

<p>COUNCIL DIRECTIVE of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC)</p>	<p>SANCO/10159/2005 06 April 2005 -</p> <p>Draft SANCO D3 working document</p> <p><i>- DOES NOT NECESSARILY REPRESENT THE VIEWS OF THE COMMISSION SERVICES</i></p> <p>DRAFT WORKING PROPOSAL for COUNCIL and PARLIAMENT REGULATION concerning the placing of plant protection products on the market</p>
<p>THE COUNCIL OF THE EUROPEAN COMMUNITIES</p>	<p>The European Parliament and the Council</p>
<p>Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof,</p> <p>Article 37 and 152 are a sufficient basis. Also the MRL Regulation, adopted by Council and Parliament refers to these 2 Articles.</p> <p>Having regard to the proposal from the Commission, Having regard to the opinion of the European Parliament, Having regard to the opinion of the Economic and Social Committee,</p>	<p>Having regard to the Treaty establishing the European Community, and in particular Articles 37 (2) and 152(4)(b) thereof,</p> <p>Having regard to the proposal from the Commission, Having regard to the opinion of the Economic and Social Committee, Having regard to the opinion of the Committee of the Regions, Acting in accordance with the procedure laid down in Article 251 of the Treaty,</p>
<p>Whereas.....</p> <div style="border: 1px solid black; padding: 5px;"> <p><i>Need to add provisions for labelling, sales data reporting, accident reporting, notification of neighbours by sprayers, container management, MS to strive to harmonise risk reduction measures, procedure to evaluate and authorise in a zone products containing several a.i.s Also need to fix the seeds problem Logbooks? Notification of neighbours? Risk Reduction Chapter?</i></p> </div>	<p>Whereas:</p> <p>INSERT RECITALS TEXT FOR ALL ARTICLES</p>

Gelöscht: COMMISSION WORKING DOCUMENT

Formatiert: Schriftart: Kursiv

HAS ADOPTED THIS DIRECTIVE	HAVE ADOPTED THIS REGULATION
	TITLE I GENERAL ISSUES
Article 1 (scope)	Article 1 Subject matter
<p>1. 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).</p> <p>The negative list will include the substances included in Directive 79/117 and gradually other substances can be included when it appeared after evaluation that they present unacceptable effects. This clarifies that such substances are unacceptable and that it would be a waste of resources to perform further studies on them.</p>	<p>1. This Regulation lays down rules for:</p> <ul style="list-style-type: none"> (a) the authorization, placing on the market, use and control within the Community of plant protection products in commercial form, active substances intended for a use specified in Article 2(1), safeners, synergists and adjuvants; (b) the designation of zones within the Community within which mutual recognition of national authorisations shall be compulsory and ; (c) the establishment at Community level of a positive list of active substances which may be used in plant protection products; (d) the establishment at Community level of a negative list of active substances which may not be used in plant protection products; (e) the establishment at Community level of a positive list of substances which may be used as safeners or synergists; (f) the establishment at Community level of a negative list of substances which may not be used as an adjuvant or as a co-formulant in plant protection products; (g) the establishment of Community procedures, criteria and assessment methods for the evaluation of active substances, safeners, synergists, adjuvants, and co-formulants as well as of uniform procedures for risk assessment to be used for the evaluation of products containing them and to be applied prior to authorisations being granted; (h) monitoring, inspection, reporting and control, (i) plant protection products containing or composed of genetically modified micro-organisms (GMMs) and the placing on the market and control of GMMs intended for inclusion in a plant protection product (j) definition of the roles of the Commission, the EFSA and the Member States (k) transitional measures to be applied pending complete harmonisation at Community level

SANCO/10159PPP Regulation rev.0 06.04.2005

	Article 2 Scope and applicability
<p>2. This Directive shall apply without prejudice to 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), as last amended by Directive 84/291/EEC 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, as last amended by Directive 90/517/EEC.</p>	
<p>3. This Directive applies to the authorization to place on the market plant protection products containing or composed of genetically modified organisms, provided that authorization to release them into the environment has been granted after the risk to the environment has been assessed in accordance with the provisions of Parts A, B and D and the relevant provisions of Part C of Directive 90/220/EEC.</p> <p>The Commission shall submit to the Council, in sufficient time for the latter to be able to act not later than two years after the date of notification of this Directive, a proposal for an amendment with a view to including in this Directive a specific procedure for evaluating the risk to the environment analogous to that provided for the Directive 90/220/EEC, and enabling this Directive to be placed on the list provided for in Article 10(3) of Directive 90/220/EEC in accordance with the procedure laid down in the said Article 10.</p> <p>Within five years of the date of notification of this Directive, the Commission, on the basis of experience gained, shall provide the European Parliament and the Council with a report on the operation of the arrangements described in the first and second subparagraphs.</p> <p>It is considered appropriate to ensure that the aspect “genetically modification” is evaluated in accordance with Directive 2001/18/EC prior to the evaluation as a plant protection product and to follow the procedures of that Directive.</p>	
<p>4. This Directive shall apply without prejudice to Council Regulation (EEC) N° 1734/88 of 16 June 1988 concerning export from and import into the Community of certain dangerous chemicals.</p>	<p>This Regulation shall apply without prejudice to:</p> <ul style="list-style-type: none"> (a) 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 (b) Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations or administrative provisions of the Member States concerning misleading advertising; (c) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health at work and individual Directives based on this Directive; (d) Council Directive 98/24/EC on the protection of the health and safety of workers against the risks of chemical agents at work;

SANCO/10159PPP Regulation rev.0 06.04.2005

	<p>(e) The provisions of Directive 1999/45/EC of the European Parliament and Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations</p> <p>(f) Directive 2000/60/EC of the European Parliament and of the Council of 23.10.2000 establishing a framework for Community action in the field of water policy. OJ N° L 327, 22.12.2000 p. 1</p> <p>(g) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organism and repealing Council Directive 90/220/EEC</p> <p>(h) <i>Insert new MRL Regulation COM(2003)117</i></p> <p>(i) Directive on hazardous waste</p> <p>(j) Regulation 1829/2003</p>
<p align="center">Article 2 (definitions)</p>	<p align="center">Article 3 Definitions</p>
<p>A number of new definitions is included, partially based on the biocides Directive or on experience and guidance documents developed</p> <p>For the purposes of this Directive the following definitions shall apply:</p> <p>1. 'plant protection products'</p> <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 or 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>For the purposes of this Regulation the following definitions shall apply:</p> <p>1. 'plant protection products'</p> <ul style="list-style-type: none"> - active substances, safeners or synergists - preparations containing one or more active substances, safeners or synergists <p>put up in the form in which they are supplied to the user, intended to:</p> <ul style="list-style-type: none"> - protect plants or plant products against all harmful organisms or prevent the action of such organisms; - influence the life processes of plants (e.g. growth regulators), other than as a nutrient; - preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives; - destroy undesired plants; or - destroy parts of plants, check or prevent undesired growth of plants.
	<p>2. 'low-risk plant protection products'</p> <p>plant protection products which contain as active substance(s) only one or more of those listed in Annex IB and which do not contain any substance(s) of concern.</p>
	<p>3. 'active substances and plant protection product candidates for substitution'</p> <p>plant protection products which contain an active substance listed in Annex ID and the active substances themselves.</p>

SANCO/10159PPP Regulation rev.0 06.04.2005

<p>2. 'residues of plant protection products'</p> <p>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>4. 'residues of plant protection products'</p> <p>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>Definition from guidance document on relevant metabolites with addition of ecotoxicological effects.</p>	<p>5. 'relevant metabolite'</p> <p>any metabolite or degradation product of an active substance for which there is reason to assume that it has comparable intrinsic properties as the active substance in terms of its biological target activity, or that it has certain toxicological or ecotoxicological properties that are considered severe and unacceptable.</p>
	<p>6. 'safener'</p> <p>a substance added to a preparation to eliminate or to reduce phytotoxic effects of the preparation to certain plants</p>
	<p>7. 'synergist'</p> <p>a substance which, whilst formally inactive or weakly active, can give enhanced activity to the active substance(s) in a preparation</p>
	<p>8. 'adjuvant'</p> <p>co-formulants and preparations containing one or more co-formulants, put up in the form in which they are supplied to the user and placed on the market with the objective as shown on the label to be mixed by the user with one or more plant protection products for the purpose of changing its or their properties or effects</p>
	<p>9. 'co-formulant'</p> <p>any substance other than an active substance, safener or synergist, which is used or intended to be used in a plant protection product or adjuvant, such as solvents or emulsifiers</p>
<p>The definitions are not amended because there was no request to do so. There are no problems with the current definitions. Possible problem with 67/548 definition: why are solvents excluded?</p> <p>3. 'substances'</p> <p>chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitable resulting from the manufacturing process;</p>	<p>10. 'substances'</p> <p>chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;</p>
<p>4. 'active substances'</p> <p>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>this definition clarifies that substances acting by physical means are not plant protection products</p>	<p>11. 'active substances'</p> <p>substances or micro-organisms including viruses, having general or specific action, by chemical or biological means:</p> <ul style="list-style-type: none"> - against harmful organisms; or - on plants, parts of plants or plant products;

SANCO/10159PPP Regulation rev.0 06.04.2005

5. 'preparations' 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;	12. ' preparations ' mixtures or solutions composed of two or more substances intended for use as a plant protection product or as an adjuvant.
Definition as in biocides Directive	13. ' substance of concern ' Any substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a plant protection product in sufficient concentration to create a significant risk of such an effect. Such a substance, unless there are other grounds for concern, would be normally a substance classified as dangerous according to 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, and present in the plant protection product at a concentration leading the product to be regarded as dangerous within the meaning of Article 3 of Council Directive 1999/45/EC of the European Parliament and Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
	14. ' basic substance ' a substance which is listed in Annex IC, whose major use is not as a plant protection product but which has some minor use as a plant protection product either directly or in a product consisting of the substance and a simple diluent which itself is not a substance of concern and which is not directly marketed for use as a plant protection product;
6. 'plants' live plants and live parts of plants, including fresh fruit and seeds;	15. ' plants ' live plants and live parts of plants, including fresh fruit and seeds;
7. 'plant products' 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;	16. ' plant products ' 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 15;
8. 'harmful organisms' pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens. Definition of Council Directive 2000/29/EC	17. ' harmful organisms ' Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.
	18. pests ;
9. 'animals' animals belonging to species normally fed and kept or consumed by man;	19. ' animals ' animals belonging to species normally domesticated, fed, kept or consumed by man;
10. 'placing on the market' any supply, whether in return for payment or free of charge, other than for storage followed by consignment from the	20. ' placing on the market ' the holding for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge

SANCO/10159PPP Regulation rev.0 06.04.2005

<p>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;</p> <p>made coherent with definition in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹ this definition also includes storage.</p>	<p>or not, and the sale, distribution, and other forms of transfer themselves. 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 Regulation;</p>
<p>11. 'authorization of a plant protection product'</p> <p>administrative act by which the competent authority of a Member State authorizes, following an application submitted by an applicant, the placing on the market of a plant protection product in its territory or in a part thereof;</p>	<p>21. 'authorization of a plant protection product'</p> <p>administrative act by which the competent authority of a Member State authorizes, subsequent to an assessment of an application submitted by an applicant, the placing on the market of a plant protection product in its territory or in a part thereof;</p> <p>21 bis 'registration'</p> <p>administrative act by which the competent authority of a Member State, following an application submitted by an applicant, after verification that the dossier meets the relevant requirements of the Directive, allows the placing on the market of a plant protection product in its territory or in a part thereof</p> <p>21 tris 'producer'</p> <ul style="list-style-type: none"> - for active substances produced within the Community, the manufacturer or a person established within the Community designated by the manufacturer as his/her sole representative fore the purpose of compliance with this Regulation, - for active substances produced outside the Community, the person established within the Community and designated by the manufacturer as his/her sole representative within the Community for the purpose of compliance with this Regulation, - for active substances for which a joint dossier is submitted, the association of producers established within the Community and designated by the producers referred to in the first or second indent for the purpose of compliance with this Regulation. <p>21 quater 'manufacturer'</p> <p>the person who manufactures the active substance on his/her own or who contracts out to another party the manufacturing of the active substance on its behalf.</p>
<p>12. 'environment'</p> <p>water, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship</p>	<p>22. 'environment'</p> <p>waters (including ground, surface, transitional and coastal), soil, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any</p>

¹ OJ L 31, 1.2.2002 p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245,29.9.2003, p. 4).

SANCO/10159PPP Regulation rev.0 06.04.2005

with living organisms;	relationship with other living organisms;
13. 'integrated control' 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.	23. ' integrated control ' 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.
Definition now also includes nematodes	24. micro-organisms any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material. For the purposes of this Regulation, nematodes used in or as plant protection products will be assimilated to micro-organisms.
	25. genetically modified micro-organisms (GMMs) Micro-organisms in which the genetic material has been altered within the meaning of article 2 (2) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC'
	26. zone Group of Member States, as defined in Annex IX, for which it is assumed a priori that the agricultural, plant health and environmental (including climatic) conditions are relatively similar
Definition in accordance with principles of EPPO (European Plant Protection Organisation)	27. Good plant protection practice Practice whereby the treatments with plant protection products applied to a given crop, in conformity with the conditions of their authorized uses, are selected, dosed and timed to ensure optimum efficacy, taking due account of local conditions and of the possibilities for cultural and biological control.
	28. Best Environmental Practice : A plant protection practice that makes use of the application of the most appropriate combination of environmental measures.
	TITLE 2 PLANT PROTECTION PRODUCTS CHAPTER 1 General provisions
Article 3 (general provisions)	Article 4 Requirement for placing on the market and use
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.	1. A Member State 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 Regulation.
Negative list of co-formulants and active substances	2. A Member State shall not authorise plant protection products containing active substances listed in Annex VIII or adjuvants and co-formulants listed in Annex IX to this Regulation .

<p>Provides that products containing only basic substances (main use is outside plant protection) may be used without authorization</p> <p>Derogation for use for research</p>	<p>3. By way of derogation from paragraph 1:</p> <p>i. Member States shall, subject to registration, allow the placing on the market and use of a low-risk plant protection product, provided that a dossier in accordance with Annex III C has been submitted and verified by the competent authorities.</p> <p>Unless otherwise specified, all provisions relating to authorisation under this Directive shall also apply to registration.</p> <p>ii. Member States shall allow the use of plant protection products containing exclusively one or more active substances listed in Annex IC</p> <p>iii. Member States shall allow the placing on the market and use of plant protection products, where the sole use is covered by Article 27 [research].</p>
<p>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:</p> <ul style="list-style-type: none"> - 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. 	<p>4. (i) 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:</p> <ul style="list-style-type: none"> - 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.
<p>3. 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>The European Plant Protection Organisation has developed guidance on good plant protection practice. This may be used as a basis for guidance at EU level</p>	<p>5. 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 5 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 and of best environmental practice.</p>
<p>4. Member States shall prescribe that active substances may not be placed on the market unless:</p> <ul style="list-style-type: none"> - 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>Part removed because the new Regulation does not</p>	<p>6. Member States shall prescribe that active substances may not be placed on the market unless:</p> <ul style="list-style-type: none"> - they are classified, packaged and labelled in accordance with Directive 67/548/EEC. <p>This condition shall not apply to active substances intended for a use under Article 27 [research].</p>

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SANCO/10159PPP Regulation rev.0 06.04.2005

provide for provisional authorizations any more..	
Article 4 (granting, review and withdrawal of authorizations of plant protection products)	Article 5 Requirements for granting authorizations
1. Member States shall ensure that a plant protection product is not authorized unless:	1. Member States shall ensure that a plant protection product is not authorized unless: - its active substances, safeners and synergists are listed in Annex I and - its conditions of use are in accordance with any conditions or requirements laid down at the inclusion of the active substances, safeners and synergist.
1(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:	2. Member States shall evaluate, in the light of current scientific and technical knowledge in an independent objective and transparent manner the dossier provided for in Annexes II and III. It shall establish in accordance with the uniform principles provided for in Annex VI whether the plant protection product meets the requirements of points 3 to 6 below, when used in accordance with Article 4(5) , and having regard to all normal conditions under which it may be used, and to the consequences of its use under the authorised conditions.
1(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 Article 3 (3), and having regard to all normal conditions under which it may be used, and to the consequences of its use: (i) it is sufficiently effective; (ii) it has no unacceptable effect on plants or plant products; (iii) it does not cause unnecessary suffering and pain to vertebrates to be controlled; (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; (v) it has no unacceptable influence on the environment, having particular regard to the following considerations: - its fate and distribution in the environment, particularly contamination of water including drinking water and groundwater, - its impact on non-target species;	3. Member States shall ensure that a plant protection product is not authorized unless it is established that the plant protection product: (i) is sufficiently effective; (ii) has no unacceptable effect on plants or plant products; (iii) does not cause unnecessary suffering and pain to vertebrates to be controlled; (iv) has no immediate or delayed harmful effect on human or animal health, directly or indirectly e.g. through drinking water, food or feed, indoor air or consequences in the place of work; (v) has no unacceptable influence on the environment, having particular regard to the following considerations: - its fate and distribution in the environment, particularly contamination of surface waters (including estuarine and coastal waters), drinking water and groundwater, - its impact on non-target species. - its impact on biodiversity
1(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;	4. Member States shall ensure that a plant protection product is not authorized unless it is established that the nature and quantity of its active substances, safeners and synergists 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 54(3) , or, if not, agreed by the authorities responsible for the authorization.
1(d) its residues, resulting from authorized uses, and which are of toxicological or environmental significance, can be determined by appropriate methods in general use;	5. Member States shall ensure that a plant protection product is not authorized unless it is established that its residues, resulting from authorized uses, and which are of toxicological or environmental significance, can be determined by appropriate methods in general use.
1(e) its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;	6. Member States shall ensure that a plant protection product is not authorized unless it is established that its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product.

Formatiert: Nicht Hervorheben

SANCO/10159PPP Regulation rev.0 06.04.2005

<p>1(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 and in Article 11 of Directive 86/362/EEC as amended by Directive 88/298/EEC. 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>Amended to ensure coherence with MRL Regulation 396/2005.</p>	<p>7. Member States shall ensure that a plant protection product is not authorized unless, where appropriate, the maximum residue levels for the agricultural products affected by the use referred to in the authorization have been set or modified in accordance with Regulation (EC) n° 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin.</p>
<p>2. 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>New obligation to warn neighbours before applying more hazardous products.</p>	<p>Article 6</p> <p>Administrative provisions concerning the authorization</p> <p>1. 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 Article 5 paragraph 3.</p> <p>These requirements may include:</p> <ul style="list-style-type: none"> - a restriction of availability of the product to certain categories of users; - for very toxic or toxic plant protection products the obligation to inform neighbours that could be exposed to the spray drift before the product is used.
<p>3. 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>2. Member States shall ensure that compliance with the requirements set out in Article 5 paragraphs 3 to 7 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>4. 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>3. Without prejudice to Articles 7 and 8,</p> <p>(a) 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>To ensure that after review of an active substance Member States check that any conditions set at the inclusion are still complied with and that data protection is applied.</p>	<p>(b) Member States may grant authorisations for periods other than 10 years where the stated objective is to synchronise the re-evaluation of similar products for the purposes of comparative assessment and potential substitution of products containing substances listed in Annex ID.</p> <p>(c) Member States shall perform a compliance check for all plant protection products after the renewal of the inclusion in Annex I of the active substance included in the plant protection product. The Member State which competent authority acted as rapporteur for the active substance shall co-ordinate the assessment of the compliance checks by the Member States. Such compliance check will be performed within the deadline foreseen in the decision on the renewal of the inclusion. The compliance check includes the check for compliance with Annex I conditions and restrictions specified in the inclusion Directive and the access to a complete Annex II and Annex III dossier, without prejudice to the provisions in Articles XX to XX [data protection]. If necessary Member States shall withdraw or modify the existing authorizations.</p> <p>4. The Commission may establish guidelines on the organisation of the compliance checks in accordance with the procedure laid down in Article 54 (3).</p>
<p>5. 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 an 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 style="text-align: center;">Article 7 Review of authorizations</p> <p>Authorizations may be reviewed at any time if there are indications or where monitoring data indicate 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 an extension of the field of application was granted in accordance with Article 11 to submit further information necessary for the review. The authorization may, where necessary, either be suspended or be extended for the period necessary to provide such further information and to complete a review.</p>
<p>6. Without prejudice to Decisions already taken 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>Modification of an authorization is now also possible on the basis of monitoring data and comparative assessment.</p> <p>It may also be cancelled or modified at the request of the</p>	<p style="text-align: center;">Article 8 Withdrawal or modification of authorizations</p> <p>1. Without prejudice to Decisions already taken pursuant to Article 14[zonal authorization], 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;</p> <p>(c) a comparative assessment performed in accordance with Article 9 has demonstrated that there are significantly safer products and the substitution of the products would not lead to a risk of an insufficient range of products being available to manage resistance</p> <p>2. Without prejudice to Decisions already taken pursuant to Article 14[zonal authorization], an authorization shall</p>

Formatiert: Nicht Hervorheben

Formatiert: Nicht Hervorheben

SANCO/10159PPP Regulation rev.0 06.04.2005

<p>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, as last amended by Directive 90/335/EEC, or Article 6(1) or Article 8(1) or (2) of this Directive.</p> <p>Council on 25-26.11.2004 (at suggestion of Sweden) requested this in framework of simplification</p>	<p>be modified if it is established that:</p> <p>(a) on the basis of developments in scientific and technical knowledge, including monitoring data at variance with the initial assessment, the manner of use and amounts used can or should be modified or</p> <p>(b) a comparative assessment performed in accordance with Article 9 has demonstrated that there are significantly safer products and the substitution of the products would not lead to a risk of an insufficient range of products being available to manage resistance.</p> <p>3. An authorization may also be cancelled or modified at the request of the holder of the authorization, who shall state the reasons therefore; amendments can be granted only if it is established that the requirements of Article 5 continue to be satisfied.</p> <p>4. Where a Member State withdraws an authorization, or after expiry of an existing authorization, the Member State 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 Article 9. When the reason for the withdrawal allows it Member States will ensure that withdrawal of authorizations and expiry of grace periods are set in such a way that they do not interfere with the normal use period of the plant protection product.</p>
	<p align="center">Article 9 Comparative assessment of plant protection products</p>
<p>Introduction of comparative assessment of plant protection products at Member State level for substances identified as being subject to comparative assessment.</p>	<p>1. Member States shall evaluate in an independent, objective and transparent manner whether for uses of plant protection products containing one or more active substances listed in Annex ID there are efficient alternatives or non-chemical control methods which, in the light of scientific or technical knowledge, present significantly less risks to health or to the environment. When performing such evaluations Member States will take into account the balance between the risks and the benefits of the use of the plant protection product, and in particular, take into consideration the following :</p> <ul style="list-style-type: none"> i. the chemical diversity of the active substances should be adequate to minimise occurrence of resistance in the target organism; ii. it should be applied only to active substances which, when used under normal conditions in authorised plant protection products, present a significantly different level of risk; iii. it should be applied only after allowing the possibility, where necessary, of acquiring experience from use in practice, if it is not already available;

SANCO/10159PPP Regulation rev.0 06.04.2005

A sufficiently long period for phase-out should be provided in order to avoid that research and development of new products would be seriously jeopardized. A long phase-out period can be justified because the substance that will be removed from the market was included in Annex I.	2. When Member States withdraw or restrict authorizations for uses of plant protection products in accordance with the provisions of paragraph 1 they will provide a phase-out period of four years from the date of that decision but not exceeding the date of expiration of inclusion in Annex ID.
	3. The Commission shall establish criteria in Annex X, using the procedure detailed in Article 54 (3) , on how such comparative assessments shall be applied uniformly in the Community.
Article 7 (information on potentially harmful effects)	
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.	.
See article 17	

Article 9 (application for authorization)	CHAPTER 2 Procedures for the application for an authorization Article 10 Application for authorization
<p>Obligation to apply initially in only one Member State of a zone in order to avoid duplication of work (authorities at least in same zone can share the work)</p> <p>If necessary the work can be redistributed if a few Member States receive too many applications.</p> <p>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.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> - 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 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>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.</p> <p>The applicant shall initially submit an application to only one Member State of a zone. The applicant shall inform the competent authorities on any application he intends to make to the competent authorities of another Member State.</p> <p>2. To avoid dossiers being evaluated by only a few Member States, the evaluation can be carried out by Member States other than the receiving one. A request for this shall be given when the dossiers are accepted, and the decision shall be taken in accordance with the procedure laid down in Article 54(3)). The decision shall be taken at the latest one month after receipt by the Commission of the request.</p>
<p>2. Every applicant shall be required to have a permanent office within the Community.</p>	<p>3. Every applicant shall be required to have a permanent office within the Community.</p>
<p>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>Similar provisions as in 91/414. Also authorization holder can apply for an extension of authorization</p>	<p>4. If requested by the Member State the applicant shall submit his application for authorisation in the national or official languages of that Member State or one of those languages. The applicant shall also provide, if requested, samples of the preparation and of its ingredients to the Member State.</p> <p>Article 11 Extension of authorizations for minor uses</p> <p>1. The authorization holder, 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.</p> <p>2. Member States shall grant an extension of the field of application of an authorized plant protection product and</p>

SANCO/10159PPP Regulation rev.0 06.04.2005

	<p>shall be obliged to grant such an extension when it is in the public interest to the extent that:</p> <ul style="list-style-type: none"> - 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 referred to in Article 5(3) (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>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 style="text-align: center;">Article 12 Deadline for examination of an application for authorization</p> <p>1. Each Member State shall 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. In principle a decision shall be taken within 12 months from the date of application. Where the Member State requests supplementary information from the applicant, the time-limit laid down above shall be suspended until that information has been provided.</p>
<p>Need to set deadlines for Member States when evaluating an application for authorization. Annex VI (uniform principles) provides currently in principle 12 months. A shorter period is foreseen for low risk products or in case an authorization has already been given in the same zone.</p> <p>For biocides the deadline is 60 days for low risk product registration.</p> <p>For veterinary medicines the deadline is 90 days for mutual recognition.</p>	<p>2. The period referred to in paragraph (1) shall not exceed 90 days for an application for authorization of a plant protection product if it is expected that, according to the evaluation carried out according to the provisions of Annex VI there is a very limited operator, consumer and environmental exposure.</p> <p>or for an application for authorization of a plant protection product where an authorization has already been granted by another Member State located in the same zone</p> <p>3.. The period referred to in paragraph (1) shall not exceed 60 days for an application for registration of a plant protection product where such product only contains active substances for which it was established according to the provisions of Article 18(7) that they present a low risk or where a registration has already been granted by another Member State located in the same zone.</p>
<p>There might be other kinds of products for which it appears in future that a short period can be foreseen for decision making.</p>	<p>4. Where necessary amendments to the provisions of paragraph 2 shall be adopted in accordance with the procedure laid down in Article 54 (3), and having regard to current scientific and technical knowledge.</p>
<p>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 them on request all information necessary for</p>	<p style="text-align: center;">Article 13 Reporting and exchange of information on applications for authorization</p> <p>1. Member States shall ensure that a file is compiled on each application. Each file shall contain at least the following:</p>

Formatiert: Nicht Hervorheben

SANCO/10159PPP Regulation rev.0 06.04.2005

<p>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>Member States are developing a registration report which would currently be helpful for worksharing but in future also in the framework of zonal authorizations</p>	<p>-a copy of the application,</p> <p>- a registration report containing information on the evaluation and decision making on the plant protection product</p> <p>- a record of the administrative decisions taken by the Member State concerning the application and concerning the particulars and documentation laid down in Article 29 together with a summary of the latter.</p> <p>2. Member States shall on request make available to the other Member States, the EFSA and to the Commission the files provided for in the previous paragraph; they shall supply to them on request all information necessary for full comprehension of applications, including any information on the identity of the plant protection product.</p> <p>Member States shall, where requested, ensure that applicants provide a copy of the technical documentation laid down in Article 29.</p>
Article 10 (mutual recognition of authorizations)	Article 14
<p>An obligatory mutual recognition between MS of the same zone is foreseen (and in EU for post harvest uses and glass house use). In order to increase the possibility for harmonized availability of products within the zone, in case industry would not apply for an authorization, also the Member State can take the initiative to accept the authorization (paragraph 5). Farmers could buy the product in another Member State of the same zone provided the MS informs them on the use instructions as is already the case for minor uses.</p> <p>Provisions are based on the system used for veterinary medicinal products (articles 32-33)</p> <p>1. 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 and workers concerned.</p> <p>Subject to compliance with the Treaty, authorization may</p>	<p>Mutual recognition of authorizations</p> <p>1. In order to obtain the mutual recognition in a Member State of an authorization already issued by a Member State (hereinafter: the reference Member State) which belongs to the same zone as defined in Annex IX, the holder of the authorization shall submit an application to the competent authority of the Member State concerned. The applicant shall submit with its applications</p> <ul style="list-style-type: none"> - a certified copy of the authorization already granted by the reference Member State. - a certification that the plant protection product is identical to that accepted by the reference Member State. <p>- a summary of the dossier as required in Article 29</p> <p>2. A Member State to which an application is made for the authorization of a plant protection product which</p> <ul style="list-style-type: none"> -is already authorized in a reference Member State. <p>or</p> <ul style="list-style-type: none"> - concerns an authorization for use in glasshouse or post-harvest treatment, <p>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 the reference Member State, - authorize the placing of that product on the market in its territory and - accept the conclusions of the reference Member State on classification, packaging and labelling of the plant protection product. <p>3. 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</p>

SANCO/10159PPP Regulation rev.0 06.04.2005

<p>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>products intended to protect the health of the distributors, users and workers concerned.</p> <p>4. A Member State may, in case no application is made to it for mutual recognition of an authorization for an authorization already granted by another Member State of the same zone, also authorize such uses on its territory. In such case the Member State shall ensure that 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>2. 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 style="text-align: center;">Article 15</p> <p>Conciliation procedure in case of refusal of a mutual recognition of authorizations</p> <p>1. Member States shall inform the applicant, the reference Member State, any other Member State concerned by the application and 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 and which they should have authorized in accordance with Article 14. The Member State shall state its reasons in detail and shall indicate what action may be necessary to correct any defect in the application.</p>
<p>Paragraph 2 is based on Article 32.3 of veterinary medicines, paragraph 3 on article 33.2. The Commission may ask the EFSA for an opinion (in case of scientific dispute)</p> <p>3. Without prejudice to Article 23, in cases where a Member State refuses to recognize comparability and accept tests and analyses 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, inter alia, 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>2. The holder of the authorization shall transmit the application to the Commission, inform it of the Member States concerned and to the dates of submission of the application and send it a copy of the authorization granted by the reference Member State. He shall also send the Commission copies of any such authorization which may have been granted by the other Member in respect of the plant protection product concerned, and shall indicate whether any application for authorization is currently under consideration in any Member State.</p> <p>3. All the Member States concerned shall use their best endeavours to reach agreement on the action to be taken in respect of the application. The rapporteur Member State which has required repetition of tests or which has refused to grant the authorization will coordinate these efforts. It shall provide the applicant with the opportunity to make his point of view known orally or in writing. However, if the Member States have not reached agreement within 90 days they shall forthwith refer the matter to the Commission. The Commission may request an opinion of the EFSA on the matter.</p> <p>4. The EFSA shall within 3 months provide to the Commission a report on its conclusion.</p> <p>5. The Commission shall decide on the matter in accordance with the procedure laid down in Article 54 (3). If it decides that there is no comparability in relation to the authorizations granted, it shall also specify the conditions of use under which the non-comparability may be deemed irrelevant. In this procedure account shall be taken, inter alia, of the serious ecological vulnerability problems that may arise in certain</p>

Formatiert: Nicht Hervorheben

	<p>Community regions or zones thereby requiring, if they do arise, specific protection measures.</p> <p>6. 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>No obligation for mutual recognition in zones for products containing substances candidate for substitution.</p> <p>Approach based on the draft proposal for Regulation for food improvement agents.</p> <p>Was article 7 in 91/414.</p>	<p>7. By way of derogation from Article 14, Member States may refuse, in accordance with the general provisions of the Treaty, mutual recognition of authorizations granted for plant protection products containing an active substance which has been included in Annex ID provided that such a limitation can be justified on environmental or health grounds and does not jeopardise the purpose of this Regulation.</p> <p>Member States shall inform each other, the EFSA and the Commission of any decision taken in this respect and indicate the scientific reasons therefore.</p> <p style="text-align: center;">Article 16</p> <p style="text-align: center;">Plant protection products containing a genetically modified micro-organism</p> <p>1. A plant protection product which contains a micro-organism falling under the scope of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC shall be examined in respect of the genetic modification according to that Directive, parallel to the assessment set out in Article 4 of this Regulation. An authorisation under this Regulation may only be granted after the plant protection product in question has been granted written consent for placing it on the market as laid down by Article 19 of Directive 2001/18/EC.</p> <p style="text-align: center;">CHAPTER 3</p> <p style="text-align: center;">Potentially harmful effects</p> <p style="text-align: center;">Article 17</p> <p style="text-align: center;">Information on potentially harmful effects</p> <p>1. The holder of an authorization or those to whom an extension of the field of application has been granted in accordance with Article 11 shall immediately notify the competent authority of all new information of which he is aware or of which he may reasonably be expected to be aware concerning an active substance or a plant</p>

	<p>protection product. In particular he shall notify 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. The obligation to notify shall include information on third country regulatory decisions or evaluations anywhere that might affect or alter the risk assessment.</p> <p>2. This obligation shall continue to apply after inclusion of an active substance in Annex I.</p> <p>3. The notification shall include an assessment on whether and how the new information would change the risk assessment originally performed by the competent authority.</p> <p>4. The parties concerned shall immediately notify this information to the other Member States, the EFSA and to the Commission. The Commission may request an opinion of the EFSA on the matter and shall refer the information to the Committee referred to in Article 54(3)</p> <p>5. The authorization holder shall record and report all suspected adverse reactions in humans related to the use of the plant protection products of which he can reasonably be expected to have knowledge, or which are brought to his attention, immediately to the competent authority of the Member State in whose territory the incident occurred, and in no case later than 15 calendar days following the receipt of the information.</p> <p>6. The authorization holder shall annually report any available information related to the lack of expected efficacy, development of resistance and to any unexpected influence on plants, plant products or the environment.</p>
<p>Article 5 (inclusion of active substances in Annex I)</p>	<p>TITLE 3 – ACTIVE SUBSTANCES</p> <p>Article 18 Criteria for inclusion of active substances in Annex I</p>
<p>1. 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 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>inclusion criteria are included in Annex VII Need to evaluate also efficacy at Annex I inclusion in</p>	<p>1. In the light of current scientific and technical knowledge, an active substance shall be included in Annex I if it may be expected that, pursuant to the inclusion criteria provided for in Annex VII, plant protection products containing the 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 and having regard to normal conditions of use, is sufficiently effective, does not have any harmful effects on human or animal health or any unacceptable influence on plants, plant products or the environment as provided for in Article 5(3).</p>

SANCO/10159PPP Regulation rev.0 06.04.2005

<p>order to reduce need for duplication at MS level and to avoid that unrealistic use conditions are proposed for Annex I inclusion. Also in biocides efficacy is a criterion for Annex I inclusion.</p>	
<p>Substances for which there is evidence after evaluation that they have unacceptable effects will be included in Annex VIII. All substances currently in 79/117 are already listed in this Annex.</p> <p>No need to clarify further the procedure. If necessary EFSA can be consulted by COM. In most cases there will be a proposal anyhow after evaluation of a dossier by EFSA.</p> <p>Substances for which the non-inclusion is based on the fact that no dossier is submitted, would not be included in this Annex.</p>	<p>2. An active substance shall be included in Annex VIII, in accordance with the procedure laid down in Article 54 (3), if it has been established that</p> <p>(a) their residues, consequent on application consistent with good plant protection practice, have a harmful effect on human or animal health or on groundwater or an unacceptable influence on the environment, or</p> <p>(b) their use, consequent on application consistent with good plant protection practice and having regard to normal conditions of use, has a harmful effect on human or animal health or an unacceptable influence on plants, plant products or the environment.</p>
<p>2. 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>Deleted and added in Annex VII</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>Deleted and added in Annex VII</p> <p>Makes text coherent with current approach in the review programme</p>	<p>3. For the first inclusion of an active substance the requirements shall be deemed to be satisfied where this has been established for a limited range of representative uses for at least one preparation containing the said active substance.</p>

SANCO/10159PPP Regulation rev.0 06.04.2005

<p>4. Inclusion of an active substance in Annex I may be subject to requirements such as:</p> <ul style="list-style-type: none"> - 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>Addition of further conditions for inclusion such as cases where confirmatory information is required.</p> <p>Addition in paragraph 5 of text concerning GMMs</p>	<p>4. Inclusion of an active substance in Annex I may be subject to requirements such as:</p> <ul style="list-style-type: none"> - 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 17, taking account of the agricultural, plant health and environmental (including climatic) conditions in question, - type of preparation, - manner of use - submission of further confirmatory information to Member States and EFSA where new requirements are established during the evaluation process as a result of new scientific and technical knowledge. - designation of categories of users (e.g. professional and non-professional) - designation of authorisation zone(s) where the active substance is supposed to be authorised according to specific conditions - Other particular conditions that result from the evaluation of information made available in the context of this Directive. - the need to impose risk mitigation measures and monitoring after use <p>5. Inclusion of an active substance which is a GMM shall be done separately for each different modification</p>
	<p>6. On request of the applicant at the application for inclusion in Annex I it may be established, using the procedure detailed in Article 54 (3) that the active substance presents a low risk</p>
<p>Similar provisions as in biocides</p>	<p>7. An active substance cannot be included in Annex IB if it is classified according to Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administration provisions relating to classification, packaging and labelling of dangerous substances as:</p> <ul style="list-style-type: none"> - carcinogenic - mutagenic - toxic for reproduction - sensitizing, or - bioaccumulative, toxic and not readily degradable. <p>An active substance cannot be included in Annex IB if there is information indicating that the active substance is an endocrine disruptor.</p> <p>A substance presenting all of the above characteristics cannot be included in Annex I.</p> <p>8. An inclusion of an active substance in Annex I may be refused or removed,</p> <ul style="list-style-type: none"> - if the evaluation of the active substance in accordance with paragraph (1) shows that, under normal conditions under which it may be used in authorised plant protection products, risks to health or the environment still give rise to concern, and - if there is another active substance on Annex I for the same product type, which, in the light of scientific or technical knowledge, presents significantly less risk to

	<p>health or to the environment.</p> <p>When such a refusal or removal is considered, an assessment of an alternative active substance or substances shall take place to demonstrate that it can be used with similar effect on the target organism without significant economic and practical disadvantages for the user and without an increased risk for health or for the environment.</p> <p>The assessment shall be circulated in accordance with the procedures in Article 20</p> <p>(ii) The refusal or removal of an Annex I inclusion shall be carried out under the following conditions:</p> <ol style="list-style-type: none"> 1. the chemical diversity of the active substances should be adequate to minimise occurrence of resistance in the target organism; 2. it should be applied only to active substances which, when used under normal conditions in authorised plant protection products, present a significantly different level of risk; 3. it should be applied only after allowing the possibility, where necessary, of acquiring experience from use in practice, if it is not already available;
<p>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 necessary to provide information requested in accordance with Article 6 (4).</p> <p>Low risk active substances or commodity substances may be included for a longer period in Annex I; substances which are candidate for substitution may be included for maximum 7 years so that they are reviewed more regularly.</p> <p>Renewal of inclusion is foreseen in Article 21</p>	<p style="text-align: center;">Article 19</p> <p>Period of inclusion of active substances in Annex I</p> <p>(1) An active substance will be included in Annex IA, IB or IC for an initial period not exceeding 10 years.</p> <p>(2) By way of derogation from paragraph (1): - an active substance may be included in Annex IB or IC for an initial period not exceeding 15 years where, after the evaluation performed in accordance with the procedure of Article 20, it is established that the active substance presents significantly less risk to health or to the environment than other active substances already included in Annex I.</p> <p>- an active substance which is included in Annex ID will be included for an initial period not exceeding 7 years.</p>
<p>Article 6</p>	<p>Article 20</p> <p>Procedure for Annex I inclusion or amending an inclusion in Annex I</p>
<p>1. 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 from Annex I if it no longer satisfies the requirements of Article 5(1) and (2). <p>Additions in order to reflect current practice (to large</p>	<p>1. Inclusion of an active substance in Annex I shall be decided in accordance with the procedure laid down in Article 54 (3).</p> <p>The following shall also be decided in accordance with that procedure:</p> <ul style="list-style-type: none"> - any conditions for inclusion, including the need for the provision of additional information, risk mitigation, monitoring, or other measures which must be applied before authorisations can be granted for products containing the substance, - amendments to Annex I, where necessary, - removal of an active substance from Annex I if it no

<p>extent based on review Regulations)</p> <p>Council on 25-26.11.2004 (at suggestion of Sweden) requested in framework of simplification that deadlines for withdrawal or grace periods should not interfere with normal use period (Council proposed to set systematically 1 January but this is not always appropriate)</p>	<p>longer satisfies the requirements of Article 6(1) and (2) or if the further information required in accordance with Article 11(13) has not been submitted within the deadlines specified</p> <ul style="list-style-type: none"> - any conditions related to the removal of an active substance from Annex I such as delayed phase-out periods in case no efficient alternatives are available;. - criteria, guidelines and requirements in Annex VII. <p>In the case that an active substance is removed from Annex I the Member States shall withdraw the authorizations of plant protection products containing the active substance; when the reasons for the withdrawal allow it the deadlines for withdrawal of authorizations and expiry of grace periods will be set in such a way that they do not interfere with the normal use period of the plant protection product.</p>
<p>2. 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>2. An applicant wishing to secure inclusion of an active substance, in Annex I shall submit to a Member State a complete dossier, or a letter of access, and a summary dossier for the active substance satisfying the requirements of Annex II and a dossier, or a letter of access, for at least one preparation containing that substance satisfying the requirements of Annex III..</p>
<p>Based on article 17.2 of genetically modified feed and food (Regulation 1829/2003)</p> <p>Based on provisions on third stage of the review programme</p>	<p>3. The national competent authority shall:</p> <ul style="list-style-type: none"> (i) acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application; (ii) inform the EFSA without delay, and (iii) invite the applicant to make the application and any supplementary information available to the EFSA. <p>The EFSA shall:</p> <ul style="list-style-type: none"> (i) inform without delay the other Member States and the Commission of the application; (ii) make the summary of the dossier referred to in paragraph 3(1) available to the public. <p>4. The summary dossier shall include the following:</p> <ul style="list-style-type: none"> (a) A limited range of representative uses of the active substance, in respect of which the data submitted by the notifier in the dossier shall demonstrate that for one or more preparations, the requirements set out in Article 18 for inclusion of the active substance in Annex I, can be met; (b) (i) for each point of Annex II the summaries and results of studies and trials, the name of the person or institute that has carried out the trials, (ii) for each point of Annex II the summaries and results of studies and trials, the name of the person or institute

Formatiert: Hervorheben

Formatiert: Nicht Hervorheben

Formatiert: Nicht Hervorheben

SANCO/10159PPP Regulation rev.0 06.04.2005

	<p>that has carried out the trials, relevant to the assessment of the criteria referred to in Article 18 for one or more preparations which are representative for the uses referred to in subparagraph (a) taking into account that data gaps in the information of the Annex II dossier resulting from the proposed limited range of representative uses of the active substance may lead to restrictions in the inclusion into Annex I</p> <p>(c) a checklist to be filled in by the notifier, demonstrating that the dossier is complete.</p> <p>5. The complete dossier shall physically contain the individual test and study reports concerning all the information referred to in paragraph 4(b).</p> <p>6. Each Member State shall define the number of copies and the format of the summary and the complete dossiers to be submitted by the applicants. In defining the format of the dossier Member States shall take account of the recommendations made in accordance with the procedure provided for in Article 54 (2).</p>
<p>No EU completeness decision any more. Also for existing active substances the current system provides that it is the rapporteur who decides on completeness without any formal Commission decision. In the biocides Directive the Commission is also not involved in the completeness (article 11 (1) (b)).</p>	<p>7. The EFSA shall at the latest three months after the receipt of such application report to the Commission whether the dossier is believed to satisfy the requirements of Annexes II and III ('completeness check'). It 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 Member States and to the Commission together with a dossier complying with Annex III on at least one preparation containing it.</p>
<p>Addition of reference to Community reference laboratories which would be created in 2005-2006 for residues of plant protection products. (see also Article 32.1.c of veterinary medicines).</p> <p>3. 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>	<p>8. In order to prepare its conclusion the EFSA shall ask the competent Authority of a Member State to act as rapporteur. In such case the rapporteur shall prepare for the EFSA the examination of the application concerned and maintain in this context the necessary contacts with the applicant and/or other data holders, in consultation with EFSA.</p> <p>The Commission, when EFSA asks for it, may request a Community reference laboratory, to verify, using samples provided by the applicant, that the analytical detection method proposed by the applicant is satisfactory and meets the requirements of Article 5.5.</p>
	<p>9 The rapporteur shall ensure that it submits to the EFSA a draft report of its assessment of the dossier as quickly as possible, and at the latest 12 months after the dossier was determined to be complete.</p>

Formatiert: Nicht Hervorheben

Formatiert: Nicht Hervorheben

SANCO/10159PPP Regulation rev.0 06.04.2005

From biocides Directive	10. The EFSA shall circulate the draft assessment report to the Member States. The EFSA shall allow a period of 90 days during which all relevant stakeholders including the applicant may submit comments to it in writing. Before finalising its conclusion the EFSA may organise a consultation of experts including from the rapporteur.
The time period for the peer review is reduced from 12 to 6 months. The peer review could already start even before the draft assessment report is finalised.	11. The EFSA shall deliver its conclusion on whether the active substance, synergist or safener can be expected to meet the safety requirements of Article 5 to the Commission at the latest 18 months after the dossier was determined to be complete. Where appropriate, the EFSA shall give its opinion on the risk mitigation options identified in the draft assessment report by the rapporteur.
	12. Where the 18 months period referred to in paragraph (11) is likely to be exceeded because of particular unusual problems with regard to the treatment of the dossier, the data which were presented or to technical aspects related to the substance concerned, the EFSA shall before the end of that period supply to the Commission and the other Member States a documented justification, with a clear and reasoned indication of the additional time required to submit its conclusion.
4. 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 unfavourable decision is envisaged. 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.	13. If the assessment of the dossier referred to in paragraph (2) shows that further information is necessary, the designated rapporteur in consultation with the EFSA, or the EFSA acting alone may ask the applicant to submit such information. Where the EFSA requests supplementary information from the applicant, the time-limit laid down in paragraphs (9) or (11) shall be suspended until that information has been provided. In such case the EFSA shall inform the Commission and the Member States of such requests.
	14. At the latest six months after receipt of the EFSA conclusion the Commission shall submit a draft review report on the substance to the Committee. On the basis of the finalised review report it shall submit to the Committee a draft Directive to include the substance in Annex I, or a draft decision addressed to the Member States to withdraw the existing authorizations of plant protection products containing it whereby that substance is not included in Annex I.
It is already current practice to consult the notifier whenever a negative decision is foreseen. See also biocides art 27 (3)	15. The applicant or his authorized representative shall be asked by the Commission to submit his remarks to it, in particular whenever an unfavourable decision is envisaged.
	16. The procedures laid down in this Article 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 18, or if renewal in accordance with Article 21 is being considered.
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	17. Amendments to the procedures concerning the submission and appraisal of applications covered by this Article shall be adopted in accordance with the procedure laid down in Article 54 (3). 18. The format for the dossier, the draft assessment report and the conclusions of the EFSA shall be adopted

Formatiert: Nicht Hervorheben

Renewal for maximum 15 years in order to bring in line with longest inclusion period foreseen for low risk substances. It should also be considered that substances have already been evaluated once and that Member States are continuously evaluating new uses during the first period of inclusion. Repeating the evaluation at EU level every 10 years could trigger a major burden which is not necessarily justified. In case of problems with a substance there is always the possibility to evaluate the substance much quicker.

In order to ensure that generic companies are informed correctly and timely about which studies could be further eligible for data protection the notifier has to inform already at the application for renewal on the claims for data protection. Notifiers should justify why they submit new studies in order to avoid that studies will obtain data protection in cases where existing studies would still be sufficient for the renewal. It should be decided in the Regulation establishing the renewal programme how this will be done.

The EFSA will make such information available to the public.

in accordance with the procedure laid down in **Article 54 (2)**.

Article 21 Renewal of Annex I inclusion

1. On request, the inclusion of a substance in Annex I may be renewed once or more. Each renewal may not exceed 15 years. An application for renewal shall be made by a producer of the active substance to a Member State in sufficient time, and in any case not less than two years before the inclusion in Annex I is due to lapse. At the application for renewal notifiers shall inform the Member States, the EFSA and the Commission which new data they intend to submit, including justifications for the submission of such information, any claims for data protection and a timetable of any new ongoing studies. The EFSA shall make this information available to the public.

Where an application has been made in time, the inclusion may be prolonged for a certain period; the length of that period will be established taking into account the following:

- the time necessary to provide information requested in accordance with **Article 20(13)**
- the time necessary to complete a review
- the need to ensure the establishment of a coherent programme as foreseen in paragraph 2.

2. The Commission shall establish a programme of work for the gradual review of active substances for which their inclusion in Annex I should be renewed. This programme may require interested parties to submit all necessary data to the Commission, the EFSA and the Member States within a period provided for in the programme.

A Regulation, adopted according to the procedure laid down in **Article 54 (3)** will set out all the provisions necessary for the implementation of the programme, including details concerning:

- the procedures concerning the submission and appraisal of applications for renewal of inclusion in Annex I
- the necessary data to be submitted;
- justifications to be submitted by notifiers for the submission of new information and any claims for data protection.

3. The inclusion of an active substance in Annex I may be renewed if it is established that the criteria referred to in **Article 18** are satisfied.

4. The renewal of inclusion of an active substance in Annex I and the prolongation of an inclusion shall be decided in accordance with the procedure laid down in **Article 54 (3)**.

5. The format for the dossier, the draft assessment report

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Formatiert: Nicht Hervorheben

SANCO/10159PPP Regulation rev.0 06.04.2005

and the conclusions of the EFSA shall be adopted in accordance with the procedure laid down in **Article 54 (2)**.

Article 22 **Review of an inclusion**

An inclusion of an active substance in Annex I may be reviewed at any time if there are indications that the criteria referred to in **Article 18** are no longer satisfied. In such case the procedures laid down in Article 20 shall be applied.

Article 23

Equivalence of new sources of an active substance

1. When a Member State receives an application for authorization of a plant protection product containing an active substance which has been produced by a person or manufacturing process other than those specified in the dossier on the basis of which the active substance was first included in Annex I, it shall ensure that the applicant submits all data regarding the identify and impurities of the new source of the active substance to the Member State which competent authority acted as rapporteur for the active substance.

That Member State shall evaluate the similarity of the chemical composition presented by the new source of technical materials. If the new source presents a similar, or lesser hazard, compared to the reference source the new source can be considered equivalent to the reference source. The Member State shall inform the Commission and the other Member States on the result of the equivalence check.

2. In accordance with the procedure of **Article 54(3)** and after consultation of the EFSA, detailed rules for the assessment of the equivalence of technical materials of active substances can be established

3. Where a Member State does not accept the conclusions of the rapporteur Member State on the equivalence it shall inform the applicant, the rapporteur Member State, any other Member State concerned and the Commission. The Member State shall state its reasons in detail.

The Member States concerned shall use their best endeavours to reach agreement on the action to be taken in respect of the application. The Member State which has not accepted the equivalence will coordinate these efforts. It shall provide the applicant with the opportunity to make his point of view known orally or in writing. However, if the Member States have not reached agreement within 90 days they shall forthwith refer the matter to the Commission. The Commission

A guidance document on equivalence already provides that the the rapporteur should be involved in the equivalence check. Detailed rules can be established on the basis of the current guidance document. If necessary also EFSA can be consulted.

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Formatiert: Nicht Hervorheben

may request an opinion of the EFSA.

4. The EFSA shall within 3 months provide to the Commission a report on its conclusion.

5. The Commission shall decide on the matter in accordance with the procedure laid down in **Article 54 (3)**.

**TITLE 4 –
SAFENERS, SYNERGISTS, ADJUVANTS
AND CO-FORMULANTS**

**Article 24
Decisions on safeners, synergists, adjuvants
and co-formulants**

1. Within 5 years of the entry into force of this Regulation, the Commission shall adopt, using the procedure detailed in **Article 54 (3)**, measures to ensure that the marketing and use of synergists and safeners, adjuvants and co-formulants used in plant protection products meet equivalent the safety standards as those adopted for active substances. These measures may include the establishment of data requirements in Annex II D, notification, evaluation, assessment and decision-making procedures, criteria for inclusion together with any restriction measures that may be required.

2. The Commission shall establish a programme of work for the gradual review of synergists and safeners on the market 5 years of the entry into force of this Regulation. This programme will require interested parties to submit all requisite data to the Commission, the EFSA and the Member States within a period provided for in the programme. A Regulation, adopted according to the procedure laid down in **Article 54 (3)**, will set out all the provisions necessary for the implementation of the programme.

3. The provisions detailed in **Article 19, 20 and 21** shall apply for synergists and safeners which were not on the market 5 years of the entry into force of this Regulation.

4. Adjuvants and co-formulants will be included in Annex VIII if it is established that they are of concern in accordance with the procedure laid down in **Article 54 (3)**.

Further implementing measures for safeners and synergists will be established by Committee procedure.

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Article 8 (transitional measures and derogations)	TITLE 5 Transitional measures and derogations
<p>The current system provides for a 3 year provisional authorization after the completeness check at EU level. It leads to duplication of work in all Member States where an application for provisional authorization is made.</p> <p>It is proposed to delete the system because inclusion decisions would be taken in the future within 2 years. Industry will have to ensure that their dossiers are complete from the start. EFSA will do the completeness check. A decision on inclusion is often delayed pending the evaluation of further information whilst at the same time MS have a provisional authorization; so there is no time pressure to come to a decision on the inclusion. COM often has to prolong the deadline of 3 years for provisional authorizations. Moreover it would not be coherent with the zonal mutual recognition and worksharing if MS have already to evaluate products for provisional authorization.</p> <p>COM also proposed in the draft legislation on additives to remove the system of provisional authorizations because the Commission wants to create a more centralized system.</p> <p>1. 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.</p>	

<p>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 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).</p> <p>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>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.</p> <p>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.</p> <p>Ten years following notification of this Directive the Commission shall present to the European Parliament and the Council a progress report on the programme. 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 a prescribed period.</p> <p>Derogation not required any more for active substances because they would all have been evaluated before the new Directive enters into force. However such derogation is necessary for safeners and synergists. A period of 10 years should be sufficient: 5 years to adopt the detailed rules, 2 years to prepare the dossiers, 3 years to do the</p>	<p style="text-align: center;">Article 25 Derogation for safeners and synergists</p> <p>By way of derogation from Article 5, a Member State may, during a period of 10 years following the entry into force of this Regulation, authorize the placing on the market in its territory of plant protection products containing synergists and safeners not listed in Annex I that are already on the market two years after the entry into force of this Regulation.</p>

Formatiert: Nicht Hervorheben

<p>evaluations and to take a decision</p>	
<p>3. 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>Paragraph deleted because not necessary any more.</p>	
<p>4. 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 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>Deletion of “unforeseeable” danger. If there are no other authorized products it is difficult to argue that the plant protection problem was unforeseeable.</p> <p>EFSA is involved in checking the risks associated with the derogations.</p>	<p style="text-align: center;">Article 26 Emergency authorization</p> <p>By way of further derogation from Article 5, in special circumstances a Member State may authorize for an emergency period not exceeding 120 days the placing on the market of plant protection products not complying with Article 5 for a limited and controlled use if such a measure appears necessary because of a 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, providing details of all the information on which the emergency authorisation was based. The Commission may request an opinion of the EFSA on the matter and shall refer the information to the Committee referred to in Article 54 (3). The EFSA shall provide an opinion to the Commission and to the Member States on the risks associated with the measure within a period of one month. It shall be decided without delay, in accordance with the procedure laid down in Article 54 (3), whether and under which conditions the action taken by the Member State may be extended for a given period, repeated, or revoked, and whether the treated crop may be safely marketed.</p> <p>This derogation does not apply to plant protection products containing or composed of GMMs.</p>

<p>Article 22 (research and development)</p>	<p>TITLE 6 RESEARCH AND DEVELOPMENT Article 27 Research & development</p>
<p>1. 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>1. 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 by the competent authorities of the Member State and under controlled conditions and for limited quantities and areas.</p>
<p>2. 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.</p> <p>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 may either prohibit them or permit them subject to such conditions as it considers necessary to prevent those consequences.</p>	<p>2. 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.</p> <p>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 may either prohibit them or permit them subject to such conditions as it considers necessary to prevent those consequences.</p>
<p>3. 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.</p>	<p>3. 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.</p>
<p>4. 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.</p>	<p>4. 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 54 (2).</p>
<p>5. This Article shall not apply to experiments or tests covered by Part B of Directive 90/220/EEC.</p>	<p>5. This Article shall not apply to experiments or tests covered by Part B of Directive 2001/18/EC.</p>
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SANCO/10159PPP Regulation rev.0 06.04.2005

TITLE 7 EXCHANGE OF INFORMATION ON AUTHORIZATIONS	
Article 12 (exchange of information)	Article 28 Obligation for exchange of information
<p>1. Within a period of one month at the end of each quarter at least, Member States shall inform each other and the Commission in 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, - 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 provisionally established. <p>- There is no need to circulate lists of information if the information is kept available on a website.</p> <p>- No need to provide information on MRLs because all MRLs will be harmonized at EU level when this Regulation enters into force</p> <p>-</p>	<p>1. Member States shall keep information electronically available on plant protection products authorized or withdrawn, in accordance with the provisions of this Regulation, 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 product, - the type of preparation, - the name and amount of each active substance which it contains, - the use or uses for which it is intended, - where relevant, the reasons for withdrawal of an authorization.
<p>2. 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.</p> <p>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>Member States shall receive sales data (same provisions as veterinary medicine – Article 38-4) but Paragraph 3 can be deleted if the Regulation developed by EUROSTAT on reporting of sales data is adopted.</p>	<p>2. Member States shall ensure that such information is regularly updated, and at least every trimester.</p> <p>[3. Authorization holders shall provide the competent authorities of the Member States with all data relating to the volume of sales of plant protection products.]</p> <p>4. In accordance with the procedure laid down in Article 54 (2)a standardized information system may be set up by the Commission to facilitate the application of paragraphs 1 to 3.</p>

<p>Article 13 (data requirements, data protection and confidentiality)</p>	<p>TITLE 8 DATA REQUIREMENTS Article 29 Data requirements</p>
<p>1. Without prejudice to Article 10, Member States shall require that applicants for authorization of a plant protection product submit with their application:</p> <p>(a) a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex III; and</p> <p>(b) for each active substance in the plant protection product, a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex II.</p>	<p>1. Without prejudice to Article 14, Member States shall require that applicants for authorization of plant protection product submit with their application:</p> <p>(a) a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex III; and</p> <p>(b) for each active substance, safener and synergist in the plant protection product, a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex II.</p>
<p>2. 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>Editorial change to refer to equivalence as foreseen in Article 23s</p>	<p>2. By way of derogation from paragraph 1, and without prejudice to the provisions of Articles 30 to 35, applicants shall be exempted from supplying the information, test and study reports 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 equivalence has been established in accordance with Article 23.</p>
<p>3. In granting authorizations, Member States shall not make use of the information referred to in Annex II for the benefit of other applicants:</p> <p>(a) unless the applicant has agreed with the first applicant that use may be made of such information; or</p> <p>(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</p> <p>(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</p> <p>(d) for a period of five years from the date of a decision, following receipt of further 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>TITLE 9 DATA PROTECTION AND DATA SHARING CHAPTER 1 Protection for data on the active substance Article 30 Data protection at first inclusion of the active substance</p> <p>1. In granting authorizations, Member States shall not make use of the information, test and study reports referred to in Annex II for the benefit of other applicants where such information, test and study reports were certified as compliant with the principles of Good Laboratory Practice less than seven years prior to the date of receipt of the application referred to in Article</p>

SANCO/10159PPP Regulation rev.0 06.04.2005

The provisions on data protection are structured in a different way in order to try to make them easier to understand.
Through use of the date of GLP certification and the date of acceptance of the dossier as being complete, as a basis for decisions on eligibility for data for protection, the system would be greatly simplified. A period of 7 years is chosen because that is the normal period for development of an active substance.

Points (b) and (c) are inserted to preclude protection being granted a second time for studies that were previously already granted protection (e.g. resolved isomers)

Article 31 (3): The change in commencement date for protection is intended to preclude erosion of the 5-year period of protection, as currently happens.

In order to ensure that generic companies are informed correctly about which studies could be further eligible for data protection, the notifier has to claim data protection and has to justify why data are new. This information will be made publicly available (see article 36)

20(3) unless:

- (a) the applicant has agreed with the first applicant that use may be made of such information, test and study reports; or
 - (b) unless any period of protection granted has expired; or
 - (c) any period of protection granted for the information, test and study reports concerned in relation to another active substance has expired.
2. The period for protection shall expire ten years after the first inclusion in Annex I of the active substance takes effect.
3. The procedure for arbitration foreseen in **Article 38** shall not apply to the information, tests and study reports referred to in paragraph 1.

Article 31

Data protection when the inclusion of the active substance is reviewed

1. In granting authorizations, Member States shall not make use of the information, test and study reports referred to in Annex II for the benefit of other applicants where such information, test and study reports :
- were certified as compliant with the principles of Good Laboratory Practice less than five years prior to date of submission and
 - are necessary either to vary the conditions for, or to maintain, the inclusion of an active substance in Annex

unless:

- (a) the applicant has agreed with the first applicant that use may be made of such information, test and study reports; or
 - (b) unless any period of protection granted has expired; or
 - (c) any period of protection granted for the information, test and study reports concerned in relation to another active substance has expired.
2. In order to be eligible for data protection, a notifier shall claim data protection and provide to Member States and the EFSA for each individual information, test or study report the following information:

SANCO/10159PPP Regulation rev.0 06.04.2005

New : data protection for Annex II data which are not required for an inclusion but for an authorization. Such protection is foreseen since at Annex I inclusion, Annex II data may not have to be submitted because they are not relevant for the limited number of uses chosen to support Annex I inclusion. Therefore it is necessary to foresee data protection as well at reregistration of the product.

In 1991 it was intended to evaluate all uses of an active substance, assuming that all Annex II data would have to be submitted for Annex I inclusion; experience showed that this is not possible.

- an acceptable justification that the submitted new information, test and study reports are the result of data requirements or criteria which were not implemented at the first inclusion of the active substance or are necessary for varying the inclusion;
 - a confirmation that the information, test and study reports were never used before their submission by a Member State in order to decide on an authorization;
 - an indication of the date at which the information, test and study reports were certified as compliant with the principles of Good Laboratory Practice.
- 3.. The protection period shall be five years, commencing six months after the date at which the amended or renewed inclusion takes effect, unless the five-year period expires before the period provided for in Article 30 , in which case the period of five years shall be extended so as to expire on the same date as that period.

Article 32

Data protection when the authorization of the plant protection product is reviewed

In granting authorizations, Member States shall not make use of the information, test and study reports referred to in Annex II for the benefit of other applicants where such information, test and study reports :

- were certified as compliant with the principles of Good Laboratory Practice or Good Experimental Practice less than five years prior to date of submission and
- are necessary to maintain the authorization of a plant protection product

unless:

- (a) the applicant has agreed with the first applicant that use may be made of such information, test and study reports; or
- (b) unless any period of protection granted has expired; or
- (c) any period of protection granted for the information, test and study reports concerned in relation to another active substance has expired.

2. In order to be eligible for data protection, a notifier shall claim data protection and provide to Member States for each individual information, test or study report the following information:

	<ul style="list-style-type: none"> -an acceptable justification that the submitted new information, test and study reports are the result of data requirements or criteria which were not implemented at the first inclusion of the active substance or are necessary for varying the inclusion; - a confirmation that the information, test and study reports were never used before their submission by a Member State in order to decide on an authorization; - an indication of the date at which the information, test and study reports were certified as compliant with the principles of Good Laboratory Practice. <p>3. The protection period shall be five years, commencing six months after the existing authorization has been amended or granted again unless the five-year period expires before the period provided for in Article 30, in which case the period of five years shall be extended so as to expire on the same date as that period.</p>
<p>4. In granting authorizations, Member States shall not make use of the information referred to in Annex III to the benefit of other applicants:</p> <p>(a) unless the applicant has agreed with the first applicant that use may be made of such information; or</p> <p>(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</p> <p>(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>Article 33.2: The period where data protection starts depends on the authorization date in each Member State individually. This intends to simplify the system – since Member States cannot easily establish the date of authorisation in other Member States of products of particular specification.</p> <p>.</p>	<p style="text-align: center;">Chapter 2</p> <p style="text-align: center;">Protection for data on the plant protection product</p> <p style="text-align: center;">Article 33</p> <p style="text-align: center;">Data protection at first authorization of the plant protection product</p> <p>1. In granting authorizations and without prejudice to paragraph (2), Member States shall not make use of the information, test and study reports referred to in Annex III for the benefit of other applicants where such information, test and study reports were certified as compliant with the principles of Good Laboratory Practice or with the principles of Good Experimental Practice less than seven years prior to date of submission unless:</p> <p>(a) the applicant has agreed with the first applicant that use may be made of such information, test and study reports; or</p> <p>(b) any period of protection granted has expired; or</p>

<p>Article 34: New: data protection for Annex III data necessary for the review of inclusion of an active substance in Annex I. At the review of existing active substances also important data in relation to the plant protection product may be required; for such data also an additional protection period should be foreseen. The extension of data protection to data which in 91/414 did not get further protection is “compensated” by the fact that there is no exclusivity for such data .</p>	<p>(c) any period of protection granted for the information in relation to another plant protection product has expired.</p> <p>2. The period for protection shall expire ten years from first authorization in each Member State for the plant protection product.</p> <p>3. The procedure for arbitration foreseen in Article 38 shall not apply to the information, tests and study reports referred to in paragraph 1.</p> <p style="text-align: center;">Article 34</p> <p style="text-align: center;">Data protection when the inclusion of the active substance is reviewed</p> <p>1. In granting authorizations, Member States shall not make use of the information, test and study reports referred to in Annex III for the benefit of other applicants where such information, test and study reports :</p> <ul style="list-style-type: none"> - were certified as compliant with the principles of Good Laboratory Practice or Good Experimental Practice less than five years prior to date of submission and - are necessary either to vary the conditions for, or to maintain, the inclusion of an active substance in Annex I unless: <ul style="list-style-type: none"> (a) the applicant has agreed with the first applicant that use may be made of such information, test and study reports; or (b) any period of protection granted has expired; or (c) any period of protection granted for the information in relation to another plant protection product has expired. <p>2. In order to be eligible for data protection, a notifier shall claim data protection and provide to Member States and the EFSA for each individual information, test or study report the following information:</p> <ul style="list-style-type: none"> -an acceptable justification that the submitted new information, test and study reports are the result of data requirements or criteria which were not implemented at the first inclusion of the active substance or are necessary for varying the inclusion; - a confirmation that the information, test and study reports were never used before their submission by
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SANCO/10159PPP Regulation rev.0 06.04.2005

Article 35: New: also data protection for studies required to review a plant protection product. Since only a limited range of uses is examined at Annex I inclusion or renewal, it is necessary to foresee data protection as well at reregistration of the product..

a Member State in order to decide on an authorization;

- an indication of the date at which the information, test and study reports were certified as compliant with the principles of Good Laboratory Practice.

3. The protection period shall be five years, commencing six months after the date inclusion takes effect unless the five-year period expires before the period provided for in Article 33, in which case the period of five years shall be extended so as to expire on the same date as those periods.

Article 35

Data protection when the authorization of the plant protection product is reviewed

1. In granting authorizations, Member States shall not make use of the information, test and study reports referred to in Annex III for the benefit of other applicants where such information, test and study reports :

- were certified as compliant with the principles of Good Laboratory Practice or Good Experimental Practice less than five years prior to date of submission and

- are necessary to maintain, the authorization of a plant protection product unless:

(a) the applicant has agreed with the first applicant that use may be made of such information, test and study reports; or

(b) any period of protection granted has expired; or

(c) any period of protection granted for the information in relation to another plant protection product has expired.

2. In order to be eligible for data protection, a notifier shall claim data protection and provide to Member States for each individual information, test or study report the following information:

-an acceptable justification that the submitted new information, test and study reports are the result of data requirements or criteria which were not implemented at the first inclusion of the active substance or are necessary for varying the inclusion;

- a confirmation that the information, test and study reports were never used before their submission by a Member State in order to decide on an

	<p>authorization;</p> <ul style="list-style-type: none"> - an indication of the date at which the information, test and study reports were certified as compliant with the principles of Good Laboratory Practice. <p>3. The protection period shall be five years, commencing six months after the existing authorization has been amended or granted again unless the five-year period expires before the period provided for in Article 31, in which case the period of five years shall be extended so as to expire on the same date as those periods.</p>
<p>5. 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 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>The requirements for submission of information and their possible protection status should be transparent in order to ensure that also generic companies can prepare themselves when applying for authorizations or for inclusion of active substances in Annex I;</p>	<p style="text-align: center;">Chapter 3</p> <p style="text-align: center;">Information on data protection</p> <p style="text-align: center;">Article 36</p> <p style="text-align: center;">Obligation to inform about data protection</p> <p>Member States shall keep available as soon as possible, and from an early stage in the procedure to evaluate active substances or plant protection products, to any interested parties the following information:</p> <ul style="list-style-type: none"> - any claims for data protection and the justifications thereto; - the list of information, test and study reports referred to in Annex II and III necessary for first inclusion of the active substance in Annex I; - the list of information, test and study reports referred to in Annex II and III necessary either to vary the conditions for, or to maintain, the inclusion of an active substance in Annex I; - - the list of information, test and study reports referred to in Annex II and III necessary for first authorization of a plant protection product; - - the list of information, test and study reports referred to in Annex II and III necessary to vary the conditions for, or to maintain, the authorization of a plant protection product. <p>It shall be indicated for all such studies whether they are certified as compliant with the principles of Good Laboratory Practice or with the principles of Good Experimental Practice less than seven or five years</p>

	<p>prior to the date of submission.</p>
<p>6. 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>Derogation, not necessary any more</p> <p>7. Notwithstanding paragraph 1, and without prejudice to Article 10, where the active substance is listed in Annex I:</p> <p>(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:</p> <ul style="list-style-type: none"> - 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. <p>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;</p> <p>(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 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>Article 37: Data sharing should be made obligatory in</p>	<p style="text-align: center;">Chapter 4</p> <p style="text-align: center;">Data sharing and avoidance of duplicative testing</p> <p style="text-align: center;">Article 37</p> <p style="text-align: center;">Data sharing</p> <p>The holder or holders of previous authorizations and the applicant for an authorization of a plant protection product shall take all reasonable steps to reach agreement on the sharing of information, test and study reports. Therefore second applicants for authorization of plant protection products shall, before carrying out experiments, enquire of the competent authority of the Member State to which they intend making application:</p> <ul style="list-style-type: none"> - 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. <p>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 above is available;</p> <p>2. 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 authorizations and shall at the same time inform the holders of the authorizations of the name and address of the applicant.</p> <p>3. The provisions of this Article apply also where information, test and study reports are requested with a view to inclusion or continued inclusion in Annex I of an</p>

SANCO/10159PPP Regulation rev.0 06.04.2005

order to avoid unnecessary testing with vertebrates and to ensure that re-evaluation of active substances does not lead to the creation of monopolies. If no agreement between companies can be found, an arbitration system is foreseen.

Data protection is a commercial issue between companies. A general arbitration system already exists in UK. Company can apply for UK (or for EU if research companies would agree. System has not yet been tested in practice. Authorities are not involved.

Paragraph 3: To extend the provision to applications involving both new and existing active substance, prior to and following inclusion in Annex I.

Paragraph 5: In the interest of limiting duplicative testing with vertebrate species, provision is proposed for binding arbitration in situations where agreement is not reached between the parties concerned to share test and study reports; this implies that a second notifier can not generate studies involving vertebrate animals himself but has to buy access to the data or to wait until the data protection period has expired.

Article 38: To set out, in broad terms, an equitable basis for establishing the amount of compensation to be paid

active substance or for the modification of the conditions or restrictions associated with the inclusion of an active substance in Annex I.

4. If, nevertheless:

- data holders requesting the sharing of information, test and study reports with a view to inclusion or renewal of such inclusion of an active substance in Annex I,
- the applicant and holders of previous authorizations of plant protection products containing the same active substance,

can still not reach an agreement on the sharing of information, test and study reports, the matter may be submitted by any of the parties directly concerned for binding arbitration to a recognized arbitration organisation unless the applicant decides to withdraw his application or to generate the data himself.

5. In case the information, tests and study reports for which no agreement on the sharing can be reached relates to testing involving vertebrate animals, the matter shall be submitted, with a view to avoiding duplicative testing on vertebrate animals, by the applicant for binding arbitration to an arbitration organisation, unless the applicant decides to withdraw its application.

6. Notwithstanding the provisions of [Article 29, 30, 32 and 33](#), the Member States shall make use of information, tests and study reports referred to in Annex II and Annex III to the benefit of other applicants where pursuant to [Article 36](#) compensation has been agreed.

Article 38 Arbitration

1. Any arbitration made shall take the following elements into account:

- the cost of generating the information discounted to reflect the period of protection remaining;
- the cost of assembling the dossier submitted to achieve the inclusion of an active substance in Annex I;
- a compensation for the risk of supporting the inclusion of an active substance in Annex I
- eventual compensation already paid to any of the parties concerned and the amounts thus paid
- the costs of the arbitration process.

2. The findings of recognized arbitration organisations shall be binding on the parties concerned and shall be disclosed to the competent authority and to other interested parties.

<p>Article 38.3: To limit the likelihood of frivolous applications for arbitration in relation to inclusion of existing active substances in Annex I or to an authorization of a ppp</p> <p>Article 39: To provide for publication of lists of arbitration organizations recognized by the Member States, and to specify the basis for such recognition and for the withdrawal of such recognition</p> <p>To provide basic rules of procedure for recognized arbitration organizations</p>	<p style="text-align: center;">Article 39</p> <p style="text-align: center;">Recognition of arbitration organisations</p> <p>The Member States shall recognise independent organisations having appropriate legal, technical and financial expertise available to them and shall publish a list of the arbitration organizations thus recognized. Recognition of an arbitration organisation shall be withdrawn where the Member State concerned is no longer satisfied as to the independence of an organisation or is no longer satisfied that it has the necessary financial, technical and legal expertise available to it.</p> <p style="text-align: center;">Article 40</p> <p style="text-align: center;">Article 41</p> <p style="text-align: center;">Transitional measures</p> <p>By way of derogation from Articles 30 to 40 the provisions on data protection foreseen in Article 13 of Directive 91/414/EEC will continue to apply for active substances already on the market on 26 July 1993 until they are included for the first time into Annex I</p> <p>The current provisions will start to apply from their second evaluation.</p>
<p style="text-align: center;">Article 14</p>	<p style="text-align: center;">TITLE 9</p> <p style="text-align: center;">PUBLIC ACCESS TO INFORMATION</p>
<p>From Regulation 1049/2001 article 4.2. Same obligations for Member States and EFSA as foreseen in 1049/2001 for the Commission. It is further clarified which information is of commercial interest.</p> <p>Member States and the Commission shall, without prejudice to Council Directive 90/313/EEC of 7 June 1990 on the</p>	<p style="text-align: center;">Article 42</p> <p style="text-align: center;">Access to information and confidentiality</p> <p>1. Member States and the EFSA shall refuse access to a document where disclosure would undermine the protection of:</p> <ul style="list-style-type: none"> - commercial interests of a natural or legal person, including intellectual property, - privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data. - court proceeding and legal advice, - the purpose of inspections, investigations and audits, <p>unless there is an overriding public interest in disclosure.</p>

<p>freedom of access to information on the environment, 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 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>Provisions are based on French study on data protection and confidentiality. However analytical methods for the determination of the a.s. are <u>not</u> considered confidential. Specification of the a.s. as well as information on relevant impurities are not considered confidential according to FAO criteria and procedures.</p> <p>Non-relevant impurities, again according to FAO procedures, are considered as confidential (because this information might reveal the manufacturing process).</p>	<p>2. The following information shall be considered as being of commercial interest:</p> <ul style="list-style-type: none"> - the method of manufacture ; - the specification of purity of the active substance except for the impurities that are considered to be relevant; - the information on the full composition of the plant protection product. <p>3. If an applicant subsequently discloses previously confidential information, he shall be required to inform the competent authority accordingly.</p>
<p>Article 15 (packaging and labelling of plant protection products)</p>	<p>TITLE 10 CLASSIFICATION, PACKAGING AND LABELLING Article 44 Classification and packaging</p>
<p>Article 5(1) of Directive 78/631/EEC shall apply to all plant protection products not covered by Directive 78/631/EEC.</p>	<p>1. Article 9 of Directive 1999/45/EC shall apply to all plant protection products .</p>

Formatiert: Nicht Hervorheben

SANCO/10159PPP Regulation rev.0 06.04.2005

	<p>2. In addition:</p> <p>a) products which may be mistaken for food, drink or feedingstuff shall be packaged so as to minimize the likelihood of such a mistake being made;</p> <p>b) products available to the general public which may be mistaken for food, drink or feedingstuff shall contain components to discourage and, if possible, prevent their accidental or deliberate consumption.</p>
Article 16 packaging and labelling of plant protection products	Article 45 Labelling
<p>Member States shall take all necessary measures to ensure that the packaging of plant protection products satisfies the following requirements as to labelling.</p> <p>1. All packaging must show clearly and indelibly the following:</p>	<p>Member States shall take all necessary measures to ensure that the packaging of plant protection products satisfies the following requirements as to labelling.</p> <p>1. All packaging must show clearly and indelibly the following:</p>
1(a) the trade name or designation of the plant protection product;	1(a) the trade name or designation of the plant protection product;
1(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;	1(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;
<p>1(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.</p> <p>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;</p>	<p>1(c) - the name of each active substance; 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;</p> <p>- the amount of each active substance, expressed according to the provisions laid down in Annex III, part A, chapter 1, point 1;</p> <p>- the name of other substances present in the plant protection product in accordance with the provisions of Article 10 (2) and (3) of Directive 1999/45/EC.</p>
1(d) the net quantity of plant protection product given in legal units of measurement;	1(d) the net quantity of plant protection product given in legal units of measurement;
1(e) the formulation batch number or some means of identifying it;	1(e) the formulation batch number or some means of identifying it;
1(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;	1(f) the information in accordance with the provisions of Article 10 (1) and (2) of Directive 1999/45/EC.
1(g) the nature of any special risks for humans, animals or the environment, by means of standard phrases selected as appropriate from those given in Annex IV;	1(g) for plant protection products classified as very toxic, toxic and harmful, the indication that the packaging cannot be reused except in the case of containers specially intended to be reused, reconditioned or refilled by the manufacturer or the distributor;
	1(h) the nature of any special risks for humans, animals or the environment, by means of standard phrases selected as appropriate from those given in Annex IV;
	1(i) information on first aid.
1(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;	1(j) 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;

SANCO/10159PPP Regulation rev.0 06.04.2005

1(i) the type of action of the plant protection product (e.g. insecticide, growth regulator, weedkiller, etc.);	1(k) the type of action of the plant protection product (e.g. insecticide, growth regulator, weedkiller, etc.);
1(j) the type of preparation (e.g. wettable powder, emulsifiable concentrate, etc.);	1(l) the type of preparation (e.g. wettable powder, emulsifiable concentrate, etc.);
1(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;	1(m) 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;
1(l) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorization;	1(n) directions for use and the dose rate, expressed in metric units, for each use provided for under the terms of the authorization;
(m) where necessary, the safety interval for each use between application and: - sowing or planting of the crop to be protected, - sowing or planting of succeeding crops, - access by humans or animals, - harvesting, - use or consumption;	1(o) where necessary, the safety interval for each use between application and: - sowing or planting of the crop to be protected, - sowing or planting of succeeding crops, - access by humans or animals, - harvesting, - use or consumption;
1(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: - the crop in question, or - subsequent crops;	1(p) 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: - the crop in question, or - subsequent crops;
1(o) if accompanied by a leaflet, as provided for in paragraph 2, the sentence 'Read accompanying instructions before use';	1(q) if accompanied by a leaflet, as provided for in paragraph 2, the sentence 'Read accompanying instructions before use';
1(p) directions for safe disposal of the plant protection product and of the packaging; and	1(r) directions for safe disposal of the plant protection product and of the packaging; and
1(q) the expiry date relevant to normal conditions of storage where the shelf life of the product is limited to less than two years.	1(s) the expiry date relevant to normal conditions of storage where the shelf life of the product is limited to less than two years.
	1(t) where relevant, measures to take in case of misuse or unintended release;
	1(u) where relevant, specific instructions for storage and handling.
2. 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.	2. Member States may permit the requirements in paragraphs 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 Regulation.
3. 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.	3. 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.
4. 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	4. 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

SANCO/10159PPP Regulation rev.0 06.04.2005

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.	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.
5. Member States may make the placing of 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.	5. Member States may make the placing of 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 paragraphs 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.
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.	6. In accordance with the procedure laid down in Article 54 (3) , 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.
	TITLE 11 CONTROLS Article 46 Record keeping
Record keeping is foreseen for food business operators in Annex I Regulation 852/2004 (food hygiene). These provisions are extended to all professional users of plant protection products and to Producers, suppliers, distributors.	Producers, suppliers, distributors and professional users of plant protection products shall keep and retain records on any plant protection products they store or use. They shall make relevant information contained in these records available to the competent authority on request. The Commission may in accordance with the procedure laid down in Article 54 (3) , lay down implementing measures to ensure the uniform application of this provision.
Article 17 (control measures)	Article 47 Monitoring and controls
Recital 3, Article 1 and Article 2.1 of Regulation 882/2004 (Food and Feed control) refer to or define that pesticides are within the scope of that Regulation. The Regulation on food law (178/2002) refers in recitals 36 and 37 and in article 5 to pesticides and plant health.	1. Member States shall carry out official controls in order to enforce compliance with this Regulation. Without prejudice to Regulation (EC) n° 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules the provisions laid down in Articles 2 to 13, 26,27 (1), 27(4)(a), 27(5) and 27(6) to (12), 28, 29, 32 to 45, 51, 53, 54, 62, 63(1) (a) to (e) and (2), 64 and 66 of that Regulation shall also apply <i>mutatis mutandis</i> to the controls on the production, storage, transport, marketing, formulation and use of plant

SANCO/10159PPP Regulation rev.0 06.04.2005

<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 year.</p>	<p>protection products.</p>

SANCO/10159PPP Regulation rev.0 06.04.2005

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	<p>2. Official controls carried out at market and on user level shall verify whether at least:</p> <p>(a) at market level:</p> <ul style="list-style-type: none"> - the products marketed correspond to those authorized - the label corresponds to the authorisation and the correct language is used - traders of plant protection products are appropriately qualified (especially traders for toxic/highly toxic products) - storage conditions are appropriate (especially for

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SANCO/10159PPP Regulation rev.0 06.04.2005

	<p>toxic/highly toxic products) and (b) at user level:</p> <ul style="list-style-type: none"> - the products stored and used are authorised - the product labels correspond to the authorisations - the products are appropriately stored - the users are appropriately qualified (especially users of toxic/highly toxic products) in those cases where there are such specific requirements on the use of the plant protection products, - the products are used according to the use specifications on the label
	<p style="text-align: center;">Article 48 Multi-annual control plans</p>
	<p>The first multi annual national control plan shall be developed within six months after the entry into force of this Regulation..</p>

SANCO/10159PPP Regulation rev.0 06.04.2005

<p align="center">Article 11</p>	<p align="center">TITLE 12 EMERGENCY MEASURES Article 52 Emergency measures and opinion by the EFSA</p>
<p>1. 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>Similar provisions as in Regulation 178/2002 (food law).</p> <p>Para 1: The Commission may specify the time limit within which EFSA shall provide an opinion: as in Article 43 of Regulation 396/2005 on setting MRLs of pesticides.</p> <p>However, contrary to food, there is no free circulation of plant protection products (products have to be authorized in each Member State) and therefore a longer deadline than the 10 days in the food law in case of national interim measures can be foreseen (see paragraph 4)..</p>	<p>1. Where it is evident that a substance included in Annex I or a product which has been authorized or is eligible for authorisation under Article 9 is likely to constitute a serious risk to human or animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, acting in accordance with the procedure provided for in Article 55(3) on its own initiative or at the request of a Member State, shall immediately take measures to restrict or prohibit the use and/or sale of that substance or of products containing it. Before taking such measures the Commission shall quickly examine the evidence and may request an opinion from the EFSA. The Commission may specify the time limit within which such an opinion shall be provided.</p> <p>2. However, in emergencies, the Commission may provisionally adopt the measures referred to in paragraph 1 after consulting the Member State(s) concerned and informing the other Member States.</p> <p>As soon as possible, and at most within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred to in Article 55 (3), and the reasons for the Commission's decision shall be made public without delay.</p> <p>3. Where a Member State officially informs of the need to take emergency measures, and where the Commission has not acted in accordance with paragraph (1) or (2), the Member State may adopt interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.</p> <p>4. Within 30 working days, the Commission shall put the matter before the Committee referred to in Article 55(1) in accordance with the procedure provided for in Article 55(3) with a view to the extension, amendment or abrogation of the national interim protective measure.</p> <p>5. The Member State may maintain its national interim protective measures until the Community measures have been adopted.</p>

Formatiert: Nicht Hervorheben

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<p>2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 19.</p>	
	<p>TITLE 13 ADMINISTRATIVE AND FINANCIAL PROVISIONS</p>
<p>Article 18 (administrative provisions)</p>	<p>Article 53 Modifications to this Regulation</p>
<p>1. 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>Ensure that the Commission can adopt the necessary implementing rules for a better functioning of the Regulation or to take into account new science</p>	<p>1. The Commission may in accordance with the procedure laid down in Article 54 (3),</p> <p>(a) Make any amendments to the Annexes to this Regulation, taking into account current scientific and technical knowledge;</p> <p>(b) Lay down implementing measures to ensure the uniform application of this Regulation;</p> <p>(c) Amend the references to dates, other legislation or technical guidance within this Regulation;</p> <p>(d) Without prejudice to the need to ensure a high level of health and environmental protection, in order to safeguard legitimate expectations, provide that Community legal implementing acts may include transitional periods for the implementation of certain measures where this is necessary to allow for the normal marketing, processing and consumption products, taking their normal shelf-life into account.</p>
<p>2. 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>New Article on sanctions (identical to article on sanctions in the feed hygiene Regulation)</p>	<p>Article 54 Sanctions</p>

Formatiert: Nicht Hervorheben

<p>See article 34 of residue Regulation 396/2005.</p>	<p>The Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take the measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions and any subsequent amendment to the Commission without delay.</p>
<p>Article 19</p>	<p>Article 55 Committee procedure</p>
<p>Where the procedure laid down in this Article is to be followed, matters shall be referred without delay by the chairman, either on his own initiative or at the request of a Member State, to the Standing Committee on Plant Health, set up by Decision 76/894/EEC, hereinafter referred to as 'the Committee'.</p> <p>The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.</p> <p>The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.</p> <p>If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.</p> <p>If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission</p> <p>54(2) is advisory procedure, 54(3) is regulatory committee procedure.</p> <p>Advisory procedure could be used eg. for definition of formats (articles 13.3, 20.6, 20.8, 21.6), guidance documents (article 59), good plant protection practice (article 3), definition of plant protection product (article 3)</p>	<p>1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, instituted by Article 58 of Regulation N° 178/2002.</p> <p>2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.</p> <p>3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof</p> <p>4. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months</p>
<p>Article 20</p>	
<p>Where the procedure laid down in this Article is to be followed, matters shall be referred by the chairman, either on his own initiative or at the request of a Member State, to the committee.</p> <p>The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft, within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by</p>	

<p>the majority laid down in Article 148(2) of the Treaty. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.</p> <p>The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.</p> <p>If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.</p> <p>If, on the expiry of a period of 15 days from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission</p>	
Article 21	
<p>Where the procedure laid down in this Article is to be followed, matters shall be referred by the Chairman, either on his own initiative or at the request of a Member State, to the committee.</p> <p>The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft, within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.</p> <p>The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.</p> <p>The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.</p> <p>Is covered by article 54(2)</p>	
	Article 56 Expenditure
<p>This text is coherent with the proposal of the Commission for the MRL Regulation</p>	<p>The Community may make a financial contribution of up to 100% to the establishment of a harmonised policy and system in the field of marketing and use of plant protection products, including:</p> <ul style="list-style-type: none"> - the development of an harmonised system, including an appropriate database for gathering and storing all information relating to Community legislation concerning the of marketing and use of plant protection products and for making such information available to the competent authorities, producers and other interested parties, - the performance of studies necessary for the preparation and development of legislation on the marketing and use of plant protection products, - the performance of studies necessary to harmonise procedures, decision-making criteria and data requirements,

SANCO/10159PPP Regulation rev.0 06.04.2005

	<ul style="list-style-type: none"> - measures to facilitate worksharing between Member States - development of guidance to facilitate the day-to-day implementation of this Regulation.. <p>The appropriations required for the above measures shall be authorised each financial year as part of the budgetary procedure.</p>
<p>Is also foreseen in the Regulations on the Review programme. Competent authorities to act as rapporteur for the evaluation of an active substance.</p>	<p style="text-align: center;">Article 57</p> <p style="text-align: center;">Designated Member State authority</p> <ol style="list-style-type: none"> 1. Each Member State shall designate an authority or authorities to carry out the obligations of the Member States as defined in this Regulation. 2. Each Member State shall designate a competent authority which shall coordinate and ensure all necessary contacts with notifiers, other Member States, the Commission and the European Food Safety Authority (EFSA) in relation to risk assessment issues. 3. Each Member State shall give the details concerning the designated national competent authority to the Commission, the EFSA and the designated coordinating national authority of each other Member State and inform them of any modifications thereof.

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	<p>Article 58 Repeal and transitional measures</p>
	<p>1. Council Directive 91/414/EEC and Council Directive 79/117/EEC are repealed with effect from the date of application referred to in Article 61. Where reference is made to those Directives in other Community legislation, such references shall be deemed to refer to this Regulation.</p> <p>2. The Commission shall establish, in accordance with the procedure laid down in Article 54 (3), Annexes IA, II, III, IV, V, VI to this Regulation.</p> <p style="text-align: center;">Article 59 Technical notes for guidance</p> <p>The Commission, in accordance with the procedure laid down in Article 54 (2), shall adopt technical and other guidance documents, to facilitate the day-to-day implementation of this Regulation. The Commission may request the EFSA to prepare such guidance documents. Such guidance documents will be kept available in “The rules governing the authorization of plant protection products at EU level”.</p>
<p>Similar provision in veterinary medicines legislation</p>	
<p>Article 23 (implementation of the Directive)</p>	
<p>1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within two years following notification thereof. They shall immediately inform the Commission thereof. The uniform principles shall be adopted one year after the date of notification.</p> <p>When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.</p>	
<p>2. Paragraph 1 notwithstanding, Member States need not bring into force laws, regulations and administrative provisions implementing Article 10(1), second indent, until one year at the latest following adoption of the uniform principles, and only in relation to the requirements of Article 4(1)(b) to (e) which are covered by the uniform principles thus adopted.</p>	

SANCO/10159PPP Regulation rev.0 06.04.2005

	Article 60 Entry into Force				
	This Regulation shall enter into force six months from the publication of the last of the Regulations establishing Annexes IA, II, III, IV, V and VI.				
Article 24	Article 61 Addressed to...				
This Directive is addressed to the Member States. Done at Brussels, 15 July 1991. For the Council, The President P. BUKMAN	This Regulation shall be binding in its entirety and directly applicable in all Member States Done at Brussels, [...] <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">For the European Parliament</td> <td style="width: 50%;">For the Council</td> </tr> <tr> <td style="text-align: center;">The President</td> <td style="text-align: center;">The President</td> </tr> </table>	For the European Parliament	For the Council	The President	The President
For the European Parliament	For the Council				
The President	The President				

ANNEXES**Annex I: List of active substances, safeners and synergists agreed at Community level for inclusion in plant protection products**

Annex IA: List of acceptable active substances

Annex IB: List of low risk substances

Annex IC: List of basic substances

Annex ID: List of active substances that are candidates for substitution

Annex IE: List of safeners and synergists

Annex II: Data requirements for substances

Annex IIA: Data requirements for chemical active substances

Annex IIB: Data requirements for microbial active substances.

Annex II C: Data requirements for safeners and synergists

Annex III: Data requirements for products

Annex IIIA: Data requirements for plant protection products with chemical active substances

Annex IIIB: Data requirements for plant protection products with microbial active substances

Annex IIIC: Data requirements for plant protection products with low risk substances

Member States shall require a dossier comprising the following data for a low-risk plant protection product;

(i) applicant;

1.1. name and address,

1.2. manufacturers of the plant protection product and the active substances, (names and addresses including location of manufacturer of the active substance)

1.3. where appropriate, a letter of access to any relevant data needed,

(ii) identity of the plant protection product;

2.1. trade name,

SANCO/10159PPP Regulation rev.0 06.04.2005

- 2.2. full composition of the plant protection product,
- 2.3. physical and chemical properties
- (iii) efficacy data,
- (iv) analytical methods,
- (v) classification, packaging and labelling, including a draft label, according to Article 45.
- (vi) safety data sheet prepared in accordance with Article 10 of Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations, and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous substances(1), or Article 27 of Directive 67/548/EEC.

Annex IV: Risk phrases

Annex V: Safety phrases

Formatiert: Englisch
(Großbritannien)

Annex VI: Uniform Principles for risk assessment

Annex VIA: Uniform principles for chemicals

Annex VIB: Uniform principles for microbials

Annex VIC: Uniform principles for GMM's?

Annex VII: Criteria for inclusion of active substances in Annex I

1. Introduction

The principles developed in this Annex aim to ensure that evaluations and decisions with regard to inclusion of active substances in Annex I result in the implementation of the requirements of Article 17 of this Directive at the high level of protection of human and animal health and the environment. These criteria should be used in the assessment of dossiers by the Rapporteur, for use by the EFSA in the peer review of draft assessment reports and for use by the Commission in the Working Groups on Plant Protection Products "Legislation" of the Standing Committee on the Food Chain and Animal Health, such that decisions can be made in an efficient way. They should also be useful for industry when developing a dossier for an active substance.

These criteria aim to ensure harmonisation in evaluation and consistency in decision making and as such would increase the acceptance of proposals made by a Rapporteur on possible inclusion of an active substance in Annex I. They also intend to facilitate a prudent use of scarce evaluative and regulatory resources.

Given that the criteria that follow are based on current scientific and technical knowledge, it is likely that they may need to be re-examined in the light of new scientific or technical knowledge

The criteria for new and existing active substances are the same.

SANCO/10159PPP Regulation rev.0 06.04.2005

All issues which are critical for the purposes of the inclusion and relate to the risks arising for human and animal health (directly or indirectly) and for the environment and to the availability of analytical methods, shall be resolved prior to decision on possible inclusion of the active substance in Annex I.

Decisions to include particular active substances in Annex I do not remove the need for Member States to apply the uniform principles and to take national decisions in relation to the authorization of plant protection products containing them. Decisions to include particular active substances in Annex I infer that it can be expected that authorizations for plant protection products containing them can be granted in at least one Member State but do not infer that such authorizations will be granted.

2. Evaluation

1. In evaluating applications it shall:

- a) Be ensured that the dossier supplied is in accordance with the requirements of Article 29 of the Directive at the latest at the time of finalization of the evaluation for the purpose of decision-making

Be ensured that the data submitted are acceptable in terms of quantity, quality, consistency and reliability and sufficient to permit a proper evaluation of the dossier,

Be Evaluated, where relevant, justifications submitted by the applicant for not supplying certain data;

- b) Be Taken into consideration other relevant technical or scientific information The applicant can reasonably possess with regard to the performance of the active substance or plant protection products containing the active substance or to potentially adverse effects of the active substance or plant protection products containing the active substance, its components or its residues;

2. Where the data and information provided are sufficient to permit completion of the evaluation for one of the proposed uses, applications must be evaluated and a decision on possible inclusion be proposed.

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

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

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

6. The evaluation and the submission of a draft assessment report shall be done in accordance with the procedure of [Article 20](#) of the Directive.

3. General decision-making criteria

1. An active substance should only be included in Annex I if, as a minimum, –

- (a) The dossier submitted satisfies the requirements of Annex II in relation to a limited range of representative uses and the requirements of Annex III in relation to at least one preparation for such uses. All relevant end-points must be addressed. A dossier shall be judged to be complete if the dossier contains physically the individual test and study reports specified in Annex II and III to the Directive or a letter of access or reasoned justifications for their non-provision, and

SANCO/10159PPP Regulation rev.0 06.04.2005

- (b) on the basis of the dossier submitted, authorization in at least one Member State is expected to be possible for the representative formulation for the supported representative uses.

2. Data gaps in relation to matters that are not critical for the proposed inclusion in Annex I

In principle an active substance can only be included in Annex I if a complete dossier is submitted. In exceptional cases it may be possible to include an active substance in Annex I even though certain information is still to be submitted where:

- 1) the data requirements have been amended or refined after the submission of the dossier;
- 2) the information is considered confirmatory in nature, required in order to increase the confidence in the decision.

In such cases the additional information would be submitted to the rapporteur Member State for evaluation with a clear deadline. The Commission will be informed of the results of the assessment, particularly where they indicate a need for an amendment of the including Directive or the review report (list of end-points) to be used by the Member States when applying the uniform principles when authorising plant protection products.

3. Application of the *Precautionary Principle*

The decision-making process in relation to the inclusion of active substances in Annex I and in relation to the imposition of conditions and restrictions to be associated with an inclusion in Annex I, should reflect the *Precautionary Principle*. (COM (2000)1 final of 2.2.2000)

Formatiert: Nicht Hervorheben

4. It can also not be excluded that, on a case by case basis, additional criteria may need to be established for certain active substances where particular concerns arise.

5. Other restrictions

In the context of the consideration of the balance of responsibilities as between issues to be addressed at EU level and those to be addressed by the Member States as well as in the context of the need to ensure that appropriate decisions are made by companies in selecting representative uses and formulations for which dossiers are compiled, it is necessary to propose that in certain circumstances conditions and restrictions be associated with inclusion of particular active substances in Annex I.

In order to ensure that the resources available to the regulatory authorities are employed as efficiently as possible it is necessary that a piece-meal approach to the provision of complete dossiers be avoided.

The criteria that follow in relation to the restrictions to be associated, where appropriate, with the inclusion of active substances in Annex I, were also developed for the purposes of improving efficiencies associated with the process leading to such decisions.

In particular the criteria are intended to discourage the submission of dossiers that -

- do not reflect normal conditions for use of plant protection products containing it,
- relate to a less important use,
- relate to formulations for specialist uses.

It is however understood that in exceptional cases dossiers may be submitted for specific uses which are less important but of high regional importance (e.g. EU minor crops).

The review report attached to the decision on Annex I inclusion will provide, in the background document, details of the uses and use conditions supported by the available data and for which a risk

SANCO/10159PPP Regulation rev.0 06.04.2005

assessment has been conducted, so facilitating the evaluation of applications for authorisations of plant protection products at national level following Annex I inclusion

Restrictions on inclusion in Annex I, where necessary, would normally be linked to:

- identification of unacceptable risks *under particular conditions*
- gaps in the risk assessment resulting from the limited range of representative uses and preparations notified by applicant.

Early discussions between the applicant and the Rapporteur Member State are encouraged in order to avoid unnecessary restrictions which would result in the need for submission by the applicant of a second dossier to remove restrictions from the decision on inclusion in Annex I.

Any such restrictions may only be removed following the submission to and evaluation by a Member State of a new dossier addressing the area of concern and a decision at Community level to remove the restriction.

Examples of possible restrictions are:

- use restricted to non-edible crops if no information on metabolism or residues in plants is provided;
- use restricted to a type of formulation if only information on a very specific formulation has been provided and important parts of the overall risk assessment have not been addressed;
- use restricted because the evaluation has established that some of the proposed uses, types of formulation or the manner of use are unacceptable
- use restricted to protected crops if insufficient information is available for outdoor uses.
- Use not authorized on crops to be used in baby food

4. Criteria for inclusion in Annex IA

4.1. Basic criteria

Criteria in relation to documentation

An active substance shall only be included in Annex I if:

1. The documentation submitted is sufficient to permit establishment where relevant of an Acceptable Daily Intake (ADI), an Acceptable Operator Exposure Level (AOEL) and an Acute Reference Dose (ARfD).
2. In the case of active substances for which there are supported food, feed or forage uses, the documentation submitted is sufficient to permit the residue of concern to be defined for the purposes of risk assessments to be carried out and for enforcement purposes.
3. Where use on food, feed or forage is supported or proposed, the documentation submitted is sufficient to:
 - calculate a supervised trials median residue level (STMR),
 - calculate, where relevant, the corresponding level reflecting the effects of processing and cooking (STMR-P),
 - identify the highest residue level (HR), and
 - derive an MRL for the commodity and if appropriate for products of animal origin if the commodity is fed to animals.

SANCO/10159PPP Regulation rev.0 06.04.2005

4. The documentation submitted is sufficient to permit where relevant, an estimate of its fate and distribution in the environment as well as its impact on non-target species.

Criteria in relation to efficacy

An active substance shall only be included in Annex I when it has been established for the limited range of representative uses that the preparation, consequent on application consistent with good plant protection practice and having regard to manual conditions of use is sufficiently effective.

Criteria in relation to the toxic relevance of breakdown products

6. Where use on food, feed or forage is supported or proposed, the documentation submitted is sufficient to permit the establishment of the toxicological relevance of breakdown products that are not metabolites found in animals and that are formed as a result of metabolism or other processes in or on treated plants, or as a result of processing or in livestock animals.

Criteria in relation to the composition of the active substance

7. An active substance shall only be included in Annex I if
- (a) its specification is defined with respect to its:
 - minimum degree of purity,
 - identity and maximum content of impurities, and where relevant of isomers / diastereoisomers and additives,and the content of impurities of toxicological, ecotoxicological or environmental concern is within acceptable limits;
 - (b) its specification is in compliance with the relevant FAO specification where such specification exists.

Criteria in relation to methods of analysis

8. An active substance shall only be included in Annex I if
- (a) the method for analysis of active substance as manufactured and for determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities ≥ 1 g/kg in the active substance as manufactured has been validated and shown to be sufficiently specific, linear, accurate and precise;
 - (b) the method for analysis in environmental matrices, as appropriate, must have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

Criteria in relation to human health

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9. An active substance shall only be included in Annex I if, where relevant, an ADI, AOEL and ARfD can be established. This means that an active substance shall only be included in Annex I if:
- (a) on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the provisions of Annex IIA point 5.4 and other available data and information, it is not or has not

SANCO/10159PPP Regulation rev.0 06.04.2005

to be classified, in accordance with the provisions of Directive 67/548/EEC², as mutagen category I;

Formatiert: Nicht Hervorheben

and

- (b) on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the provisions of Annex IIA point 5.4 and other available data and information, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC³, as mutagen category II unless a threshold dose has been demonstrated which provides acceptable safety margins for humans;

Formatiert: Nicht Hervorheben

and

- (c) on the basis of assessment of carcinogenicity testing carried out in accordance with Annex IIA point 5.5 and other available data and information, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as carcinogen category I;

Formatiert: Nicht Hervorheben

and

- (d) on the basis of assessment of carcinogenicity testing carried out in accordance with Annex IIA point 5.5 and other available data and information, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as carcinogen category II unless a threshold dose has been demonstrated which provides acceptable safety margins for humans

Formatiert: Nicht Hervorheben

and

- (e) on the basis of assessment of reproductive toxicity testing carried out in accordance with the provisions of Annex IIA points 5.6 and other available data and information, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as toxic for reproduction category I unless the formulation type and use conditions are such that exposure to humans is unlikely.

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Criteria in relation to fate and behaviour in the environment

10. An active substance shall only be included in Annex I if it is not considered to be a persistent organic pollutant in accordance with the Stockholm Convention on persistent organic pollutants.

A persistent organic pollutant is defined as follows:

(a) Persistence:

- (i) Evidence that its DT50 in water is greater than two months, or that its DT50 in soil is greater than six months, or that its DT50 in sediment is greater than six months;

and

(b) Bio-accumulation:

- (i) Evidence that its bio-concentration factor or bio-accumulation factor in aquatic species is greater than 5,000 or, in the absence of such data, that the log K_{ow} is greater than 5;
- (ii) Evidence that a chemical presents other reasons for concern, such as high bio-accumulation in other species, high toxicity or ecotoxicity;

² 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

³ 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

and

- (c) Potential for long-range environmental transport:
- (i) Measured levels of the active substance in locations distant from the sources of its release that are of potential concern;
 - (ii) Monitoring data showing that long-range environmental transport of the active substance, with the potential for transfer to a receiving environment, may have occurred via air, water or migratory species; or
 - (iii) Environmental fate properties and/or model results that demonstrate that the active substance has a potential for long-range environmental transport through air, water or migratory species, with the potential for transfer to a receiving environment in locations distant from the sources of its release. For an active substance that migrates significantly through the air, its DT50 in air should be greater than two days.

Criteria for toxicity, PBT, VPVB and endocrine disruptors to be included as appropriate

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(Note: criteria a(i) and b(i) are in accordance with the Reach criteria for very persistent substances.)

Criteria in relation to the residue definition

Where relevant, residue definitions for the purposes of risk assessment and for enforcement purposes shall be agreed at time of inclusion of an active substance in Annex I. However, in particular for new active substances the residue definition may have to be revised as extensions of use occur.

4.2. Evidence by national authorizations of a plant protection product containing the active substance

1. Normal conditions of use

For the inclusion of an active substance in Annex I, notifiers are required to demonstrate that, consequent on application consistent with good plant protection practice; there is at least one acceptable use for a plant protection product containing the active substance in relation to the normal conditions of use. However, the dossier to be presented shall also contain information demonstrating acceptable use of a plant protection product containing the active substance concerned in relation to the realistic worst case conditions in order to:

- identify possible areas of concern
- reduce the workload for both notifiers and Member States.

2. A limited range of representative uses

For the purposes of inclusion of an active substance in Annex I, it is sufficient to provide a dossier in relation to a limited range of representative uses of a plant protection product containing the active substance concerned.

3. Use conditions to be evaluated

SANCO/10159PPP Regulation rev.0 06.04.2005

The Directive recognises that agricultural, plant health and environmental (including climatic) conditions throughout the European Union are different which can result in different decisions at Member State level on authorisation of plant protection products.

However, in order to increase efficiency and to share work between the Member States it is desirable, where possible, to perform a risk assessment for broad conditions of use (e.g. the standard scenarios developed by the FOCUS work groups for groundwater and surface water).

4. Uniform principles

An active substance shall only be included in Annex I if the basic criteria referred to in point 3.2 are fulfilled and it can be shown that among the limited range of representative uses of the preparation(s) for which a dossier is provided at least one use is acceptable when applying the uniform principles as established in Annex VI of the Directive.

When applying the uniform principles the Rapporteur Member State shall make use of all further guidance developed in the framework of the Standing Committee on Plant Health in order to refine, where relevant, the risk assessment referred to in the uniform principles.

5. Criteria for inclusion in Annex IB

An active substance can only be listed on Annex IB if

- a dossier is submitted demonstrating that the representative product(s) meet(s) the definition of Article 3, point (2)
- the criteria referred to under point 4 are satisfied
- the inclusion in Annex IB is not prohibited by the provisions of Article 18 (7).

The inclusion of a substance in Annex IB may be subject to conditions, for example regarding categories of users where the use does not seem to pose risk of concern.

Annex VIII: List of active substances which are not accepted for inclusion in plant protection products

- **1,2 – Dibromoethane**
- **1,2 – Dichloroethane**
- **Aldrin**
- **Alkoxyalkyl and aryl mercury compounds**
- **Alkyl mercury compounds**
- **Binapacryl**
- **Camphchlor**
- **Captafol**
- **Chlordane**
-
- **DDT**
- **Dicofol containing less than 78% of p.p – dicofol or more than 1 g/kg DDT and DDT related compounds**
- **Dieldrin**
- **Dinoseb, its acetate and salts**
- **Endrin**
- **Ethylene oxide**
- **HCH containing less than 99.0% of the gamma isomer**
- **Heptachlor**
- **Hexachlorobenzene**
- **Maleic hydrazide and its salts, other than its choline, potassium and sodium salts; choline, potassium and sodium salts of maleic hydrazide containing more than 1 mg/kg of free hydrazine expressed on the basis of the acid equivalent**

SANCO/10159PPP Regulation rev.0 06.04.2005

- Mercuric oxide, Mercurous chloride (calomel) and other inorganic mercury compounds
- Nitrofen
- Quintozene containing more than 1g/kg of HCB or more than 10g/kg pentachlorobenzene

Annex IX: List of adjuvants and co-formulants which are not accepted for inclusion in plant protection products

Annex X: Definition of zones for the authorization of plant protection products

Zone A – North

The following Member States are belonging to this zone:

Denmark, Estonia, Latvia, Lithuania, Finland, Sweden

Zone B – Center

The following Member States are belonging to this zone:

Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxemburg, Netherlands, Poland, Slovakia, Slovenia, United Kingdom

Zone C – South

The following Member States are belonging to this zone:

Cyprus, France, Greece, Italy, Malta, Portugal, Spain

Annex XI: Criteria for the application of comparative assessment