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I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 1766/95
of 21 July 1995
fixing the agricultural conversion rates

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 3813/92 of 28 December 1992 on the unit of account and the conversion rates to be applied for the purposes of the common agricultural policy ⁽¹⁾, as last amended by Regulation (EC) No 150/95 ⁽²⁾, and in particular Article 3 (1) thereof,

Whereas the agricultural conversion rates were fixed by Commission Regulation (EC) No 1726/95 ⁽³⁾;

Whereas Article 4 of Regulation (EEC) No 3813/92 provides that, subject to confirmation periods being triggered, the agricultural conversion rate for a currency is to be adjusted where the monetary gap between it and the representative market rate exceeds certain levels;

Whereas the representative market rates are determined on the basis of basic reference periods or, where applicable, confirmation periods, established in accordance with Article 2 of Commission Regulation (EEC) No 1068/93 of 30 April 1993 on detailed rules for determining and applying the agricultural conversion rates ⁽⁴⁾, as last amended by Regulation (EC) No 1053/95 ⁽⁵⁾; whereas paragraph 2 of that Article provides that, in cases where the absolute value of the difference between the monetary gaps in two Member States, calculated from the average of the ecu rates for three consecutive quotation days, exceeds six points, the representative market rates are to be adjusted on the basis of the three quotation days in question;

Whereas, as a consequence of the exchange rates recorded from 14 to 23 July 1995, it is necessary to fix a new agricultural conversion rate for the Danish krone and Spanish peseta;

Whereas Article 15 (2) of Regulation (EEC) No 1068/93 provides that an agricultural conversion rate fixed in advance is to be adjusted if the gap between that rate and the agricultural conversion rate in force at the time of the operative event applicable for the amount concerned exceeds four points; whereas, in that event, the agricultural conversion rate fixed in advance is brought more closely into line with the rate in force, up to the level of a gap of four points with that rate; whereas the rate which replaces the agricultural conversion rate fixed in advance should be specified,

HAS ADOPTED THIS REGULATION:

Article 1

The agricultural conversion rates are fixed in Annex I hereto.

Article 2

In the case referred to in Article 15 (3) of Regulation (EEC) No 1068/93, the agricultural conversion rate fixed in advance shall be replaced by the ecu rate for the currency concerned, shown in Annex II:

- Table A, where the latter rate is higher than the rate fixed in advance,
- Table B, where the latter rate is lower than the rate fixed in advance.

Article 3

Regulation (EC) No 1726/95 is hereby repealed.

Article 4

This Regulation shall enter into force on 24 July 1995.

⁽¹⁾ OJ No L 387, 31. 12. 1992, p. 1.

⁽²⁾ OJ No L 22, 31. 1. 1995, p. 1.

⁽³⁾ OJ No L 163, 14. 7. 1995, p. 27.

⁽⁴⁾ OJ No L 108, 1. 5. 1993, p. 106.

⁽⁵⁾ OJ No L 107, 12. 5. 1995, p. 4.

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

Done at Brussels, 21 July 1995.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX I

Agricultural conversion rates

ECU 1 =	39,5239	Belgian and Luxembourg francs
	7,49997	Danish kroner
	1,90616	German marks
	302,927	Greek drachmas
	198,202	Portuguese escudos
	6,61023	French francs
	5,88000	Finnish marks
	2,14021	Dutch guilders
	0,829498	Irish punt
	2 248,15	Italian lire
	13,4084	Austrian schillings
	165,198	Spanish pesetas
	9,91834	Swedish kroner
	0,843954	Pound sterling

ANNEX II

Agricultural conversion rates fixed in advance and adjusted

Table A			Table B		
ECU 1 =	38,0038	Belgian and Luxembourg francs	ECU 1 =	41,1707	Belgian and Luxembourg francs
	7,21151	Danish kroner		7,81247	Danish kroner
	1,83285	German marks		1,98558	German marks
	291,276	Greek drachmas		315,549	Greek drachmas
	190,579	Portuguese escudos		206,460	Portuguese escudos
	6,35599	French francs		6,88566	French francs
	5,65385	Finnish marks		6,12500	Finnish marks
	2,05789	Dutch guilders		2,22939	Dutch guilders
	0,797594	Irish punt		0,864060	Irish punt
	2 161,68	Italian lire		2 341,82	Italian lire
	12,8927	Austrian schillings		13,9671	Austrian schillings
	158,844	Spanish pesetas		172,081	Spanish pesetas
	9,53687	Swedish kroner		10,3316	Swedish kroner
	0,811494	Pound sterling		0,879119	Pound sterling

**AMENDMENTS TO THE RULES OF PROCEDURE OF THE COURT OF FIRST
INSTANCE OF THE EUROPEAN COMMUNITIES****of 6 July 1995**

THE COURT OF FIRST INSTANCE OF THE EUROPEAN COMMUNITIES,

Having regard Article 168a of the Treaty establishing the European Community,

Having regard to Article 32d of the Treaty establishing the European Coal and Steel Community,

Having regard to Article 140a of the Treaty establishing the European Atomic Energy Community,

Having regard to the Protocol on the Statute of the Court of Justice of the European Community, signed in Brussels on 17 April 1957, and in particular Article 46 thereof as amended by the Council Decision of 6 June 1995 (OJ No L 131, 15. 6. 1995, p. 33),

Having regard to Council Decision 88/591/ECSC, EEC, Euratom of 24 October 1988 establishing a Court of First Instance of the European Communities (OJ No L 319, 25. 11. 1988, p. 1), as amended by Council Decision 93/350/Euratom, ECSC, EEC of 8 June 1993 (OJ No L 144, 16. 6. 1993, p. 21), Council Decision 94/149/ECSC, EC of 7 March 1994 (OJ No L 66, 10. 3. 1994, p. 29) and the Act of Accession of Austria, Finland and Sweden,

Having regard to the agreement of the Court of Justice,

Having regard to the unanimous approval of the Council, given on 6 June 1995,

Whereas it is necessary to take account, by special rules of procedure, of the specific features of the proceedings relating to intellectual property rights which the Court of First Instance is called upon to hear and determine in particular by virtue of Article 63 of Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark (OJ No L 11, 14. 1. 1994, p. 1) and of Article 73 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ No L 227, 1. 9. 1994, p. 1);

Whereas it is a feature of the intellectual property field that it involves disputes between private parties; whereas it is therefore necessary in particular to adopt specific rules on the procedural rights of interveners and on the use of languages by private parties in the course of proceedings before the Court of First Instance in compliance with the Communities general rules governing the use of languages,

HEREBY ADOPTS THE FOLLOWING AMENDMENTS TO ITS RULES OF PROCEDURE:

Article 1

The Rules of Procedure of the Court of First Instance of the European Communities, adopted on 2 May 1991 (OJ No L 136, 30. 5. 1991, p. 1), amended on 15 September 1994 (OJ No L 249, 24. 9. 1994, p. 17) and on 17 February 1995 (OJ No L 44, 28. 2. 1995, p. 64), shall be amended as follows:

1. The following new Title 4 shall be inserted after Article 129:

TITLE 4

PROCEEDINGS RELATING TO INTELLECTUAL PROPERTY RIGHTS

Article 130

§ 1

Subject to the special provisions of this Title, the provisions of these Rules of Procedure shall apply to proceedings brought against the Office for Harmonization in the Internal Market (Trade Marks and Designs) and against the Community Plant Variety Office, (both hereinafter referred to as "the Office"), and concerning the application of the rules relating to an intellectual property regime.

§ 2

The provisions of this Title shall not apply to actions brought directly against the Office without prior proceedings before a Board of Appeal.

Article 131

§ 1

The application shall be drafted in one of the languages described in Article 35 (1), according to the applicant's choice.

§ 2

The language in which the application is drafted shall become the language of the case if the applicant was the only party to the proceedings before the Board of Appeal or if another party to those proceedings does not object to this within a period laid down for that purpose by the Registrar after the application has been lodged.

If, within that period, the parties to the proceedings before the Board of Appeal inform the Registrar of their agreement on the choice, as the language of the case, of one of the languages referred to in Article 35 (1), that language shall become the language of the case before the Court of First Instance.

In the event of an objection to the choice of the language of the case made by the applicant within the period referred to above and in the absence of an agreement on the matter between the parties to the proceedings before the Board of Appeal, the language in which the application for registration in question was filed at the Office shall become the language of the case. If, however, on a reasoned request by any party and after hearing the other parties, the President finds that the use of that language would not enable all parties to the proceedings before the Board of Appeal to follow the proceedings and defend their interests and that only the use of another language from among those mentioned in Article 35 (1) makes it possible to remedy that situation, he may designate that other language as the language of the case; the President may refer the matter to the Court of First Instance.

§ 3

In the pleadings and other documents addressed to the Court of First Instance and during the oral procedure, the

applicant may use the language chosen by him in accordance with paragraph 1 and each of the other parties may use a language chosen by that party from those mentioned in Article 35 (1).

§ 4

If, by virtue of paragraph 2, a language other than that in which the application is drafted becomes the language of the case, the Registrar shall cause the application to be translated into the language of the case.

Each party shall be required, within a reasonable period to be prescribed for that purpose by the Registrar, to produce a translation into the language of the case of the pleadings or documents other than the application that are lodged by that party in a language other than the language of the case pursuant to paragraph 3. The party producing the translation, which shall be authentic within the meaning of Article 37, shall certify its accuracy. If the translation is not produced within the period prescribed, the pleading or the procedural document in question shall be removed from the file.

The Registrar shall cause everything said during the oral procedure to be translated into the language of the case and, at the request of any party, into the language used by that party in accordance with paragraph 3.

Article 132

§ 1

Without prejudice to Article 44, the application shall contain the names of all the parties to the proceedings before the Board of Appeal and the addresses which they had given for the purposes of the notifications to be effected in the course of those proceedings.

The contested decision of the Board of Appeal shall be appended to the application. The date on which the applicant was notified of that decision must be indicated.

§ 2

If the application does not comply with paragraph 1, Article 44 (6) shall apply.

Article 133

§ 1

The Registrar shall inform the Office and all the parties to the proceedings before the Board of Appeal of the lodging of the application. He shall arrange for service of the application after determining the language of the case in accordance with Article 131 (2).

§ 2

The application shall be served on the Office, as defendant, and on the parties to the proceedings before the Board of Appeal other than the applicant. Service shall be effected in the language of the case.

Service of the application on a party to the proceedings before the Board of Appeal shall be effected by registered post with a form of acknowledgment of receipt at the address given by the party concerned for the purposes of the notifications to be effected in the course of the proceedings before the Board of Appeal.

§ 3

Once the application has been served, the Office shall forward to the Court of First Instance the file relating to the proceedings before the Board of Appeal.

Article 134

§ 1

The parties to the proceedings before the Board of Appeal other than the applicant may participate, as interveners, in the proceedings before the Court of First Instance.

§ 2

The interveners referred to in paragraph 1 shall have the same procedural rights as the main parties.

They may support the form of order sought by a main party and they may apply for a form of order and put forward pleas in law independently of those applied for and put forward by the main parties.

§ 3

An intervener, as referred to in paragraph 1, may, in his response lodged in accordance with Article 135 (1), seek an order annulling or altering the decision of the Board of Appeal on a point not raised in the application and put forward pleas in law not raised in the application.

Such submissions seeking orders or putting forward pleas in law in the intervener's response shall cease to have effect should the applicant discontinue the proceedings.

§ 4

In derogation from Article 122, the default procedure shall not apply where an intervener, as referred to in paragraph 1 of this Article, has responded to the application in the manner and within the period prescribed.

Article 135

§ 1

The Office and the interveners referred to in Article 134 (1) may submit responses to the application within a period of two months from the service of the application.

Article 46 shall apply to the responses.

§ 2

The application and the responses may be supplemented by replies and rejoinders by the parties, including the

interveners referred to in Article 134 (1), where the President, on a reasoned application made within two weeks of service of the responses or replies, considers such further pleading necessary and allows it in order to enable the party concerned to put forward its point of view.

The President shall prescribe the period within which such pleadings are to be submitted.

§ 3

Without prejudice to the foregoing, in the cases referred to in Article 134 (3), the other parties may, within a period of two months of service upon them of the response, submit a pleading confined to responding to the form of order sought and the pleas in law submitted for the first time in the response of an intervener. That period may be extended by the President on a reasoned application from the party concerned.

§ 4

The parties' pleadings may not change the subject-matter of the proceedings before the Board of Appeal.

Article 136

§ 1

Where an action against a decision of a Board of Appeal is successful, the Court of First Instance may order the Office to bear only its own costs.

§ 2

Costs necessarily incurred by the parties for the purposes of the proceedings before the Board of Appeal and costs incurred for the purposes of the production, prescribed by the second subparagraph of Article 131 (4), of translations of pleadings or other documents into the language of the case shall be regarded as recoverable costs.

In the event of inaccurate translations being produced, the second subparagraph of Article 87 (3) shall apply.'

2. Article 130 shall become Article 137.

Article 2

These amendments, which are authentic in the languages mentioned in Article 35 (1), shall be published in the *Official Journal of the European Communities*. They shall enter into force on the first day of the second month from the date of publication.

Done at Luxembourg, 6 July 1995.

The Registrar
JUNG

The President
J. L. DA CRUZ VILAÇA

COMMISSION DIRECTIVE 95/35/EC

of 14 July 1995

amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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⁾, as last amended by Commission Directive 94/79/EC⁽²⁾, and in particular Article 18 (2) thereof,

Whereas Annexes II and III to Directive 91/414/EEC set out the requirements for the dossier to be submitted by applicants respectively for the inclusion of an active substance in Annex I and for the authorization of a plant protection product;

Whereas it is necessary, in Annexes II and III to Directive 91/414/EEC, to indicate to the applicants as precisely as possible any details on the required information, such as the circumstances, conditions and technical protocols under which certain data has to be generated; whereas those details should be introduced as soon as available in order to permit applicants to use them in the preparation of their dossiers;

Whereas the introductions to Annexes II and III to Directive 91/414/EEC currently refer to the application of the principles of good laboratory practice (GLP) where testing is conducted to obtain data on the properties and safety of the substances and preparations; whereas therefore, without prejudice to the provisions of Article 9 (1), third subparagraph thereof, GLP should in principle be applied to residue studies, in particular when they are necessary for the dossiers to be submitted with a view to the inclusion of active substances in Annex I to the said Directive;

Whereas, however, it has become evident that in certain Member States the necessary infrastructure is not yet available for applying GLP requirements to residue studies from supervised trials on crops, food or feeding-stuffs; whereas on the other hand Member States already applying GLP requirements should be allowed to continue to do so in trials performed on their territory; whereas this principle should also be clarified for the purpose of the derogations from GLP already contained in the Directive;

Whereas it is necessary to provide for a temporary derogation for the application of GLP requirements for active

substances already on the market two years after notification of Directive 91/414/EEC whenever a number of precautionary conditions are satisfied; whereas, however, it is not necessary to provide for such a derogation service for active substances not brought onto the market two years after the notification of the said Directive;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II and III to Directive 91/414/EEC are amended 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 by 30 June 1996. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such a reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive shall enter into force on 1 July 1995.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 14 July 1995.

For the Commission

Ritt BJERREGAARD

Member of the Commission

⁽¹⁾ OJ No L 230, 19. 8. 1991, p. 1.

⁽²⁾ OJ No L 354, 31. 12. 1994, p. 16.

ANNEX

Annexes II and III to Directive 91/414/EEC are amended as follows :

1. Annex II is amended as follows :

(a) Point 2.2 of the introduction is replaced by the following :

'2.2 By way of derogation from point 2.1, Member States may provide that tests and analyses, performed on their territory in order to obtain data on the properties and/or safety of the substances with respect to honey-bees and beneficial arthropods other than bees shall be conducted by official or officially-recognized testing facilities or organizations which satisfy at least the requirements as set out under points 2.2 and 2.3 of the introduction to Annex III.

This derogation applies to trials actually started on or before 31 December 1999.'

(b) The following point 2.3 is added to the introduction :

'2.3 By way of derogation from point 2.1, Member States may provide that supervised residue trials performed on their territory in accordance with the provisions of Section 6 'Residues in or on treated products, food and feed' on plant protection products containing active substances already on the market two years after notification of the Directive shall be conducted by official or officially-recognized testing facilities or organizations which satisfy at least the requirements under points 2.2 and 2.3 of the introduction to Annex III.

This derogation applies for supervised residue trials actually started on or before 31 December 1997.'

2. Annex III is amended as follows :

(a) Point 2.4 of the introduction is replaced by the following :

'2.4 By way of derogation from point 2.1, Member States may apply the provisions of points 2.2 and 2.3, by extension, to tests and analyses performed on their territory in order to obtain data on the properties and/or safety of the preparations with respect to honey-bees and beneficial arthropods other than bees and actually started on or before 31 December 1999.'

(b) The following point 2.5 is inserted into the introduction :

'2.5 By way of derogation from point 2.1, Member States may apply the provisions of points 2.2 and 2.3, by extension, to supervised residue trials performed on their territory in accordance with the provisions of Section 8 'Residues in or on treated products, food and feed' with plant protection products containing active substances already on the market two years after notification of the Directive and actually started on or before 31 December 1997.'

COMMISSION DIRECTIVE 95/36/EC

of 14 July 1995

amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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⁾, as last amended by Commission Directive 95/35/EC⁽²⁾, and in particular Article 18 (2) thereof,

Whereas Annexes II and III to Directive 91/414/EEC provide the requirements for the dossier to be submitted by applicants respectively for the inclusion of an active substance in Annex I and for the authorization of a plant protection product;

Whereas it is necessary to indicate, in Annexes II and III to Directive 91/414/EEC, to the applicants as precisely as possible any details on the required information, such as the circumstances, conditions and technical protocols under which certain data have to be generated; whereas these provisions should be introduced as soon as available in order to permit applicants to use them in the preparation of their files;

Whereas it is possible to introduce now more precision with regard to the data requirements concerning fate and behaviour in the environment of the active substance provided for in Annex II, Part A, Section 7;

Whereas it is also possible to introduce now more precision with regard to the data requirements concerning fate and behaviour in the environment of the plant protection product provided for in Section 9 of Part A of Annex III, Part A, Section 9;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Plant Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 91/414/EEC is amended as follows:

1. in Part A of Annex II, the section headed '7. Fate and behaviour in the environment' is replaced by Annex I hereto;
2. in Part A of Annex III, the section headed '9. Fate and behaviour in the environment' is replaced by Annex II hereto.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply, not later than 30 April 1996, with the provisions of this Directive. They shall immediately inform the Commission thereof.

When Member States adopt these measures, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by the Member States.

Article 3

This Directive shall enter into force on 1 July 1995.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 14 July 1995.

For the Commission

Ritt BIERREGAARD

Member of the Commission

⁽¹⁾ OJ No L 230, 19. 8. 1991, p. 1.

⁽²⁾ See page 6 of this Official Journal.

ANNEX I

7. FATE AND BEHAVIOUR IN THE ENVIRONMENT

Introduction

- (i) The information provided, taken together with that for one or more preparations containing the active substance, must be sufficient to permit an assessment of the fate and behaviour of the active substance in the environment, and of the non-target species likely to be at risk from exposure to the active substance, its metabolites, degradation and reaction products, where they are of toxicological or environmental significance.
- (ii) In particular, the information provided for the active substance, together with other relevant information, and that provided for one or more preparations containing it, should be sufficient to :
 - decide whether, or not, the active substance can be included in Annex I,
 - specify appropriate conditions or restrictions to be associated with any inclusion in Annex I,
 - classify the active substance as to hazard ;
 - specify the hazard symbols, the indications of danger, and relevant risk and safety phrases for the protection of the environment, which are to be included on packaging (containers),
 - predict the distribution, fate, and behaviour in the environment of the active substance and relevant metabolites, degradation and reaction products as well as the times courses involved,
 - identify non-target species and populations for which hazards arise because of potential exposure, and
 - identify measures necessary to minimize contamination of the environment and impact on non-target species.

- (iii) A detailed description (specification) of the material used, as provided for under Section 1, point 11 must be provided. Where testing is done using active substance the material used should be of that specification that will be used in the manufacture of preparations to be authorized except where radio-labelled material is used.

Where studies are conducted using active substance produced in the laboratory or in a pilot plant production system, the studies must be repeated using active substance as manufactured, unless it can be justified that the test material used is essentially the same for the purposes of environmental testing and assessment.

- (iv) Where radio-labelled test material is used, radio-labels should be positioned at sites (one or more as necessary), to facilitate elucidation of metabolic and degradative pathways and to facilitate investigation of the distribution of the active substance and of its metabolite, reaction and degradation products in the environment.
- (v) It may be necessary to conduct separate studies for metabolites, degradation or reaction products, where these products can constitute a relevant risk to non-target organisms or to the quality of water, soil and air and where their effects cannot be evaluated by the available results relating to the active substance. Before such studies are performed the information from the Sections 5 and 6 has to be taken into account.
- (vi) Where relevant, tests should be designed and data analysed using appropriate statistical methods.

Full details of the statistical analysis should be reported (e.g. all point estimates should be given with confidence intervals, exact p-values should be given rather than stating significant/non significant).

7.1. Fate and behaviour in soil

All relevant information on the type and the properties of the soil used in the studies, including pH, organic carbon content, cation exchange capacity, particle size distribution and water holding capacity, particle size distribution and water holding capacity at $pF=0$ and $pF=2,5$ has to be reported in accordance with relevant ISO or other international standards.

The microbial biomass of soils used for laboratory degradation studies must be determined just prior to the commencement and at the end of the study.

It is recommended to use as much as possible the same soils throughout all laboratory soil studies.

The soils used for degradation or mobility studies must be selected such that they are representative of the range of soils typical of the various Community regions where use exists or is anticipated, and be such that :

- they cover a range of organic carbon content, particle size distribution and pH values ; and
- where on the basis of other information, degradation or mobility are expected to be pH dependent (e.g. solubility and hydrolysis rate — paragraphs 2.7 and 2.8), they cover the following pH ranges :
 - 4,5 to 5,5
 - 6 to 7, and
 - 8 (approximately).

Soils used must, wherever possible, be freshly sampled. If use of stored soils is unavoidable, storage should be properly carried out for a limited time under defined and reported conditions. Soils stored for longer periods of time can only be used for adsorption/desorption studies.

The soil chosen to begin studying should not have extreme characteristics with respect to parameters such as particle size distribution, organic carbon content and pH.

Soils should be collected and handled in accordance with ISO 10381-6 (*Soil quality — Sampling — Guidance on the collection, handling and storage of soil for the assessment of microbial processes in the laboratory*). Any deviations must be reported and justified.

Field studies should be carried out in conditions as close to normal agricultural practice as possible on a range of soil types and climatic conditions representative of the area(s) of use. Weather conditions shall be reported in cases where field studies are conducted.

7.1.1. *Route and rate of degradation*

7.1.1.1. Route of degradation

Aim of the tests

The data and information provided, together with other relevant data and information, should be sufficient to :

- identify, where feasible, the relative importance of the types of process involved (balance between chemical and biological degradation),
- identify the individual components present which at any time account for more than 10 % of the amount of active substance added, including, where feasible, non-extractable residues,
- identify where possible also individual components present which account for less than 10 % of the amount of active substance added,
- establish the relative proportions of the components present (mass balance), and
- permit the soil residue of concern and to which non-target species are or may be exposed, to be defined.

Where a reference is made to non-extractable residues these 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.

7.1.1.1.1. Aerobic degradation

Circumstances in which required

The degradation pathway or pathways must always be reported except where the nature and manner of use of preparations containing the active substance, preclude soil contamination such as uses on stored products or wound healing treatments for trees.

Test conditions

The degradation pathway or pathways must be reported for one soil.

Results obtained must be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label as a function of time, as between :

- active substance,
- CO₂,
- volatile compounds other than CO₂,
- individual identified transformation products,
- extractable substances not identified, and
- non-extractable residues in soil.

The investigation of degradation pathways must include all feasible steps to characterise and quantify non-extractable residues formed after 100 days when exceeding 70 % of the applied dose of the active substance. The techniques and methodologies applied are best selected on a case-by-case basis. A justification must be provided where the compounds involved are not characterized.

The duration of the study is normally 120 days, except where after a shorter period the levels of non-extractable residues and CO₂ are such that they can be extrapolated in a reliable way to 100 days.

Test guideline

Setac — Procedures for assessing the environmental fate and ecotoxicity of pesticides⁽¹⁾.

7.1.1.1.2. Supplementary studies

— Anaerobic degradation

Circumstances in which required

An anaerobic degradation study must be reported unless it can be justified that exposure of the plant protection products containing the active substance to anaerobic conditions is unlikely to occur.

Test conditions and test guideline

The same provisions as provided for under the corresponding paragraph of point 7.1.1.1.1 apply.

— Soil photolysis

Circumstances in which required

A soil photolysis study must be reported unless it can be justified that deposition of the active substance at the soil surface is unlikely to occur.

Test guideline

Setac — Procedures for assessing the Environmental fate and ecotoxicity of pesticides.

⁽¹⁾ Society of Environmental Toxicology and Chemistry (SETAC), 1995. Procedures for assessing the environmental fate and ecotoxicity of pesticides, ISBN 90-5607-002-9.

7.1.1.2. Rate of degradation

7.1.1.2.1. Laboratory studies

Aim of the tests

The soil degradation studies should provide best possible estimates of the time taken for degradation of 50 % and 90 % (DT_{50lab} and DT_{90lab}), of the active substance, and of relevant metabolites, degradation and reaction products under laboratory conditions.

— Aerobic degradation

Circumstances in which required

The rate of degradation in soil must always be reported, except where the nature and manner of use of plant protection products containing the active substance preclude soil contamination such as uses on stored products or wound healing treatments for trees.

Test conditions

The rate of aerobic degradation of the active substance in three soil types additional to that referred to in paragraph 7.1.1.1.1. must be reported.

In order to investigate the influence of temperature on degradation, one additional study at 10 °C has to be performed on one of the soils used for the investigation of degradation at 20 °C until a validated Community calculation model for the extrapolation of degradation rates at low temperatures is available.

The duration of the study is normally 120 days except if more than 90 % of the active substance is degraded before that period expires.

Similar studies for three soil types must be reported for all relevant metabolites, degradation and reaction products which occur in soil and which at any time during the studies account for more than 10 % of the amount of active substance added, except where their DT_{50} values were able to be determined from the results of the degradation studies with the active substance.

Test guideline

Setac — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

— Anaerobic degradation

Circumstances in which required

The rate of anaerobic degradation of the active substance must be reported where an anaerobic study has to be performed according to point 7.1.1.1.2.

Test conditions

The rate of anaerobic degradation of the active substance must be carried out in the soil used in the anaerobic study performed according to point 7.1.1.1.2.

The duration of the study is normally 120 days except if more than 90 % of the active substance is degraded before that period expires.

Similar studies for one soil must be reported for all relevant metabolites, degradation and reaction products which occur in soil and which at any time during the studies account for more than 10 % of the amount of active substance added, except where their DT_{50} values were able to be determined from the results of the degradation studies with the active substance.

Test guideline

Setac — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

7.1.1.2.2. Field studies

— Soil dissipation studies

Aim of the test

The soil dissipation studies should provide estimates of the time taken for dissipation of 50 % and 90 % (DT_{50f} and DT_{90f}), of the active substance under field conditions. Where relevant, information on relevant metabolites, degradation and reaction products must be reported.

Circumstances in which required

The tests have to be conducted in those conditions where DT_{50lab} determined at 20 °C and at a moisture content of the soil related to a pF value of 2 to 2,5 (suction pressure) is greater than 60 days.

Where plant protection products containing the active substance are intended to be used in cold climatic conditions, the tests have to be conducted where DT_{soil} , determined at 10 °C and at a moisture content of the soil related to a pF value of 2 to 2,5 (suction pressure) is greater than 90 days.

Test conditions

Individual studies on a range of representative soils (normally four different types) must be continued until > 90 % of the amount applied have dissipated. The maximum duration of the studies is 24 months.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

— Soil residue studies

Aim of the test

Soil residue studies should provide estimates of the soil residue levels at harvest or at time of cowing or planting succeeding crops.

Circumstances in which required

Soil residue studies must be reported where DT_{soil} is greater than one-third of the period between the application and harvest and where absorption by the succeeding crop is possible, except where soil residues at sowing or planting of a succeeding crop can be reliably estimated from the data of the soil dissipation studies or where it can be justified that these residues can not be phytotoxic to or leave unacceptable residues in rotational crops.

Test conditions

Individual studies must be continued until harvest or time of sowing or planting succeeding crops, unless > 90 % of the amount applied have dissipated.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

— Soil accumulation studies

Aim of the tests

The tests should provide sufficient data to evaluate the possibility of accumulation of residues of the active substance and of relevant metabolites, degradation and reaction products.

Circumstances in which required

Where on the basis of soil dissipation studies it is established that $DT_{90\%}$ > one year and where repeated application is envisaged, whether in the same growing season or in succeeding years, the possibility of accumulation of residues in soil and the level at which a plateau concentration is achieved must be investigated except where reliable information can be provided by a model calculation or another appropriate assessment.

Test conditions

Long term field studies must be done on two relevant soils and involve multiple applications.

Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.

7.1.2. *Adsorption and desorption*

Aim of the test

The data and information provided, together with other relevant data and information, should be sufficient to establish the absorption coefficient of the active substance and of relevant metabolites, degradation and reaction products.

Circumstances in which required

The studies must always be reported except where the nature and manner of use of preparations containing the active substance, preclude soil contamination such as uses on stored products or wound healing trees.

Testo conditions

Studies on the active substance must be reported for four soil types.

Similar studies, for at least three soil types, must be reported for all relevant metabolites, degradation and reaction products which in soil degradation studies account at any time for more than 10 % of the amount of active substance added.

Test guideline

OECD method 106

7.1.3. *Mobility in the soil*

7.1.3.1. Column leaching studies

Aim of the test

The test should provide sufficient data to evaluate the mobility and leaching potential of the active substance and if possible of relevant metabolites, degradation and reaction products.

Circumstances in which required

Studies in four soils must be carried out where in the absorption and desorption studies provided for under point 7.1.2 it is not possible to obtain reliable absorption coefficient values.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

7.1.3.2. Aged residue column leaching

Aim of the test

The test should provide sufficient data to estimate the mobility and leaching potential of relevant metabolites, degradation and reaction products.

Circumstances in which required

The studies must be performed except:

- where the nature and manner of use of preparations containing the active substance, preclude soil contamination such as uses on stored products or wound healing treatments for trees, or
- where a separate study for the metabolite, degradation or reaction product in accordance to point 7.1.2 or 7.1.3.1 was performed.

Test conditions

The period(s) of ageing should be determined from inspection of the degradation patterns of active substance and metabolites to ensure that a relevant spectrum of metabolites is present at the time of leaching.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

7.1.3.3. Lysimeter studies or field leaching studies

Aim of the tests

The test should provide data on:

- the mobility in soil,
- the potential for leaching to ground water,
- The potential distribution in soil.

Circumstances in which required

Expert judgement will be necessary to decide whether lysimeter studies or field leaching studies should be carried out, taking into account the results of degradation and other mobility studies and the predicted environmental concentrations in groundwater (PEC_{GW}), calculated in accordance with the provisions of Annex III, Section 9. The type and conditions of the study to be conducted should be discussed with the competent authorities.

Test conditions

Great care is necessary in design of both experimental installations and individual studies, to ensure that results obtained can be used for assessment purposes. Studies should cover the realistic worst case situation, taking into account the soil type, climatic conditions, the application rate and the frequency and period of application.

Water percolating from soil columns must be analyzed at suitable intervals, while residues in plant material must be determined at harvest. Residues in the soil profile in at least five layers must be determined on termination of experimental work. Intermediate sampling must be avoided, since removal of plants (except for harvesting according to normal agricultural practice) and soil cross influences the leaching process.

Precipitation, soil and air temperatures have to be recorded at regular intervals (at least on a weekly base).

— Lysimeter studies

Test conditions

The minimal depth of the lysimeters should be 100 cm ; their maximal depth should be 130 cm. The soil cross must be undisturbed. Soil temperatures must be similar to those pertaining in the field. Where necessary, supplementary irrigation must be provided to ensure optimal plant growth and to ensure that the quantity of infiltration water is similar to that in the regions for which authorization is sought. When during the study the soil has to be disturbed for agricultural reasons it must not be disturbed deeper than 25 cm.

— Field leaching studies

Test conditions

Information on the groundwater table in the experimental fields must be submitted. If soil cracking is observed during the study this must be fully described.

Great attention should be given to the number and the location of water collection devices. The placement of these devices in the soil should not result in preferential flow paths.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

7.2. Fate and behaviour in water and air

Aim of the tests

The information and data provided , taken together with that provided for one or more preparations containing the active substance, and other relevant information, should be sufficient to establish, or permit estimation of :

- persistence in water systems (bottom sediment and water, including suspended particles),
- the extent to which water, sediment organisms and air are at risk,
- potential for contamination of surface water and groundwater.

7.2.1. *Route and rate of degradation in aquatic systems (as far as not covered by point 2.9)*

Aim of the tests

The data and information provided, together with other relevant data and information, should be sufficient to :

- identify the relative importance of the types of processes involved (balance between chemical and biological degradation),
- where possible, identify the individual components present,
- establish the relative proportions of the components present and their distribution as between water, including suspended particles, and sediment, and
- permit the residue of concern and to which non-target species are or may be exposed, to be defined.

7.2.1.1. Hydrolytic degradation

Circumstances in which required

The test must always be performed for relevant metabolites, degradation and reaction products which account at any time for more than 10 % of the amount of active substance added unless sufficient information on their degradation is available from the test performed in accordance with point 2.9.1.

Test conditions and test guideline

The same provisions as provided under the corresponding paragraphs of point 2.9.1 apply.

7.2.1.2. Photochemical degradation**Circumstances in which required**

The test must always be performed for relevant metabolites, degradation and reaction products which account at any time for more than 10 % of the amount of active substance added unless sufficient information on their degradation is available from the test performed in accordance with points 2.9.2 and 2.9.3.

Test conditions and test guideline

The same provisions as provided under the corresponding paragraphs of points 2.9.2 and 2.9.3 apply.

7.2.1.3. Biological degradation**7.2.1.3.1. "Ready biodegradability"****Circumstances in which required**

The test must always be performed unless it is not required under the provisions of Annex VI to Directive 67/548/EEC for the classification of the active substance.

Test guideline

EEC method C4.

7.2.1.3.2. Water/sediment study**Circumstances in which required**

The test must be reported unless it can be justified that contamination of surface water will not occur.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

7.2.1.4. Degradation in the saturated zone**Circumstances in which required**

Transformation rates in the saturated zone of active substances and of relevant metabolites, degradation and reaction products can provide useful information on the fate of these substances in the groundwater.

Test conditions

Expert judgement is required to decide whether this information is necessary. Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.

7.2.2. *Route and rate of degradation in air (as far as not covered by point 2.10)*

Guidance under development.

7.3. Definition of the residue

In the light of the chemical composition of residues occurring in soil, water or air, resulting from use, or proposed use, of a plant protection product containing the active substance a proposal for the definition of the residue must be submitted, taking account of both the levels found and their toxicological and environmental significance.

7.4. Monitoring data

Available monitoring data concerning fate and behaviour of the active substance and relevant metabolites, degradation and reaction products must be reported.

ANNEX II

9. FATE AND BEHAVIOUR IN THE ENVIRONMENT

Introduction

- (i) The information provided, taken together with that for the active substance as provided for in Annex II, must be sufficient to permit an assessment of the fate and behaviour of the plant protection product in the environment, and of the non-target species likely to be at risk from exposure to it.
- (ii) In particular, the information provided for the plant protection product, together with other relevant information, and that provided for the active substance, should be sufficient to :
 - specify the hazard symbols, the indications of danger, and relevant risk and safety phrases for the protection of the environment, which are to be included on packaging (containers),
 - predict the distribution, fate, and behaviour in the environment as well as the time courses involved,
 - identify non-target species and populations for which hazards arise because of potential exposure, and
 - identify measures necessary to minimize contamination of the environment and impact on non-target species.
- (iii) Where radio-labelled test material is used, the provisions of Annex II, Chapter 7, introduction, point (iv) apply.
- (iv) Where relevant tests should be designed and data analysed using appropriate statistical methods.

Full details of the statistical analysis should be reported (e.g. all point estimates should be given with confidence intervals, exact p-values should be given rather than stating significant/non significant).
- (v) Predicted environmental concentrations in soil (PEC_s), water (PEC_{sw} and PEC_{gw}) and air (PEC_A).

Justified estimates must be made of the expected concentrations of the active substance and relevant metabolites, degradation and reaction products, in soil, groundwater, surface water and air, following use as proposed or already occurring. In addition a realistic worst-case estimation must be made.

For the purposes of the estimation of such concentrations the following definitions apply :

- *Predicted environmental concentration in soil (PEC_s)*

The level of residues in the top layer of the soil and to which non-target soil organisms may be exposed (acute and chronic exposure).
- *Predicted environmental concentration in surface water (PEC_{sw})*

The level of residues, in surface water to which non-target aquatic organisms may be exposed (acute and chronic exposure).
- *Predicted environmental concentration in groundwater (PEC_{gw})*

The level of residues in groundwater.
- *Predicted environmental concentration in air (PEC_A)*

The level of residues in air, to which man, animals and other non-target organisms may be exposed (acute and chronic exposure).

For the estimation of these concentrations all relevant information on the plant protection product and on the active substance must be taken into account. A useful approach for these estimations is provided in the EPPO schemes for environmental risk assessment⁽¹⁾. Where relevant the parameters provided for in this section should be used.

When models are used for estimation of predicted environmental concentrations they must :

- make a best-possible estimation of all relevant processes involved taking into account realistic parameters and assumptions,

⁽¹⁾ OEPP/EPPO (1993). Decision-making schemes for the environmental risk assessment of plant protection products. Bulletin OEPP/EPPO Bulletin 23, 1-154 and Bulletin 24, 1-87.

- where possible 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.

The information provided must, where relevant, include that referred to in Annex II, Part A, point 7: and

9.1 Fate and behaviour in soil

Where appropriate, the same provisions relating to the information to be provided on the soil used and on its selection apply as provided for under Annex II, point 7.1.

9.1.1. *Rate of degradation in soil*

9.1.1.1. Laboratory studies

Aim of the test

The soil degradation studies should provide best possible estimates of the time taken for degradation of 50 and 90 % (DT_{50lab} and DT_{90lab}) of the active substance under laboratory conditions.

Circumstances in which required

The persistence and behaviour of plant protection products in soil must be investigated unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance to the requirements of Annex II, point 7.1.1.2. This extrapolation is, for example, not possible for slow release formulations.

Test conditions

The rate of aerobic and/or anaerobic degradation in soil must be reported.

The duration of the study is normally 120 days except if more than 90 % of the active substance is degraded before that period expires.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

9.1.1.2. Field studies

— Soil dissipation studies

Aim of the test

The soil dissipation studies should provide best-possible estimates of the time taken for dissipation of 50 and 90 % (DT_{50f} and DT_{90f}), of the active substance under field conditions. Where relevant, information on relevant metabolites, degradation and reaction products must be collected.

Circumstances in which required

The dissipation and behaviour of plant protection products in soil must be investigated unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance to the requirements of Annex II, point 7.1.1.2. This extrapolation is, for example, not possible for slow-release formulations.

Test conditions and test guideline

The same provisions as provided under the corresponding paragraph of Annex II, point 7.1.1.2.2. apply.

— Soil residue studies

Aim of the test

Soil residue studies should provide estimates of the soil residue levels at harvest or at time of sowing or planting succeeding crops.

Circumstances in which required

Soil residue studies must be reported unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance with the requirements of Annex II, point 7.1.1.2.2. This extrapolation is, for example, not possible for slow-release formulations.

Test conditions

The same provisions as provided under the corresponding paragraph of Annex II, point 7.1.1.2.2. apply.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

— Soil accumulation studies

Aim of the tests

The tests should provide sufficient data to evaluate the possibility of accumulation of residues of the active substance and of relevant metabolites, degradation and reaction products.

Circumstances in which required

Soil accumulation studies must be reported unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance with the requirements of Annex II, point 7.1.1.2.2. This extrapolation is, for example, not possible for slow-release formulations.

Test conditions

The same provisions as provided under the corresponding paragraph of Annex II, point 7.1.1.2.2. apply.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

9.1.2. *Mobility in the soil*

Aim of the test

The test should provide sufficient data to evaluate the mobility and leaching potential of the active substance and relevant metabolites, degradation and reaction products.

9.1.2.1. Laboratory studies

Circumstances in which required

The mobility of plant protection products in soil must be investigated unless it is possible to extrapolate from data obtained in accordance with the requirements of Annex II, points 7.1.2 and 7.1.3.1. This extrapolation is, for example, not possible for slow-release formulations.

Test guideline

SETAC — Procedures for assessing the environmental fate and ecotoxicity of pesticides.

9.1.2.2. Lysimeter studies or field leaching studies

Aim of the tests

The test should provide data on :

- the mobility of the plant protection product in soil,
- the potential for leaching to ground water,
- the potential distribution in soils.

Circumstances in which required

Expert judgement will be necessary to decide whether field leaching studies or lysimeter studies should be carried out, taking into account the results of degradation and mobility studies and the calculated PEC_s. The type of study to be conducted should be discussed with the competent authorities.

These studies must be performed unless it is possible to extrapolate from data obtained on the active substance and relevant metabolites, degradation and reaction products in accordance with the requirements of Annex II, point 7.1.3. This extrapolation is, for example, not possible for slow release formulations.

Test conditions

The same provisions as provided for under the corresponding paragraph of Annex II, point 7.1.3.3 apply.

9.1.3. *Estimation of expected concentrations in soil*

PEC_s estimations must relate both to a single application at the highest rate of application for which authorization is sought, and to the maximum number and highest rates of application for which authorization is sought, for each relevant soil tested, and are expressed in terms of mg of active substance and of relevant metabolites, degradation and reaction products per kg of soil.

The factors to be considered in making PEC_s estimations relate to direct and indirect application to soil, drift, run off, and leaching and include processes such as volatilization, adsorption, hydrolysis, photolysis, aerobic and anaerobic degradation. For the purposes of PEC_s calculations, the bulk density of soils can be assumed to be 1,5 g/cm³ dry weight, while the depth of the soil layer is assumed to be 5 cm for applications at the soil surface and 20 cm when incorporation in the soil is involved. Where ground cover is present at time of application, it is to be assumed that 50 % (minimum) of the applied dose reaches the soil surface unless actual experimental data give more specific information.

Initial, short-term and long-term PEC, calculations (time weighted averages) must be provided :

- initial : immediately after application,
- short-term : 24 hours, 2 days and 4 days after last application,
- long-term : 7, 28, 50 and 100 days after last application, where relevant.

9.2. Fate and behaviour in water

9.2.1. Estimation of concentrations in groundwater

The groundwater contamination routes have to be defined taking into account relevant agricultural, plant health, and environmental (including climatic) conditions.

Suitable estimations (calculations) of predicted environmental concentration in groundwater PEC_{GW} , of active substance and relevant metabolites, degradation and reaction products, must be submitted.

PEC estimations must relate to the maximum number and highest rates of application, for which authorization is sought.

Expert judgment is required to decide if additional field tests could provide useful information. Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.

9.2.2. Impact on water treatment procedures

In cases where this information is necessary in the framework of a conditional authorization as meant in Annex VI, Part C, point 2.5.1.2 (b), the information provided should permit to establish or to estimate effectiveness of water treatment procedures (drinking water and sewage treatment), and impact on such procedures. Before performing any studies the applicant shall seek the agreement of the competent authorities on the type of information to be provided.

9.2.3. Estimation of concentrations in surface water

The surface water contamination routes have to be defined taking into account relevant agricultural, plant health, and environmental (including climatic) conditions.

Suitable estimations (calculations) of predicted environmental concentration in surface water PEC_{sw} , of active substance and relevant metabolites, degradation and reaction products, must be submitted.

PEC estimations must relate to the maximum number and highest rates of application, for which authorization is sought, and be relevant to lakes, ponds, rivers, canals, streams, irrigation/drainage canals and drains.

The factors to be considered in making PEC_{sw} estimations relate to direct application to water, drift, run-off, discharge via drains and atmospheric deposition, and include processes such as volatilization, adsorption, advection, hydrolysis, photolysis, biodegradation, sedimentation and re-suspension.

Initial, short-term and long-term PEC_{sw} calculations relevant to static and slow moving water bodies (time weighted averages) must be provided :

- initial : immediately after application,
- short-term : 24 hours, 2 days and 4 days after last application,
- long-term : 7, 14, 21, 28, and 42 days after last application, where relevant.

Expert judgment is required to decide if additional field tests could provide useful information. Before performing these studies the applicant shall seek the agreement of the competent authorities on the type of study to be performed.

9.3. Fate and behaviour in air

Guidance under development.'

COMMISSION DIRECTIVE 95/37/EC
of 18 July 1995
amending Council Directive 70/524/EEC concerning additives in feedingstuffs
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs⁽¹⁾, as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Article 7 thereof,

Whereas Directive 70/524/EEC provides for regular amendment of the content of its Annexes to take account of advances in scientific and technical knowledge; whereas the Annexes were consolidated by Commission Directive 91/248/EEC⁽²⁾;

Whereas a new use of an additive belonging to the group of 'Antibiotics' and a new additive belonging to the group of 'Coccidiostats and other medicinal substances' have been widely tested in several Member States; whereas, on the basis of experience gained and studies undertaken, it appears that this new use and this new additive can be authorized throughout the Community;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Feedingstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 70/524/EEC is hereby amended as set out in the Annex of this Directive.

Article 2

1. Member States shall bring into force the laws, regulations or administrative provisions necessary to comply with this Directive by 30 June 1996 at the latest. They shall immediately inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 18 July 1995.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ No L 270, 14. 12. 1970, p. 1.

⁽²⁾ OJ No L 124, 18. 5. 1991, p. 1.

ANNEX

Annex I to Directive 70/524/EEC, is amended as follows:

1. In part A 'Antibiotics', the following is added to entry No E 717, 'Avilamycin':

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions
					mg/kg of complete feedingstuff	mg/kg of complete feedingstuff		
			'Chickens for fattening	—	2,5	10	—	

2. In part D 'Coccidiostats and other medicinal substances', the following item is added:

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions
					mg/kg of complete feedingstuff			
'E 772	Narasin/Nicarbazin (mixture of (a) narasin and (b) nicarbazin in a 1/1 ratio	(a) $C_{14}H_{22}O_{11}$ (polyether monocarboxylic acid produced by Streptomyces aureofaciens), in granular form (b) Equimolecular complex of 1,3 bis (4-nitrophenyl) urea and 4,6-dimethyl pyrimidin-2-ol, in granular form	Chickens for fattening	—	80	100	Use prohibited at least five days before slaughter. Indicate in the instructions for use : — "Dangerous for equines" — "This feedingstuff contains an ionophore ; simultaneous use with certain medicinal substances (e.g. tiamulin) can be contra-indicated"	

II

(Acts whose publication is not obligatory)

COUNCIL

DECISION OF THE REPRESENTATIVES OF THE GOVERNMENTS OF THE
MEMBER STATES OF THE EUROPEAN COMMUNITIES

of 17 July 1995

appointing members of the Court of First Instance

(95/278/EC, Euratom, ECSC)

THE REPRESENTATIVES OF THE GOVERNMENTS OF
THE MEMBER STATES OF THE EUROPEAN COMMUNI-
TIES,

Having regard to the Treaty establishing the European
Community, and in particular Article 168a thereof,

Having regard to the Treaty establishing the European
Coal and Steel Community, and in particular Article 32d
thereof,

Having regard to the Treaty establishing the European
Atomic Energy Community, and in particular Article
140a thereof,

Having regard to Council Decision 88/591/ECSC, EEC,
Euratom of 24 October 1988 establishing a Court of First
Instance of the European Communities ⁽¹⁾,

Having regard to Decision 95/1/EC, Euratom, ECSC of
the Council of the European Union of 1 January 1995
adjusting the instruments concerning the accession of
new Member States to the European Union ⁽²⁾, and in
particular Article 10 amending Article 2 (1) of Decision

88/591/ECSC, EEC, Euratom and Article 31 (2) amending
Article 157 (2) of the Act of Accession thereof,

HAVE DECIDED AS FOLLOWS:

Sole Article

The following are hereby appointed judges to the Court
of First Instance for the period 1 September 1995 to 30
August 2001:

Mr Donal Barrington,
Mr Christopher Bellamy,
Mr Rafael García-Valdecasas y Fernández,
Dr Heinrich Kirschner,
Ms Pernilla Lindh,
Mr André Potocki,
Dr Antonio Saggio.

Done at Brussels, 17 July 1995.

The President
J. SOLANA

⁽¹⁾ OJ No L 319, 25. 11. 1988, p. 1 by OJ No C 215, 21. 8. 1989,
p. 1. Decision amended by Decision 93/350/Euratom, ECSC,
EEC (OJ No L 144, 16. 6. 1993, p. 21).

⁽²⁾ OJ No L 1, 1. 1. 1995, p. 1.

COMMISSION

COMMISSION DECISION

of 12 July 1995

laying down certain provisions for implementing Council Decision 93/588/EEC on the adoption of a programme of Community action on the subject of the vocational training of indirect taxation officials

(95/279/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 93/588/EEC of 29 October 1993 on the adoption of a programme of Community action on the subject of the vocational training of indirect taxation officials (Matthaeus-Tax)⁽¹⁾,

Whereas, pursuant to Article 4 (c) of that Decision, the Commission is required to establish common training programmes for indirect taxation officials;

Whereas such programmes are vital to achieving the objectives of the Matthaeus-Tax programme, and especially that of ensuring improved application of Community law;

Whereas they are made necessary by differences in teaching given to indirect tax officials at colleges in the Member States;

Whereas they are an appropriate means of providing officials with comparable training across the Community;

Whereas it is vital to draw up, as a priority, a common programme for officials receiving initial training; whereas this programme must cover the whole range of tax matters;

Whereas a substantial part of the programme must be devoted to studying the Community institutions and their origins because indirect taxation officials are increasingly required to take these aspects into account;

Whereas certain international conventions are an important source of Community law; whereas it is important, therefore, for indirect taxation officials to be aware of the provisions of these conventions and of their impact on Community law;

Whereas this common programme will constitute a unified approach on indirect taxation in the Community and help indirect taxation officials more rapidly to appreciate the growing Community dimension of their work;

Whereas the action provided for in this Decision is consistent with the opinion of the Matthaeus-Tax Committee,

HAS ADOPTED THIS DECISION:

Article 1

A common programme of vocational training for indirect tax officials, hereinafter referred to as the 'common programme', the content of which is set out in the Annex, is hereby instituted at training colleges in the Member States.

Article 2

For the purposes of this Decision:

1. *college* means any establishment in which indirect taxation officials receive instruction in the form of vocational training;
2. *officials receiving initial training* means officials who have just entered the profession or been assigned to a new grade, as well as officials who have been working for a tax administration for not more than five years.

⁽¹⁾ OJ No L 280, 13. 11. 1993, p. 27.

Article 3

The common programme shall be intended for indirect taxation officials required to apply Community law, irrespective of their place of work.

Article 4

1. The common programme shall concern all officials receiving initial training.
2. In the case of officials who have completed their initial training, the national administrations shall, where appropriate, disseminate the content of the common programme at seminars providing continuing training.

Article 5

The implementation of the common programme shall be spread over a period corresponding to the length of initial training in each of the national indirect tax administrations. In the case of indirect tax administrations which currently do not provide initial training, this period shall not exceed three years.

Article 6

Each Member State shall communicate to the Commission its provisions and procedures for implementing the common programme.

Article 7

Implementation of the common programme shall not preclude implementation of supplementary national programmes in colleges.

Article 8

The Member States shall apply the common programme with effect from 1 June 1995.

Article 9

This Decision is addressed to the Member States.

Done at Brussels, 12 July 1995.

For the Commission

Mario MONTI

Member of the Commission

ANNEX

COMMON PROGRAMME OF VOCATIONAL TRAINING FOR MEMBER STATES' INDIRECT TAXATION OFFICIALS RECEIVING INITIAL TRAINING*Introductory note*

Teaching under the common training programme, described below, is not intended to be exhaustive.

The aim is to give Member States' indirect taxation officials a basic level of uniform training vital to a sound understanding of their duties and to the performance of their work.

I. The European Communities

- Legal bases : the Treaty of Paris (ECSC) and the Treaty of Rome (Euratom, EC), as amended by the Single European Act and the Treaty on European Union
- Community institutions and their functioning :
 - the European Parliament
 - the Council
 - the Commission
 - the Court of Justice and Court of First Instance
 - the Court of Auditors
- The European Council (Article D of the Treaty on European Union)
- Supervisory and advisory bodies :
 - the Committee of the Regions
 - the Economic and Social Committee
- Community own resources :
 - customs duties
 - agricultural levies
 - VAT own resources
 - additional resource based on the sum of the gross national product of the Member States

II. The pillars of the Community

- The customs union
- The Single Market :
 - free movement of goods
 - free movement of persons
 - free movement of capital
 - free movement of services.
- Common policies, in particular :
 - the common commercial policy
 - the common agricultural policy
 - the common fisheries policy
 - the common transport policy

III. Sources of Community law

- Sources within the Community :
 - the Treaties
 - secondary legislation
 - the case-law of the Court of Justice
- International law :
 - international conventions to which the European Community is a contracting party and agreements concluded by the Community
 - agreements concluded by the Member States

IV. Community law in matters of indirect taxation

1. The legal context : the Treaty, Directives and Regulations, national transposition
2. Excise duties ⁽¹⁾
 - (a) Definition and the history of harmonization of excise duties
 - (b) General arrangements :
 - scope
 - chargeable event
 - chargeability of tax
 - duty suspension and products concerned : tax warehouse, authorized warehouse keeper, registered trader, non-registered trader, tax representative
 - (c) Movement of goods under suspension arrangements :
 - guarantee obligations
 - accompanying document and discharge
 - products acquired by private individuals
 - distance sales
 - movements through EFTA countries
 - irregularities and offences
 - reimbursements and exemptions
 - (d) Structures and rates on products subject to excise duties :
 - manufactured tobacco
 - mineral oils
 - alcohol and alcoholic beverages
3. Value added tax ⁽²⁾
 - (a) History and characteristics of VAT
 - (b) General principles of VAT
 - scope
 - territoriality
 - taxable persons
 - taxable operations
 - chargeable event and chargeability of tax
 - taxable amount
 - rates
 - exemptions
 - deductions
 - persons liable to pay the tax
 - obligations of persons liable to pay the tax
 - special regimes
 - (c) Application of the principles of :
 - internal operations
 - operations between Member States
 - operations with third countries
4. Administrative cooperation and mutual assistance between tax administrations of Member States
 - (a) The mutual assistance Directive 77/799/EEC
 - (b) The administrative cooperation Regulation (EEC) No 218/92
 - (c) The mutual assistance Directive on recovery 76/308/EEC

⁽¹⁾ For Member States in which separate administrative structures apply to VAT and excise areas, training on this subject shall be optional for the VAT administration.

⁽²⁾ For Member States in which separate administrative structures apply to VAT and excise areas, training on this subject shall be optional for the excise administration.

COMMISSION DECISION

of 14 July 1995

amending the information contained in the list in the Annex to Commission Regulation (EC) No 3206/94 establishing, for 1995, the list of vessels exceeding eight metres length overall and permitted to fish for sole within certain areas of the Community using beam trawls whose aggregate length exceeds nine metres

(95/280/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 3094/86 of 7 October 1986 laying down certain technical measures for the conservation of fishery resources⁽¹⁾, as last amended by Regulation (EC) No 1173/95⁽²⁾,

Having regard to Commission Regulation (EEC) No 3554/90 of 10 December 1990 adopting provisions for the establishment of the list of vessels exceeding eight metres overall which are permitted to fish for sole within certain areas of the Community using beam trawls of an aggregate length exceeding nine metres⁽³⁾, as amended by Regulation (EC) No 3407/93⁽⁴⁾, and in particular Article 2 thereof,

Whereas Commission Regulation (EC) No 3206/94⁽⁵⁾ establishes, for 1995, the list of vessels exceeding eight metres overall which are permitted to fish for sole within certain areas of the Community using beam trawls of an aggregate length exceeding nine metres as provided in Article 9 (3) (c) of Regulation (EEC) No 3094/86;

Whereas the authorities of the Member States concerned have applied for the information in the list provided for in Article 9 (3) (c) of Regulation (EEC) No 3094/86 to be

amended; whereas the said authorities have provided all the information supporting their applications pursuant to Article 2 of Regulation (EEC) No 3554/90; whereas it has been found that the information complies with the requirements and whereas, therefore, the information in the list annexed to the Regulation should be amended,

HAS ADOPTED THIS DECISION:

Article 1

The information in the list annexed to Regulation (EC) No 3206/94 is amended as shown in the Annex hereto.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 14 July 1995.

For the Commission

Emma BONINO

Member of the Commission

⁽¹⁾ OJ No L 288, 11. 10. 1986, p. 1.

⁽²⁾ OJ No L 118, 25. 5. 1995, p. 15.

⁽³⁾ OJ No L 346, 11. 12. 1990, p. 11.

⁽⁴⁾ OJ No L 310, 14. 12. 1993, p. 19.

⁽⁵⁾ OJ No L 337, 24. 12. 1994, p. 37.

ANEXO — BILAG — ANHANG — ΠΑΡΑΡΤΗΜΑ — ANNEX — ANNEXE — ALLEGATO — BIJLAGE — ANEXO —
LIITE — BILAGA

A. Datos que se retiran de la lista — Oplysninger, der skal slettes i listen — Aus der Liste herauszunehmende Angaben — Στοιχεία που διαγράφονται από τον κατάλογο — Information to be deleted from the list — Renseignements à retirer de la liste — Dati da togliere dall'elenco — Inlichtingen te schrappen uit de lijst — Informações a retirar da lista — Luettelosta poistettavat tiedot — Uppgifter som skall tas bort från förteckningen

1	2	3	4	5
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ALEMANIA / TYSKLAND / DEUTSCHLAND / ΓΕΡΜΑΝΙΑ / GERMANY / ALLEMAGNE / GERMANIA /
DUITSLAND / ALEMANHA / SAKSA / TYSKLAND

FRI	7	Polarstern	DIRH	Friedrichshoog	151
NOR	210	Hannes Kröger	DCVQ	Norddeich	180
SD	4	Kerstin	DFCQ	Friedrichskoog	147
SD	25	Nordfriesland	DJHW	Friedrichskoog	153
VAR	7	Falke I	DJDW	Varel	130

B. Datos que se añaden a la lista — Oplysninger, der skal anføres i listen — In die Liste hinzuzufügende Angaben — Στοιχεία που προστίθενται στον κατάλογο — Information to be added to the list — Renseignements à ajouter à la liste — Dati da aggiungere all'elenco — Inlichtingen toe te voegen aan de lijst — Informações a aditar à lista — Luetteloon lisättävät tiedot — Uppgifter som skall läggas till i förteckningen

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ALEMANIA / TYSKLAND / DEUTSCHLAND / ΓΕΡΜΑΝΙΑ / GERMANY / ALLEMAGNE / GERMANIA /
DUITSLAND / ALEMANHA / SAKSA / TYSKLAND

NEU	234	Beluga	DFCQ	Neuharlingersiel	164
SPI	4	Polarstern	DIRH	Spieka	151
ST	9	Nordfriesland	DJHW	Tönning	153
VAR	7	Falke I	DJDW	Varel	151

COMMISSION DECISION

of 14 July 1995

amending the information contained in the list in the Annex to Commission Regulation (EEC) No 55/87 establishing the list of vessels exceeding eight metres length overall permitted to use beam trawls within certain coastal areas of the Community

(95/281/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 3094/86 of 7 October 1986 laying down certain technical measures for the conservation of fishery resources⁽¹⁾, as last amended by Regulation (EC) No 1173/95⁽²⁾,

Having regard to Commission Regulation (EEC) No 55/87 of 30 December 1986 establishing the list of vessels exceeding eight metres length overall permitted to use beam trawls within certain coastal areas of the Community⁽³⁾, as last amended by Regulation (EC) No 3410/93⁽⁴⁾, and in particular Article 3 thereof,

Whereas authorities of the Member States concerned have applied for the information in the list provided for in Article 9 (3) (b) of Regulation (EEC) No 3094/86 to be amended; whereas the said authorities have provided all the information supporting their applications pursuant to Article 3 of Regulation (EEC) No 55/87; whereas it has been found that the information complies with the re-

quirements and whereas, therefore, the information in the list annexed to the Regulation should be amended,

HAS ADOPTED THIS DECISION:

Article 1

The information in the list annexed to Regulation (EEC) No 55/87 is amended as shown in the Annex hereto.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 14 July 1995.

For the Commission

Emma BONINO

Member of the Commission

⁽¹⁾ OJ No L 288, 11. 10. 1986, p. 1.

⁽²⁾ OJ No L 118, 25. 5. 1995, p. 15.

⁽³⁾ OJ No L 8, 10. 1. 1987, p. 1.

⁽⁴⁾ OJ No L 310, 14. 12. 1993, p. 27.

ANEXO — BILAG — ANHANG — ΠΑΡΑΡΤΗΜΑ — ANNEX — ANNEXE — ALLEGATO — BIJLAGE — ANEXO —
LIITE — BILAGA

A. Datos que se retiran de la lista — Oplysninger, der skal slettes i listen — Aus der Liste herauszunehmende Angaben — Στοιχεία που διαγράφονται από τον κατάλογο — Information to be deleted from the list — Renseignements à retirer de la liste — Dati da togliere dall'elenco — Inlichtingen te schrappen uit de lijst — Informações a retirar da lista — Luettelosta poistettavat tiedot — Uppgifter som skall tas bort från förteckningen

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ALEMANIA / TYSKLAND / DEUTSCHLAND / ΓΕΡΜΑΝΙΑ / GERMANY / ALLEMAGNE / GERMANIA /
DUITSLAND / ALEMANHA / SAKSA / TYSKLAND

NEU	234	Beluga	DFCQ	Neuharlingersiel	164
SPI	4	Polarstern	DIRH	Spieka	151
ST	9	Nordfriesland	DJHW	Tönning	153
VAR	7	Falke I	DJDW	Varel	151

B. Datos que se añaden a la lista — Oplysninger, der skal anføres i listen — In die Liste hinzuzufügende Angaben — Στοιχεία που προστίθενται στον κατάλογο — Information to be added to the list — Renseignements à ajouter à la liste — Dati da aggiungere all'elenco — Inlichtingen toe te voegen aan de lijst — Informações a aditar à lista — Luetteloon lisättävät tiedot — Uppgifter som skall läggas till i förteckningen

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ALEMANIA / TYSKLAND / DEUTSCHLAND / ΓΕΡΜΑΝΙΑ / GERMANY / ALLEMAGNE / GERMANIA /
DUITSLAND / ALEMANHA / SAKSA / TYSKLAND

FRI	7	Polarstern	DIRH	Friedrichskoog	151
SD	4	Kerstin	DFCQ	Friedrichskoog	147
SD	25	Nordfriesland	DJHW	Friedrichskoog	153
VAR	7	Falke I	DJDW	Varel	130