

Example 2
TABLE OF CONCORDANCE OF LEGISLATIVE PROVISIONS

COUNCIL DIRECTIVE
of 23 November 1976
relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables
(76/895/EEC)

1. Title of the EU legislation and the subject and objective of its regulatory scope				
COUNCIL DIRECTIVE of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC) This Directive concerns the authorization, placing on the market, use and control within the Community of plant protection products in commercial form and the placing on the market and control within the Community of active substances intended for a use specified in Article 2 (1)				
2. Title of the draft legislation and the subject and objective of its regulatory scope				
DRAFT LAW ON PLANT PROTECTION PRODUCTS The purpose of this Law is the regulation of placement in the market and control of active substances of products for plant protection, authorization, circulation, use, residue in plants and plant products, record keeping of natural and legal persons included for placement in the market and use of products for plant protection, technical requests for equipment used for application and their elements, responsibilities of authority competent for implementation of this law and its monitoring				
3. Compatibility with the primary sources of EU law 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) (3), as last amended by Directive 84/291/EEC (4) and, where active substances are concerned, without prejudice to the provisions concerning classification, packaging and labelling of Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (5), as last amended by Directive 90/517/EEC (6).				
4. Compatibility with EU legislation (secondary legislation) Council Regulation (EEC) No 1734/88 of 16 June 1988 concerning export from and import into the Community of certain dangerous chemicals				
a) Provisions and demands of EU legislation (article, paragraph, item)	b) Provisions of the draft legislation (title, section, article, paragraph, item, etc).	c) Compatibility between the draft legislation with the provisions of EU legislation (fully compatible, partially compatible, not compatible)	d) Reasons for partial compatibility or non-compatibility	e) Date foreseen to achieve full compatibility
Art. 2 Definitions: 1. <i>'plant protection products'</i>	Draft Law on Plant Protection Products, article 2, section on	Full transposition		31 December 2008

<p>active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:</p> <p>1.1. protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;</p> <p>1.2. influence the life processes of plants, other than as a nutrient, (e.g. growth regulators);</p> <p>1.3. preserve plant products, in so far as such substances or products are not subject to special Council of Commission provisions on preservatives;</p> <p>1.4. destroy undesired plants; or</p> <p>1.5. destroy parts of plants, check or prevent undesired growth of plants;</p>	<p>definitions</p>			
<p>2. '<i>residues of plant protection products</i>' one or more substances present in or on plants or products of plant origin, edible animal products or elsewhere in the environment and resulting from the use of a plant protection product, including their metabolites and products resulting from their degradation or reaction;</p>	<p>Draft Law on Plant Protection Products, article 2, section on definitions</p>	<p>Full transposition</p>		<p>31 December 2008</p>
<p>3. '<i>substances</i>' chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitable resulting from the manufacturing process;</p>	<p>Draft Law on Plant Protection Products, article 2, section on definitions</p>	<p>Full transposition</p>		<p>31 December 2008</p>
<p>4. '<i>active substances</i>' substances or micro-organisms including viruses, having general or specific action:</p> <p>4.1. against harmful organisms; or</p> <p>4.2. on plants, parts of plants or plant products;</p>	<p>Draft Law on Plant Protection Products, article 2, section on definitions</p>	<p>Full transposition</p>		<p>31 December 2008</p>

5. <i>'preparations'</i> mixtures or solutions composed of two or more substances of which at least one is an active substance, intended for use as plant protection products;	Draft Law on Plant Protection Products, article 2, section on definitions	Full transposition		31 December 2008
6. <i>'plants'</i> live plants and live parts of plants, including fresh fruit and seeds;	Draft Law on Plant Protection Products, article 2, section on definitions	Full transposition		31 December 2008
7. <i>'plant products'</i> products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves as defined in point 6;	Draft Law on Plant Protection Products, article 2, section on definitions	Full transposition		31 December 2008
8. <i>'harmful organisms'</i> pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens;	Draft Law on Plant Protection Products, article 2, section on definitions	Full transposition		31 December 2008
9. <i>'animals'</i> animals belonging to species normally fed and kept or consumed by man;	Draft Law on Plant Protection Products, article 2, section on definitions	Full transposition		31 December 2008
10. <i>'placing on the market'</i> any supply, whether in return for payment or free of charge, other than for storage followed by consignment from the territory of the Community or disposal. Importation of a plant protection product into the territory of the Community shall be deemed to constitute placing on the market for the purposes of this Directive;	Draft Law on Plant Protection Products, article 2, section on definitions	Partly transposed	Full transposition will be done by sub legal act of the Ministry.	31 December 2011
11. <i>'authorization of a plant protection product'</i> administrative act by which the competent authority of a Member State authorizes, following an application submitted by an	Draft Law on Plant Protection Products, article 2, section on definitions	Full transposition		31 December 2008

applicant, the placing on the market of a plant protection product in its territory or in a part thereof;				
12. <i>'environment'</i> water, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms;	Draft Law on Plant Protection Products, article 2, section on definitions	Full transposition		31 December 2008
13. <i>'integrated control'</i> the rational application of a combination of biological, biotechnological, chemical, cultural or plant-breeding measures whereby the use of chemical plant protection products is limited to the strict minimum necessary to maintain the pest population at levels below those causing economically unacceptable damage or loss.	Draft Law on Plant Protection Products, article 2, section on definitions	Full transposition		31 December 2008
Art. 3.1 1. Member States shall prescribe that plant protection products may not be placed on the market and used in their territory unless they have authorized the product in accordance with this Directive, except where the intended use is covered by Article 22.	Draft Law on Plant Protection Products, article 3. 1 section on Placement in the Market and use of Plant Protection Products	Full transposition		31 December 2008
Art. 3.2 Member States shall not, on the grounds that a plant protection product is not authorized for use in their territory, impede the production, storage or movement of such products intended for use in another Member State, provided that: — the product is authorized in another Member State, and — the inspection requirements laid down by the Member States in order to ensure compliance with paragraph 1 are satisfied.	Draft Law on Plant Protection Products, article 3. 2 section on Placement in the Market and use of Plant Protection Products	Full transposition		31 December 2008
Art. 3.3				

<p>Member States shall prescribe that plant protection products must be used properly. Proper use shall include compliance with the conditions established in accordance with Article 4 and specified on the labelling, and the application of the principles of good plant protection practice as well as, whenever possible, the principles of integrated control.</p>				
<p>Art. 4.1 Member States shall prescribe that active substances may not be placed on the market unless: — they are classified, packaged and labelled in accordance with Directive 67/548/EEC, and — where the active substance was not on the market two years after notification of this Directive, a dossier has been forwarded to the Member States and to the Commission, in accordance with Article 6, with the declaration that the active substance is intended for a use specified in Article 2 (1). This condition shall not apply to active substances intended for a use under Article 22.</p>				
<p>Art. 4. Member States shall ensure that a plant protection product is not authorized unless: (a) its active substances are listed in Annex I and any conditions laid down therein are fulfilled, and, with regard to the following points (b), (c), (d) and (e), pursuant to the uniform principles provided for in Annex VI, unless: (b) it is established, in the light of current scientific and technical knowledge and shown from appraisal of the dossier provided for in Annex III, that when used in accordance with</p>				

<p>Article 3 (3), and having regard to all normal conditions under which it may be used, and to the consequences of its use:</p> <p>(i) it is sufficiently effective;</p> <p>(ii) it has no unacceptable effect on plants or plant products;</p> <p>(iii) it does not cause unnecessary suffering and pain to vertebrates to be controlled;</p> <p>(iv) it has no harmful effect on human or animal health, directly or indirectly (e.g. through drinking water, food or feed) or on groundwater;</p> <p>(v) it has no unacceptable influence on the environment, having particular regard to the following considerations:</p> <ul style="list-style-type: none"> — its fate and distribution in the environment, particularly contamination of water including drinking water and groundwater, — its impact on non-target species; <p>(c) the nature and quantity of its active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants can be determined by appropriate methods, harmonized according to the procedure provided in Article 21, or, if not, agreed by the authorities responsible for the authorization;</p> <p>(d) its residues, resulting from authorized uses, and which are of toxicological or environmental significance, can be determined by appropriate methods in general use;</p> <p>(e) its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;</p>				
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<p>(f) maximum residue levels in the agricultural products referred to in the authorization have been provisionally established by the Member State and notified to the Commission in accordance with Article 12; within three months of the said notification, the Commission shall consider whether the provisional maximum levels established by the Member State are acceptable, and in accordance with the procedure laid down in Article 19 it shall establish provisional maximum levels throughout the Community and these shall remain in force until the corresponding maximum levels are adopted pursuant to the procedure provided for in the second subparagraph of Article 1 (1) of Directive 90/462/EEC (1) and in Article 11 of Directive 86/362/EEC (2), as amended by Directive 88/298/EEC (3).</p> <p>In particular:</p> <p>(i) Member States may not prohibit or impede the introduction into their territory of products containing pesticide residues provided the residue level does not exceed the provisional maximum levels set in accordance with the first subparagraph;</p> <p>(ii) Member States must ensure that the conditions for approval are applied in such a way that the provisional maximum levels are not exceeded</p>				
<p>Art. 4.2</p> <p>The authorization must stipulate the requirements relating to the placing on the market and use of the product or at least those aimed at ensuring compliance with the provisions of paragraph 1 (b).</p>				

<p>Art.4.3</p> <p>Member States shall ensure that compliance with the requirements set out in paragraph 1 (b) to (f) is established by official or officially recognized tests and analyses carried out under agricultural, plant health and environmental conditions relevant to use of the plant protection product in question and representative of these prevailing where the product is intended to be used, within the territory of the Member State concerned.</p>				
<p>Art. 4.4</p> <p>Without prejudice to paragraphs 5 and 6, authorizations shall be granted for a fixed period of up to 10 years only, determined by the Member States; they may be renewed after verification that the conditions imposed in paragraph 1 are still satisfied. Renewal may be granted for the period necessary to the competent authorities of the Member States, for such verification, where an application for renewal has been made.</p>				
<p>Art. 4.5</p> <p>Authorizations may be reviewed at any time if there are indications that any of the requirements referred to in paragraph 1 are no longer satisfied. In such instances the Member States may require the applicant for authorization or party to whom extension of the field of application was granted in accordance with Article 9 to submit further information necessary for the review. The authorization may, where necessary, be extended for the period necessary to complete a review and provide such further information.</p>				
<p>4.6</p> <p>Without prejudice to Decisions already taken</p>				

<p>pursuant to Article 10, an authorization shall be cancelled if it is established that:</p> <p>(a) the requirements for obtaining the authorization are not or are no longer satisfied;</p> <p>(b) false or misleading particulars were supplied concerning the facts on the basis of which the authorization was granted; or modified if it is established that:</p> <p>(c) on the basis of developments in scientific and technical knowledge the manner of use and amounts used can be modified.</p> <p>It may also be cancelled or modified at the request of the holder of the authorization, who shall state the reasons therefor; amendments can be granted only if it is established that the requirements of Article 4 (1) continue to be satisfied.</p> <p>Where a Member State withdraws an authorization, it shall immediately inform the holder of the authorization; moreover, it may grant a period of grace for the disposal, storage, placing on the market and use of existing stocks, of a length in accordance with the reason for the withdrawal, without prejudice to any period provided for by decision taken under Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances (1), as last amended by Directive 90/533/EEC (2), or Article 6 (1) or Article 8 (1) or (2) of this Directive.</p>				
<p>Art. 5. 1</p> <p>In the light of current scientific and technical knowledge, an active substance shall be included in Annex I for an initial period not exceeding 10 years, if it may be expected that plant protection products containing the</p>				

<p>active substance will fulfil the following conditions:</p> <p>(a) their residues, consequent on application consistent with good plant protection practice, do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, and the said residues, in so far as they are of toxicological or environmental significance, can be measured by methods in general use;</p> <p>(b) their use, consequent on application consistent with good plant protection practice, does not have any harmful effects on human or animal health or any unacceptable influence on the environment as provided for in Article 4 (1) (b) (iv) and (v).</p>				
<p>Art. 5.2</p> <p>For inclusion of an active substance in Annex I, the following shall be taken into particular account:</p> <p>(a) where relevant, an acceptable daily intake (ADI) for man;</p> <p>(b) an acceptable operator exposure level if necessary;</p> <p>(c) where relevant, an estimate of its fate and distribution in the environment as well as its impact on non-target species.</p> <p>3. For the first inclusion of an active substance which was not yet on the market two years after notification of this Directive, the requirements shall be deemed to be satisfied where this has been established for at least one preparation containing the said active substance.</p>				
<p>Art. 5.3</p> <p>Inclusion of an active substance in Annex I may be subject to requirements such as:</p> <p>— the minimum degree of purity of the</p>				

<p>active substance, — the nature and maximum content of certain impurities, — restrictions arising from evaluation of the information referred to in Article 6, taking account of the agricultural, plant health and environmental (including climatic) conditions in question, — type of preparation, — manner of use.</p>				
<p>Art. 5.4 Inclusion of an active substance in Annex I may be subject to requirements such as: — the minimum degree of purity of the active substance, — the nature and maximum content of certain impurities, — restrictions arising from evaluation of the information referred to in Article 6, taking account of the agricultural, plant health and environmental (including climatic) conditions in question, — type of preparation, — manner of use.</p>				
<p>Art. 5.5 On request, the inclusion of a substance in Annex I may be renewed once or more for periods not exceeding 10 years; such inclusion may be reviewed at any time if there are indications that the criteria referred to in paragraphs 1 and 2 are no longer satisfied. Renewal shall be granted for the period necessary to complete a review, where an application has been made for such renewal in sufficient time, and in any case not less than two years before the entry is due to lapse, and shall be granted for the period</p>				

necessary to provide information requested in accordance with Article 6 (4).				
<p>Art. 6. 1</p> <p>Inclusion of an active substance in Annex I shall be decided in accordance with the procedure laid down in Article 19.</p> <p>The following shall also be decided in accordance with that procedure:</p> <ul style="list-style-type: none"> — any conditions for inclusion, — amendments to Annex I, where necessary, — removal of an active substance form Annex I if it no longer satisfies the requirements of Article 5 (1) and (2). 				
<p>Art. 6.2.</p> <p>A Member State receiving an application for the inclusion of an active substance in Annex I shall without undue delay ensure that a dossier which is believed to satisfy the requirements of Annex II is forwarded by the applicant to the other Member States and to the Commission together with a dossier complying with Annex III on at least one preparation containing that active substance. The Commission shall refer the dossier to the Standing Committee on Plant Health referred to in Article 19 for examination.</p>				
<p>Art. 6.3</p> <p>Without prejudice to the provisions of paragraph 4, at the request of a Member State, and within three to six months after the date of referral to the committee mentioned in Article 19, it shall be established by the procedure laid down in Article 20 whether the dossier has been submitted in accordance with the requirements of Annexes II and III.</p>				
Art. 6. 4				

<p>If the assessment of the dossier referred to in paragraph 2 shows that further information is necessary, the Commission may ask the applicant to submit such information. The applicant or his authorized representative may be asked by the Commission to submit his remarks to it, in particular whenever an unfavorable decision is envisaged.</p> <p>These provisions shall also apply if, after inclusion of an active substance in Annex I, facts emerge that cast doubt on its conformity with the requirements indicated in Article 5 (1) and (2), or if renewal in accordance with Article 5 (5) is being considered.</p>				
<p>Art. 6.5 The procedure concerning the submission and appraisal of applications for inclusion in Annex I and setting or varying any conditions for inclusion shall be adopted in accordance with the procedure laid down in Article 21.</p>				
<p>Art. 7 Member States shall prescribe that the holder of an authorization or those to whom an extension of the field of application has been granted in accordance with Article 9 (1) must immediately notify the competent authority of all new information on the potentially dangerous effects of any plant protection product, or of residues of an active substance on human or animal health or on groundwater, or their potentially dangerous effects on the environment. Member States shall ensure that the parties concerned immediately notify this information to the other Member States and to the Commission, which shall refer the information to the committee referred to in Article 19.</p>				
<p>Art. 8. 1</p>				

<p>By way of derogation from Article 4, a Member State may, to enable a gradual assessment to be made of the properties of new active substances and to make it easier for new preparations to be made available for use in agriculture, authorize, for a provisional period not exceeding three years, the placing on the market of plant protection products containing an active substance not listed in Annex I and not yet available on the market two years after notification of this Directive, provided that:</p> <p>(a) following application of Article 6 (2) and (3) it is found that the dossier on the active substance satisfies the requirements of Annexes II and III in relation to the projected uses;</p> <p>(b) the Member State establishes that the active substance can satisfy the requirements of Article 5 (1) and that the plant protection product may be expected to satisfy the requirements of Article 4 (1) (b) to (f).</p> <p>In such cases the Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorization, giving at least the information provided for in Article 12 (1).</p> <p>Following the evaluation of the dossier as provided for in Article 6 (3), it may be decided, in accordance with the procedure laid down in Article 19, that the active substance does not satisfy the requirements specified in Article 5 (1). In such cases the Member States shall ensure that the authorizations must be withdrawn. By way of derogation from Article 6, if, on expiry of the three-year period, a decision has not been taken concerning the inclusion of an active</p>				
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<p>substance in Annex I, a further period may be ordered by the procedure referred to in Article 19 to enable a full examination to be made of the dossier and, where appropriate, of any additional information requested in accordance with Article 6 (3) and (4). The provisions of Article 4 (2), (3), (5) and (6) shall apply to authorizations granted under the terms of this paragraph without prejudice to the foregoing subparagraphs.</p>				
<p>Art. 8. 2 By way of derogation from Article 4 and without prejudice to paragraph 3 or to Directive 79/117/EEC, a Member State may, during a period of 12 years following the notification of this Directive, authorize the placing on the market in its territory of plant protection products containing active substances not listed in Annex I that are already on the market two years after the date of notification of this Directive. After the adoption of this Directive, the Commission shall commence a programme of work for the gradual examination of these active substances within the 12-year period referred to in the foregoing subparagraph. This programme may require interested parties to submit all requisite data to the Commission and the Member States within a period provided for in the programme. A Regulation, adopted according to the procedure laid down in Article 19, will set out all the provisions necessary for the implementation of the programme. Ten years following notification of this Directive the Commission shall present to the European Parliament and the Council a progress report on the programme.</p>				

<p>Depending upon the conclusions of the report, it may be decided, according to the procedure laid down in Article 19, whether, for certain substances, the 12-year period referred to in the first subparagraph is to be extended for a period to be determined.</p> <p>During the 12-year period referred to in the first subparagraph it may, following examination by the Committee referred to in Article 19 of such active substance, be decided by the procedure laid down in that Article that the substance can be included in Annex I and under which conditions, or, in cases where the requirements of Article 5 are not satisfied or the requisite information and data have not been submitted within the prescribed period, that such active substance will not be included in Annex I. The Member States shall ensure that the relevant authorizations are granted, withdrawn or varied, as appropriate, within prescribed period.</p>				
<p>Art. 8. 3</p> <p>Where they review plant protection products containing an active substance in accordance with paragraph 2, and before such review has taken place, Member States shall apply the requirements laid down in Article 4 (1) (b) (i) to (v), and (c) to (f) in accordance with national provisions concerning the data to be provided.</p>				
<p>Art. 8. 4</p> <p>By way of further derogation from Article 4, in special circumstances a Member State may authorize for a period not exceeding 120 days the placing on the market of plant protection products not complying with Article 4 for a limited and controlled use if such a measure</p>				

<p>appears necessary because of an unforeseeable danger which cannot be contained by other means. In this case, the Member State concerned shall immediately inform the other Member States and the Commission of its action. It shall be decided without delay, in accordance with the procedure laid down in Article 19, whether and under which conditions the action taken by the Member State may be extended for a given period, repeated, or revoked.</p>				
<p>Art. 9. 1 Application for authorization of a plant protection product shall be made by or on behalf of the person responsible for first placing it on the market in a Member State to the competent authorities of each Member State where the plant protection product is intended to be placed on the market. Official or scientific bodies involved in agricultural activities or professional agricultural organizations and professional users may request that the field of application of a plant protection product already authorized in the Member State in question be extended to purposes other than those covered by this authorization. Member States shall grant an extension of the field of application of an authorized plant protection product and shall be obliged to grant such an extension when it is in the public interest to the extent that: — the documentation and information to support an extension of the field of application has been submitted by the applicant, — they have established that the conditions</p>				

<p>referred to in Article 4 (1) (b) (iii), (iv) and (v) are satisfied, — the intended use is minor in nature, — users are fully and specifically informed as to instructions for use, by means of an addition to the labelling or, failing that, by means of an official publication.</p>				
<p>Art. 9.2 Every applicant shall be required to have a permanent office within the Community</p>				
<p>Art. 9.3 Member States may require that applications for authorization be submitted in their national or official languages or one of those languages. They may also require that samples of the preparation and of its ingredients be provided.</p>				
<p>Art. 9.4 Each Member State shall agree to consider any application for authorization made to it and shall decide thereon within a reasonable period, provided that it has the necessary scientific and technical structures at its disposal.</p>				
<p>9.5 Member States shall ensure that a file is compiled on each application. Each file shall contain at least a copy of the application, a record of the administrative decisions taken by the Member State concerning the application and concerning the particulars and documentation laid down in Article 13 (1) together with a summary of the latter. Member States shall on request make available to the other Member States and to the Commission the files provided for in this paragraph; they shall supply to themon</p>				

<p>request all information necessary for full comprehension of applications, and shall where requested ensure that applicants provide a copy of the technical documentation laid down in Article 13 (1) (a).</p>				
<p>Art. 10. 1</p> <p>At the request of the applicant, who must substantiate the claim to comparability with documentary evidence, a Member State to which an application is made for the authorization of a plant protection product already authorized in another Member State must:</p> <ul style="list-style-type: none"> — refrain from requiring the repetition of tests and analyses already carried out in connection with the authorization of the product in that Member State, and to the extent that agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product are comparable in the regions concerned, and — to the extent that the uniform principles have been adopted in accordance with Article 23, where the product contains only active substances listed in Annex I, also authorize the placing of that product on the market in its territory, to the extent that agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product are comparable in the regions concerned. <p>Authorization may be subject to conditions resulting from the implementation of other measures in accordance with Community law, relating to the conditions for distribution and use of plant protection products intended to protect the health of the distributors, users</p>				

<p>and workers concerned.</p> <p>Subject to compliance with the Treaty, authorization may also be accompanied by restrictions on use arising from differences in dietary patterns and necessary in order to avoid exposure of consumers of treated products to the risks of dietary contamination in excess of the acceptable daily intake of the residues concerned.</p> <p>Authorization may be subject, with the agreement of the applicant, to changes in the conditions of use in order to render, in the regions concerned, any non-comparable agricultural, plant health or environmental (including climatic) conditions irrelevant for the purpose of comparability.</p>				
<p>Art. 10. 2</p> <p>Member States shall inform the Commission of cases where they have required repetition of a test and of cases where they have refused to authorize a plant protection product already authorized in another Member State, in respect of which the applicant had claimed that the agricultural, plant health and environmental (including climatic) conditions relevant to use of the product in the regions concerned in the Member State where the test was carried out or for which authorization was granted were comparable to those in their own territory. They shall notify the Commission of the grounds on which repetition of the test was required or authorization was refused.</p>				
<p>Art. 10. 3</p> <p>Without prejudice to Article 23, in cases where a Member State refuses to recognize comparability and accept tests and analyses</p>				

<p>or authorize the placing on the market of a plant protection product in the relevant regions of its territory, the decision as to whether or not comparability exists shall be taken in accordance with the procedure laid down in Article 19 and, if the decision is negative, it shall also specify the conditions of use under which the non-comparability may be deemed irrelevant. In this procedure account shall be taken, <i>inter alia</i>, of the serious ecological vulnerability problems that may arise in certain Community regions or zones thereby requiring, if they do arise, specific protection measures. The Member State shall without delay accept the tests and analyses or authorize the placing of the plant protection product on the market, subject in the latter case to any terms which the above decision may set.</p>				
<p><i>Art. 11.1</i> Where a Member State has valid reasons to consider that a product which it has authorized or is bound to authorize under Article 10 constitutes a risk to human or animal health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.</p>				
<p><i>Art. 11.2</i> A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 19.</p>				
<p><i>Art. 12.1</i> Within a period of one month at the end of each quarter at least, Member States shall inform each other and the Commission in</p>				

<p>writing of any plant protection products authorized or withdrawn, in accordance with the provisions of this Directive, indicating at least:</p> <ul style="list-style-type: none"> — the name or business name of the holder of the authorization, — the trade name of the plant protection product, <ul style="list-style-type: none"> — the type of preparation, — the name and amount of each active substance which it contains, — the use or uses for which it is intended, — the maximum residue levels provisionally established where they have not already been set by Community rules, — where relevant, the reasons for withdrawal of an authorization, — the dossier needed for the evaluation of the maximum residue levels <ul style="list-style-type: none"> — provisionally established. 				
<p><i>Art. 12 2</i> Each Member State shall draw up an annual list of the plant protection products authorized in its territory and shall communicate that list to the other Member States and the Commission. In accordance with the procedure laid down in Article 21 a standardized information system shall be set up to facilitate the application of paragraphs 1 and 2.</p>				
<p><i>Art. 13. 1</i> Without prejudice to Article 10, Member States shall require that applicants for authorization of a plant protection product submit with their application:</p> <ul style="list-style-type: none"> (a) a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex III; and (b) for each active substance in the plant 				

<p>protection product, a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex II.</p>				
<p><i>Art.13. 2</i> By way of derogation from paragraph 1, and without prejudice to the provisions of paragraphs 3 and 4, applicants shall be exempted from supplying the information required under paragraph 1 (b) except for that identifying the active substance if the active substance is already listed in Annex I, taking into account the conditions of inclusion in Annex I, and does not differ significantly in degree of purity and nature of impurities, from the composition registered in the dossier accompanying the original application.</p>				
<p><i>Art. 13. 3</i> In granting authorizations, Member States shall not make use of the information referred to in Annex II for the benefit of other applicants: (a) unless the applicant has agreed with the first applicant that use may be made of such information; or (b) for a period of 10 years from first inclusion in Annex I of an active substance not on the market two years after the date of notification of this Directive; or (c) for periods not exceeding 10 years from the date of the decision in each Member State and provided for in existing national rules, concerning an active substance on the market two years after the date of notification of this Directive; and (d) for a period of five years from the date of a decision, following receipt of further</p>				

<p>information necessary for first inclusion in Annex I, or to vary the conditions for, or to maintain the inclusion of an active substance in Annex I, which has been taken either to vary the conditions for, or to maintain, the inclusion of an active substance in Annex I, unless the five-year period expires before the period provided for in paragraphs 3 (b) and (c), in which case the period of five years shall be extended so as to expire on the same date as those periods.</p>				
<p><i>Art. 13.4</i> In granting authorizations, Member States shall not make use of the information referred to in Annex III to the benefit of other applicants: (a) unless the applicant has agreed with the first applicant that use may be made of such information; or (b) for a period of 10 years from first authorization of the plant protection product in any Member State, where authorization follows the inclusion in Annex I of any active substance contained in the product; or (c) for periods not exceeding 10 years and provided for in existing national rules after the first authorization of the plant protection product in each Member State, where that authorization precedes inclusion in Annex I of any active substance contained in the product.</p>				
<p><i>Art. 13.5</i> Member States, on examination of an application for authorization, shall inform the Commission of instances where they consider an active substance as listed in Annex I, which has been produced by a person or manufacturing process other than those specified in the dossier on the basis of which</p>				

<p>the active substance was first included in Annex I. They shall transmit to it all data regarding the identify and impurities of the active substance.</p>				
<p><i>Art. 13. 6</i> By way of derogation from paragraph 1, for active substances already on the market two years after notification of this Directive, Member States may, with due regard for the provisions of the Treaty, continue to apply previous national rules concerning data requirements as long as such substances are not included in Annex I.</p>				
<p><i>Art. 13. 7</i> Notwithstanding paragraph 1, and without prejudice to Article 10, where the active substance is listed in Annex I: (a) applicants for authorization of plant protection products shall, before carrying out experiments involving vertebrate animals, enquire of the competent authority of the Member State to which they intend making application: — whether the plant protection product for which an application is to be made is the same as a plant protection product for which authorization has been granted, and — as to the name and address of the holder or holders of the authorization or authorizations. The enquiry shall be supported by evidence that the prospective applicant intends to apply for authorization on his own behalf and that the other information specified in paragraph 1 is available; (b) the competent authority of the Member State, if satisfied that the applicant intends to apply, shall provide the name and address of the holder or holders of previous relevant</p>				

<p>authorizations and shall at the time inform the holders of the authorizations of the name and address of the applicant.</p> <p>The holder or holders of previous authorizations and the applicant shall take all reasonable steps to reach agreement on the sharing of information so as to avoid the duplication of testing on vertebrate animals.</p> <p>Where data is requested with a view to inclusion in Annex I of an active substance already on the market two years after notification of this Directive, the competent authorities of the Member State shall encourage data holders to cooperate in the provision of the requested data, with a view to limiting the duplication of testing on vertebrate animals.</p> <p>If, nevertheless, the applicant and holders of previous authorizations of the same product can still not reach an agreement on the sharing of data, Member States may introduce national measures obliging the applicant and holders of previous authorizations located within their territory to share the data with a view to avoiding duplicative testing on vertebrate animals and determine both the procedure for utilizing information, and the reasonable balance of the interests of the parties concerned</p>				
<p><i>Art. 14</i></p> <p>Member States and the Commission shall, without prejudice to Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment (1), ensure that information submitted by applicants involving industrial and commercial secrets is treated as confidential if the applicant wishing to have an active substance included in Annex I or the</p>				

<p>applicant for authorization of a plant protection product so requests, and if the Member State or the Commission accepts that the applicant's request is warranted.</p> <p>Confidentiality shall not apply to:</p> <ul style="list-style-type: none"> — the names and content of the active substance or substances and the name of the plant protection product, — the name of other substances which are regarded as dangerous under Directives 67/548/EEC and 78/631/EEC, — physico-chemical data concerning the active substance and plant protection product, — any ways of rendering the active substance or plant protection product harmless, — a summary of the results of the tests to establish the substance's or product's efficacy and harmlessness to humans, animals, plants and the environment, — recommended methods and precautions to reduce handling, storage, transport, fire or other hazards, — methods of analysis referred to in Articles 4 (1) (c) and (d) and 5 (1), — methods of disposal of the product and of its packaging, — decontamination procedures to be followed in the case of accidental spillage or leakage, — first aid and medical treatment to be given in the case of injury to persons. <p>If the applicant subsequently discloses previously confidential information, he shall be required to inform the competent authority accordingly.</p>				
<p><i>Art. 15</i> Article 5 (1) of Directive 78/631/EEC shall</p>				

<p>apply to all plant protection products not covered by Directive 78/631/EEC.</p>				
<p><i>Art. 16</i> Member States shall take all necessary measures to ensure that the packaging of plant protection products satisfies the following requirements as to labelling. 1. All packaging must show clearly and indelibly the following: (a) the trade name or designation of the plant protection product; (b) the name and address of the holder of the authorization and the authorization number of the plant protection product and, if different, the name and address of the person responsible for the final packaging and labelling or for the final labelling of the plant protection product on the market; (c) the name and amount of each active substance expressed as provided for in Article 6 of Directive 78/631/EEC and in particular paragraph (2) (d) of that Article. The name must be as given in the list contained in Annex I to Directive 67/548/EEC or, if not included therein, its ISO common name. If the latter is not available, the active substance shall be designated by its chemical designation according to IUPAC rules; (d) the net quantity of plant protection product given in legal units of measurement; (e) the formulation batch number or some means of identifying it; (f) the particulars required under Article 6 of Directive 78/631/EEC, in particular those mentioned in paragraph 2 (d), (g), (h) and (i), and paragraphs 3 and 4 of that Article and information on first aid; (g) the nature of any special risks for humans,</p>				

<p>animals or the environment, by means of standard phrases selected as appropriate From those given in Annex IV;</p> <p>(h) safety precautions for the protection of humans, animals or the environment, in the form of standard phrases selected as appropriate from those given in Annex V;</p> <p>(i) the type of action of the plant protection product (e.g. insecticide, growth regulator, weedkiller, etc.);</p> <p>(j) the type of preparation (e.g. wettable powder, emulsifiable concentrate, etc.);</p> <p>(k) the uses for which the plant protection product has been authorized and any specific agricultural, plant health and environmental conditions under which the product may be used or should not be used; (l) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorization;</p> <p>(m) where necessary, the safety interval for each use between application and:</p> <ul style="list-style-type: none"> — sowing or planting of the crop to be protected, — sowing or planting of succeeding crops, — access by humans or animals, — harvesting, — use or consumption; <p>(n) particulars of possible phytotoxicity, varietal susceptibility, and any other direct or indirect adverse side effects on plants or products of plant origin together with the intervals to be observed between application and sowing or planting of:</p> <ul style="list-style-type: none"> — the crop in question, or — subsequent crops; <p>(o) if accompanied by a leaflet, as provided for in paragraph 2, the sentence ‘Read</p>				
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<p>accompanying instructions before use’; (p) directions for safe disposal of the plant protection product and of the packaging; and (q) the expiry date relevant to normal conditions of storage where the shelf life of the product is limited to less than two years.</p>				
<p><i>Art. 16. 2</i> Member States may permit the requirements in paragraph 1 (l), (m) and (n) to be indicated on a separate leaflet accompanying the package if the space available on the package is too small. Such a leaflet shall be regarded as part of the label for the purposes of this Directive.</p>				
<p><i>Art. 16. 3</i> Taking account of the rules in force within their territories regarding the supply of certain plant protection products to certain categories of users, pending Community harmonization, the Member States shall require that it be indicated on the label whether a product is restricted to certain categories of users.</p>				
<p><i>Art. 16. 4</i> In no circumstances may the label of the packaging of a plant protection product bear the indications ‘non-toxic’, ‘harmless’, or similar indications. However, information to the effect that the plant protection product may be used when bees or other non-target species are active, or when crops or weeds are in flower or other such phrases to protect bees or other non-target species may be given on the label, if the authorization relates explicitly to use during the season for bees or other specified organisms and presents minimal hazard to them.</p>				
<p><i>Art. 16. 5</i> Member States may make the placing of</p>				

<p>plant protection products on the market in their territories subject to their being labelled in their national language or languages, and may require that samples, models or drafts of the packaging, labelling and leaflets referred to in this Article be submitted. By way of derogation from paragraph 1 (g) and (h), Member States may require additional phrases to be clearly and indelibly marked on packaging where they are deemed to be necessary for the protection of human beings, animals or the environment; in that event they shall notify the other Member States and the Commission forthwith of each derogation granted and shall forward the additional phrase or phrases and the reasons for these requirements.</p> <p>In accordance with the procedure laid down in Article 19, a decision shall be taken that the additional phrase or phrases is or are justified and hence that Annexes IV and V must be amended accordingly, or that the Member States concerned must no longer require such phrase(s). The Member State shall be entitled to maintain its requirement until such time as a decision has been taken.</p>				
<p><i>Art. 17</i></p> <p>Member States shall make the necessary arrangements for plant protection products which have been placed on the market and for their use to be officially checked to see whether they comply with the requirements of this Directive and in particular with the requirements of the authorization and information appearing on the label.</p> <p>The Member States shall report annually before 1 August to the other Member States and the Commission on the results of the inspection measures taken in the previous</p>				

year.				
<p><i>Art. 18. 1</i> The Council, acting by a qualified majority on a proposal from the Commission, shall adopt the 'uniform principles' referred to in Annex VI.</p>				
<p><i>Art. 18. 2</i> In accordance with the procedure laid down in Article 19 and having regard to current scientific and technical knowledge, the necessary amendments to Annexes II, III, IV, V and VI shall be adopted.</p>				
<p><i>Art. 19. 1</i> The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up pursuant to Article 58 of Regulation (EC) No 178/2002 (1).</p>				
<p><i>Art. 19. 2</i> The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up pursuant to Article 58 of Regulation (EC) No 178/2002 (1).</p>				
<p><i>Art. 19. 3</i> Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (2) shall apply. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.</p>				
<p><i>Art. 19. 4</i> The Committee shall adopt its Rules of Procedure.</p>				
<p><i>Art. 20. 1</i> The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.</p>				
<p><i>Art. 20. 2</i> Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC</p>				

<p>shall apply. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.</p>				
<p><i>Art. 21. 1</i> The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.</p>				
<p><i>Art. 21. 2</i> Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC shall apply.</p>				
<p><i>Art. 22. 1</i> The Member States shall prescribe that any experiment or test for research or development purposes involving the release into the environment of an unauthorized plant protection product may only be carried out after authorization for trial purposes has been granted and under controlled conditions and for limited quantities and areas.</p>				
<p><i>Art. 22.2</i> The persons concerned shall submit an application to the competent authority of the Member State in whose territory the experiment or test is to be conducted, within time periods prescribed by the Member State before the commencement of the experiment or test, together with a dossier containing all the available data to permit an assessment to be made of possible effects on human or animal health or the possible impact on the environment. If the proposed experiments or tests referred to in paragraph 1 are liable to have harmful effects on human or animal health or to have an unacceptable adverse influence on the environment, the Member State concerned</p>				

may either prohibit them or permit them subject to such conditions as it considers necessary to prevent those consequences.				
<i>Art. 22. 3</i> Paragraph 2 shall not apply if the Member State has granted the person concerned the right to undertake certain experiments and tests and has determined the conditions under which the experiments and tests have to be undertaken.				
<i>Art. 22. 4</i> Common conditions for the application of this Article, in particular the maximum quantities of pesticides that may be released during experiments covered by paragraph 1, and the minimum data to be submitted in accordance with paragraph 2, shall be adopted in accordance with the procedure laid down in Article 19.				
<i>Art. 22. 5</i> This Article shall not apply to experiments or tests covered by Part B of Directive 90/220/EEC.				
Annex I ACTIVE SUBSTANCES AUTHORISED FOR USE IN PLANT PROTECTION PRODUCTS				
Annex II REQUIREMENTS FOR THE DOSSIER TO BE SUBMITTED FOR THE INCLUSION OF AN ACTIVE SUBSTANCE IN ANNEX I				
ANNEX III REQUIREMENTS FOR THE DOSSIER TO BE SUBMITTED FOR THE AUTHORIZATION OF A PLANT PROTECTION PRODUCT				
ANNEX IV STANDARD PHRASES FOR SPECIAL RISKS FOR HUMANS OR THE				

ENVIRONMENT AS REFERRED TO IN ARTICLE 16				
ANNEX V STANDARD PHRASES FOR SAFETY PRECAUTIONS FOR THE PROTECTION OF HUMANS OR THE ENVIRONMENT AS REFERRED TO IN ARTICLE 16				
ANNEX VI UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORIZATION OF PLANT PROTECTION PRODUCTS				