact on non-target species

- 2.5.2.1. Where there is a possibility of birds and other non-target terrestrial vertebrates being exposed, no authorization shall be granted if:
- the acute and short-term toxicity/exposure ratio for birds and other non-target terrestrial vertebrates is less than 10 on the basis of LD₅₀ or the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact occurs after use of the plant protection product according to the proposed conditions of use,
 - the bioconcentration factor (BCF, related to fat tissue) is greater than 1, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable effects occur — directly or indirectly — after use of the plant protection product according to the proposed conditions of use.
- 2.5.2.2. Where there is a possibility of aquatic organisms being exposed, no authorization shall be granted if:

⁽¹⁾ OJ No L 194, 25. 7. 1975, p. 34. Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

- the toxicity/exposure ratio for fish and Daphnia is less than 100 for acute exposure and less than 10 for long-term exposure, or
 - the algal growth inhibition/exposure ratio is less than 10, or
 - the maximum bioconcentration factor (BCF) is greater than 1 000 for plant protection products containing active substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact on the viability of exposed species (predators) occurs — directly or indirectly — after use of the plant protection product according to the proposed conditions of use.
- 2.5.2.3. Where there is a possibility of honeybees being exposed, no authorization shall be granted if the hazard quotients for oral or contact exposure of honeybees are greater than 50, unless it is clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on honeybee larvae, honeybee behaviour, or colony survival and development after use of the plant protection product according to the proposed conditions of use.
- 2.5.2.4. Where there is a possibility of beneficial arthropods other than honeybees being exposed, no authorization shall be granted if more than 30 % of the test-organisms are affected in lethal or sublethal laboratory tests conducted at the maximum proposed application rate, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on those organisms after use of the plant protection product according to the proposed conditions of use. Any claims for selectivity and proposals for use in integrated pest management systems shall be substantiated by appropriate data.
- 2.5.2.5. Where there is a possibility of earthworms being exposed, no authorization shall be granted if the acute toxicity/exposure ratio for earthworms is less than 10 or the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions earthworm populations are not at risk after use of the plant protection product according to the proposed conditions of use.
- 2.5.2.6. Where there is a possibility of non-target soil micro-organisms being exposed, no authorization shall be granted if the nitrogen or carbon mineralization processes in laboratory studies are affected by more than 25 % after 100 days, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on microbial activity after use of the plant protection product according to the proposed conditions of use, taking account of the ability of micro-organisms to multiply.

2.6. *Analytical methods*

The methods proposed must reflect the state of the art. The following criteria must be met in order to permit validation of the analytical methods proposed for post-registration control and monitoring purposes:

2.6.1. for formulation analysis:

the method must be able to determine and to identify the active substance(s) and where appropriate any toxicologically, ecotoxicologically or environmentally significant impurities and co-formulants;

2.6.2. for residue analysis:

- (i) the method must be able to determine and confirm residues of toxicological, ecotoxicological or environmental significance;
- (ii) the mean recovery rates should be between 70 % and 110 % with a relative standard deviation of ≤ 20 %;

(iii) the repeatability must be less than the following values for residues in foodstuffs:

<i>Residue level mg/kg</i>	<i>Difference mg/kg</i>	<i>Difference in %</i>
0,01	0,005	50
0,1	0,025	25
1	0,125	12,5
> 1		12,5

Intermediate values are determined by interpolation from a log-log graph;

(iv) the reproducibility must be less than the following values for residues in foodstuffs:

<i>Residue level mg/kg</i>	<i>Difference mg/kg</i>	<i>Difference in %</i>
0,01	0,01	100
0,1	0,05	50
1	0,25	25
> 1		25

Intermediate values are determined by interpolation from a log-log graph;

(v) in the case of residue analysis in treated plants, plant products, foodstuffs, feedingstuffs or products of animal origin, except where the MRL or the proposed MRL is at the limit of determination, the sensitivity of the methods proposed must satisfy the following criteria:

Limit of determination in relation to the proposed provisional or Community MRL:

<i>MRL (mg/kg)</i>	<i>Limit of determination (mg/kg)</i>
> 0,5	0,1
0,5—0,05	0,1—0,02
< 0,05	MRL × 0,5.

2.7. *Physical and chemical properties*

2.7.1. Where an appropriate FAO specification exists, that specification must be met.

2.7.2. Where no appropriate FAO specification exists, the physical and chemical properties of the product must meet the following requirements:

(a) Chemical properties:

Throughout the shelf-life period, the difference between the stated and the actual content of the active substance in the plant protection product must not exceed the following values:

<i>Declared content in g/kg or g/l at 20 °C</i>	<i>Tolerance</i>
up to 25	± 15 % homogeneous formulation ± 25 % non-homogeneous formulation
more than 25 up to 100	± 10 %
more than 100 up to 250	± 6 %
more than 250 up to 500	± 5 %
more than 500	± 25 g/kg or ± 25 g/l

(b) Physical properties:

The plant protection product must fulfil the physical criteria (including storage stability) specified for the relevant formulation type in the "Manual on the development and use of FAO specifications for plant protection products".

- 2.7.3. Where the proposed label claims include requirements or recommendations for use of the preparation with other plant protection products or adjuvants as a tank mix and/or where the proposed label includes indications on the compatibility of the preparation with other plant protection products as a tank mix, those products or adjuvants must be physically and chemically compatible in the tank mix.'
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