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Amended Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

concerning the placing of plant protection products on the market

(presented by the Commission pursuant to Article 250 (2) of the EC Treaty)

EXPLANATORY MEMORANDUM

1) PROCEDURE

- (a) On 12 July 2006, the Commission adopted the proposal for a European Parliament and Council Regulation concerning the placing of plant protection products on the market [COM(2006) 388]. The Proposal was transmitted to the European Parliament and the Council on 19 July 2006.
- (b) The Economic and Social Committee adopted its opinion on 31 May 2007.
- (c) The Committee of the Regions adopted its opinion on 13 February 2007.
- (d) The Council welcomed the proposal and began analysing it in September 2006 within the Working Party on Agricultural Questions and has continued working on it regularly since then under the Finnish, German and Portuguese Presidency. The Presidency prepared on 9 July 2007 a revised text.
- (e) The Parliament has given in first reading a favourable opinion on the proposal on 23 October 2007.
- (f) The present Proposal amends the original proposal [COM(2006) 388 – 2006/0136 COD] to take into account the amendments of the European Parliament that were accepted by the Commission.

With regard to the original proposal, the European Parliament adopted 247 amendments. The Commission had indicated to the plenary meeting on 23 October 2007 that a number of amendments could have been accepted, wholly or in part, and or subject to rewording. From the adopted amendments the following could not be accepted by the Commission: 1, 2, 3, 8, 12, 13, 15, 16, 17, 23, 28, 30, 35, 37, 38, 40, 42, 44, 47, 48, 52, 55, 58, 68, 69, 70, 71, 73, 74, 81, 83, 85, 86, 88, 90, 91, 97, 101, 103, 104, 105, 106, 110, 111, 113, 117, 118, 120, 126, 127, 128, 129, 132, 135, 137, 138, 139, 141, 142, 143, 144, 146, 147, 148, 150, 152, 154, 158, 161, 162, 164, 165, 166, 168, 171, 173, 179, 185, 186, 187, 191, 192, 194, 198, 202, 204, 205, 207, 208, 210, 211, 214, 216, 219, 221, 222, 223, 224, 226, 227, 228, 229, 230, 232, 235, 236, 237, 238, 239, 240, 241, 242, 245, 246, 249, 250, 253, 255, 267, 276, 281, 287, 293, 295, 299, 303, 304.

The amendments in the revised proposal are in **bold and underlined**. A number of amendments have been reformulated so as to ensure consistency of the terminology used throughout the proposal or in other relevant legislation as the Commission proposal for a Directive establishing a framework for Community action to achieve a sustainable use of pesticides (COM(2006) 373).

2) OBJECTIVES OF THE PROPOSAL

(a) Grounds for the proposal

On 26 July 2001, the Commission submitted a progress report to Council and Parliament on the functioning of Directive 91/414/EEC (ref.COM(2001) 444 final). The report highlighted a number of areas where the Directive could be improved. Both Parliament and Council in reacting to the progress report, called on the Commission to bring forward proposals to amend the Directive.

(b) Objectives

The proposed Regulation replaces Directive 91/414/EEC concerning the placing of plant protection products on the market and repeals Council Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances. It would replace the existing legislation in this domain, thoroughly revising the procedures for the safety evaluation of active substances and authorisation of plant protection products. However, it keeps the 2 steps procedure of the Directive: approval of active substances at EU level and authorisation of plant protection products, containing approved substances, by Member States.

For simplification, it would also repeal Council Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances.

The main aim of the proposal is to maintain a high level of protection for humans, animals and the environment; to reduce the administrative burdens of the present approval and authorisation procedures and to achieve a higher level of harmonization. In summary, it contains the following elements:

- the establishment at EU level of a positive list of active substances, safeners and synergists based on a scientific assessment by the Member States and the European Food Safety Authority;
- the compulsory mutual recognition of authorisations in Member States belonging to the same zone;
- the comparative assessment of products with a view to encouraging the substitution of dangerous substances by safer alternatives;
- detailed and simplified rules on data protection and transparency;
- provisions on packaging, labelling and advertising of plant protection products;
- an obligation to keep records;
- an obligation for official controls;
- simplified procedures for low risk substances and products.

This proposal should be seen as part of a package together with the Thematic Strategy on the Sustainable Use of Pesticides which consists of a Communication and a Directive establishing a framework for Community action (COM(2006) 372 and 373). A third element is a proposal for a Regulation on the collection of statistics regarding the placing on the market and the use of plant protection products (COM(2006)778).

3) OVERVIEW OF THE AMENDMENTS OF THE EUROPEAN PARLIAMENT

(a) Technical / Editorial amendments

Amendments 20, 22, 26, 36, 41, 43, 45, 49, 51, 56, 57, 64,67, 92, 93, 96, 107, 114, 119, 124, 130, 131, 145, 153, 155, 156, 157, 159, 160, 167, 170, 184, 188, 189, 190, 195, 197, 201, 203, 206, 212, 213, 217 and 220 aim to improve the proposal from a technical and editorial point of view and have been taken up by the Commission, in some cases subject to some editorial changes. Amendment 5, 6, 8, 9, 11, 18, 19, 24, 25, 34, 39, 50, 53, 62, 94, 98, 99, 95, 100, 108, 109, 116, 122, 134, 136, 140, 169, 177, 180, 196 and 209 were partially accepted.

(b) Legal basis

Amendment 1 did not approve the dual basis (Articles 37(2) and 152(4)(b)) in the Commission proposal, and proposed instead Article 152(4)b and 175 (1) of the EC Treaty as the legal basis for the Regulation. In Commission proposal, the first is a “classic” basis (equivalent to Article 43 EEC which was the basis for Directive 91/414). The second covers any plant or animal measure which “has as its direct object” protecting human health. This legal basis implies the co-decision procedure.

As the two procedures are incompatible, the Commission has proposed the co-decision procedure. This approach has been followed in the past – e.g. Regulation 396/2005 on pesticide residues and Regulation 183/2005 on feed hygiene. Other texts have also combined Articles 37 and 152(4)(b).

The fact that an agricultural measure may also take account of environmental or health issues does not bring it within the scope of the environmental or health rules of the Treaty. The same applies to public health: all EC legislation must take account of public health, so a text remains agricultural even if it has an effect on health.

Therefore, there is no need to change the current legal basis to reflect any aspects of the text which might assist the free movement of goods or the protection of the environment.

(c) **Scope (Article 2)**

Amendment 35 aims to introduce a future limitation to the scope excluding micro-organisms, viruses, pheromones and biological products once a specific regulation related to these products will be adopted. The Commission retains that there is no need for a specific regulation as specific data requirements and criteria for authorisation are already in place and for some of these substances the provisions concerning low risk substances could potentially apply. Therefore, the amendment has not been endorsed by the Commission.

(d) **Definitions (Article 3)**

Amendments 36 to 59 introduce clarification or new definitions which are linked to other amendments. The Commission incorporated only partly the proposed amendments which were in some cases subject to rewording. They were included when they represented a clarification of the text (as in amendments 36, 41, 46, 54, 56, 57) or were required by the incorporation of a new provision as in amendment 43, 45, 46, 49, 51, 54, 59 concerning the definition of low risk, parallel trade, vulnerable groups, non chemical methods of plant protection, minor uses.

(e) **Approval criteria and range of uses (Article 4)**

The Commission proposal sets criteria for the approval of active substances. The Commission proposed that for category 1 and 2 substances (category 1: sufficient evidence for concerns in humans; category 2: strong presumption of relevance to humans), a substance cannot be approved unless exposure is negligible. The amendments 62 and 64 consist mainly in clarifications which have been mostly accepted by the Commission. Moreover, extensions of criteria are proposed in amendments to Annex II (235-236-237-238-239-240-241-242-245-246-248-249-293-300-304). The Commission has kept the original proposal in line with related European legislation and accepted to amend the text to introduce as a clarification that neurotoxic and immunotoxic substances should be approved as candidates for substitution.

The precision introduced by amendment 300 on negligible exposure is acceptable because it keeps the risk based approach foreseen in the original Commission proposal and further clarifies it.

Amendment 232 laid down the provision for evaluation of an extensive number of representative uses. As it is impossible to know the complete range of potential uses in the evaluation phase, therefore, on the basis of the subsidiarity principle and for efficiency reasons, the Commission has kept the original proposal that a limited number of uses must be evaluated at EU level and other uses are left to Member States which have to apply uniform criteria when granting authorisations.

(f) **Approval procedure, renewal and review (Article 7 to 21)**

Amendments 69 to 89 refer to procedural aspects which only partly have been taken up in the amended text as improving clarity of the text. Among others, amendment 69 regarding the role of EFSA as coordinator of the approval procedure has been rejected as one of the basic principles of Food law is the separation of risk assessment and risk management. Therefore, EFSA should coordinate the scientific evaluation but not the approval procedure. The variations proposed for extension or reduction of deadlines foreseen for various consultations and decisional phases (81-83-85-86-141-154) were rejected.

Amendments 90 to 100 concern the renewal and review of the approvals. The Commission has incorporated those which clarify the original proposal. Others such as amendment 90 on repeated renewal have been rejected.

The proposal of the Commission not to review an approval every 10 years aims to ensure simplification and reduction of administrative burden and costs. It ensures that authorities focus on the most important issues. In any case, the Commission can always review the approval of an active substance if unfavourable information becomes available. This is also done in other sectors (e.g. medicines).

(g) **Low risk and basic substances (Article 22 and 23)**

Amendment 301 aims to define criteria for definition of low risk substances and has been incorporated. Amendment 103 has not been accepted since there is no need to apply different criteria to biological control agents. Also amendments 101, 104, 105 related to basic substances have been rejected as the Commission considers that basic substances should be approved for an unlimited period and on the basis of evaluations performed in other areas.

On the other hand, amendment 274 has been included because it provides that foodstuffs should be considered as basic substances.

Amendment 168 aims to introduce a new article for reduced risk plant protection products and amendment 287 foresees different periods of data protection for the two categories of low risk products. The Commission has not accepted these proposals as the original proposal already provides for specific rules for low risk substances.

(h) **Safeners, synergists and co-formulants (Article 25 to27)**

Amendment 107 has been accepted as clarification of the text, though amendments 108 and 118 have been only partly accepted as the proposed timetable for the review of the synergists and safeners already on the market is considered too short due to the fact that first detailed criteria and data requirements must be adopted and transitional measures ensured. Therefore, also amendment 229 deleting temporary derogation for safeners and synergists has been rejected. Amendments 109, 110, 113, 129 and proposed amendment 250 of Annex III, have only been partly incorporated as the approval of co-formulants is rejected as it would create an overlapping obligation with respect to existing legislation on chemicals (REACH).

(i) **Zonal authorisation system and provisional authorisation (Article 39 to 41 and 281)**

The European Parliament rejects the zonal authorisation system for plant protection products, linked to compulsory mutual recognition of authorisation within a zone (amendments 52, 126, 128, 134, 137, 138, 147, 149, 150, 151, 152, 161, 166 and 230). The amendments have not been accepted as they would have considerably undermined the Commission proposal and would have removed one of its key elements. Currently, as the proposal stands, Member States can only impose stricter national measures for worker protection, as EU legislation in this field achieves minimum harmonisation only.

Therefore, these provisions have not been taken up by the Commission.

Amendment **281** would introduce a system of provisional authorisation which the Commission has rejected, as it is incompatible with the zonal authorisation system and Regulation (EC) Nr 396/2005 on maximum residue levels for pesticides.

(j) **Systematic information (Article 64)**

Amendment 216 on accessibility of the records of farmers to the public/residents and retailers and on the introduction of a "pesticide passport" has not been included. The Commission has kept the original text of the proposal which provides that information should be made available to neighbours upon request. Furthermore, a pesticide passport for every lot of fruit and vegetables would be unrealistic because batches of crops are mixed in trade. Moreover, it could have the effect that controls would be done only on declared pesticides.

(k) **Comparative assessment and substitution principle (Article 48)**

Amendments 106, 171, 173 and amendment 251 and 253 to Annex IV propose to extend comparative assessment to all plant protection products and to reduce the approval period for substances which are candidates for substitution. The Commission has not endorsed these proposals because they are not risk based. Also the additional administrative workload is not justified and would have only a minor effect on protection of human/animal health or the environment. When the comparative assessment shows that there are no alternatives, the authorisations should not be withdrawn.

(l) **Minor uses (Article 49)**

Amendments from 175 to 180 and 196 refer to provisions which should facilitate the extension of authorisation for minor uses. The Commission has taken up most of these proposals subject to legal rewording. Amendment 276 proposes to create an European Promotion Fund for minor uses. This has been rejected as it does not fall within the aim of this proposal.

(m) **Parallel trade (new Article 49 a)**

The introduction of provisions concerning the trade of plant protection products already authorised in other Member States has been taken up in the text amended. Amendment 286 has been accepted but subject to rewording to make the text compatible with the Treaty and Case Law of the Court of Justice.

(n) **Data protection and data sharing (Article 56 to 59)**

Amendments 194 and 198 undermine the data protection system proposed, in particular by introducing data protection for studies submitted for renewal or review of authorisations. It would weaken competition and reduce availability of plant protection products to farmers. This issue has been carefully analysed in the impact assessment, which compared three options for data protection at renewal: no data protection, forced data sharing with financial compensation or status-quo (which means 5 year data protection). The economical impact of no data protection or forced data sharing at renewal would be similar, but the administrative burden would be very high for the latter. The status quo reduces competition.

Amendments 205 and 208 have been rejected as the Commission is of the opinion that all studies on vertebrate animals should be protected in the same way as other studies; however there is an obligation to share results and not to repeat studies.

(o) **Confidentiality and public access to information (Article 60)**

Amendment 210 provides for the confidentiality of the names of institutes and persons involved in vertebrate studies. Under Article 60 of the proposal, any person can request that disclosure of information which may undermine the protection of his/her privacy and integrity shall be refused, in line with the general legislation on access to documents and protection of personal data.

Therefore the Commission has not taken up the proposed amendment

(p) **Integrated Pest Management and Good Environmental Practice (Article 52)**

Amendment 305 provides to make the principles of integrated pest management (IPM) obligatory from 2012 onwards.

Amendment 185 deletes the obligation for compulsory compliance with the principles of good environmental practice.

The Commission rejected both amendments and kept the original proposal in consistency with the proposal for a Directive establishing a framework for Community action to achieve a sustainable use of pesticides (COM(2006)373).

(q) **Comitology and link between the proposed Regulation and Regulation 396/2005**

Since the proposal was adopted before Decision 2006/512/EC amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission was adopted, the Commission proposal referred to the normal regulatory procedure. Therefore the need for an alignment of the amended proposal with Decision 2006/512/EC is generally endorsed by the Commission. Amendments **93, 108, 109, 119, 141, 184, 221, 227** are acceptable.

However, amendments **88, 94, 99, 100, 142, 143, 158, 185, 219, 224, 226, 227** introduce the regulatory procedure with scrutiny in cases where the Commission sees the need for curtailment of time limits for certain cases (e.g. efficiency to respect time limits of renewal of approvals, urgency to be applied in case of threat to human or animal health). Moreover, as the approval of an active substance is of an individual scope, the normal regulatory procedure should apply. In addition, for very technical measures, the Commission would retain the advisory procedure as originally proposed.

The part of amendment **77** which proposes Co-Decision for setting data requirements for safeners and synergists is not acceptable. The Commission can accept the regulatory procedure with scrutiny.

Amendments 108, 120, 204, 221, 225 and 267 are not acceptable as the co-decision procedure would not be appropriate for technical provisions which need to be continuously updated.

We need to mention here the link between the proposed Regulation and Regulation 396/2005 on the setting of maximum residue levels (MRLs) for pesticides in food and feed. The latter is currently subject to a co-decision procedure on the amendment of the comitology procedure to include scrutiny. The Commission has proposed comitology with scrutiny for the adoption of MRLs, with curtailment of time limits for reasons of efficiency. The Commission has also proposed to apply the "urgency" procedure, i.e. without time-limits, in case of threat to human or animal health. An agreement on the above is imminent. Should curtailment of time-limits not be accepted, as the adoption of an EU MRL is a pre-requisite for authorisation, we would need to prolong by 6 months the delay for Member States to reach a decision on plant protection products in Article 36, to make time limits in the two Regulations compatible. The situation should normally be clarified after the Plenary session of the European Parliament end of November 2007.

- 4) PURSUANT TO ARTICLE 250(2) OF THE EC-TREATY, THE COMMISSION AMENDS ITS PROPOSAL IN ACCORDANCE WITH THE LINES SET OUT ABOVE.**

Amended Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

concerning the placing of plant protection products on the market

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37(2) and 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European 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,

Whereas:

- (1) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market¹ provides for rules governing plant protection products and the active substances contained in those products.
- (2) In their conclusions on the progress report² presented by the Commission under Directive 91/414/EEC, the European Parliament and the Council asked the Commission to review the Directive and identified a number of issues for the Commission to address.
- (3) In the light of the experience gained from the application of Directive 91/414/EEC and of recent scientific and technical developments, Directive 91/414/EEC should be replaced.
- (4) By way of simplification, the new act should also repeal Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances³.
- (5) To simplify application of the new act and to ensure consistency throughout the Member States, it should take the form of a Regulation.

¹ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/xxx/EC (OJ L xxx, xx.xx.xxxx, p. xx).

² COM(2001) 444.

³ OJ L 33, 8.2.1979, p. 36. Directive as last amended by Regulation (EC) No 850/2004 of the European Parliament and the Council (OJ L 158, 30.4.2005, p. 7, corrected version in OJ L 229, 29.6.2004, p. 5).

- (6) Plant production has a very important place in the Community. One of the most important ways of protecting plants and plant products against harmful organisms, including weeds, and of improving agricultural production is the use of plant protection products.
- (7) Plant protection products can also have non-beneficial effects on plant production. Their use may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorised and if incorrectly used. Therefore, harmonised rules should be adopted on the placing on the market of plant protection products.
- (8) The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment, **and at the same time to safeguard the competitiveness of European agriculture**. Particular attention should be paid to the protection of vulnerable groups of the population, ~~including pregnant women, infants and children~~. The precautionary principle should be applied and ensure that industry demonstrates that substances or products produced or placed on the market do not adversely affect human health or the environment.
- (9) Substances should only be included in plant protection products where it has been demonstrated that they present a clear benefit for plant production and they are not expected to have any harmful effect on human or animal health or any unacceptable influence on the environment. In order to achieve the same **high** level of protection in all Member States, the decision on acceptability or non-acceptability of such substances should be taken at Community level.
- (10) In the interest of predictability, efficiency and consistency, a detailed procedure should be laid down for assessing whether an active substance can be approved. The information to be submitted by interested parties for the purposes of approval of a substance should be specified. In view of the amount of work connected with the approval procedure, it is appropriate that the evaluation of such information be performed by a Member State acting as a *rapporteur* for the Community. To ensure consistency in evaluation, an independent scientific review should be performed by the European Food Safety Authority established by Article 22 of Regulation (EC) No 178/2002 of the European Parliament and 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 safety⁴ (hereinafter referred to as ‘the Authority’). It should be clarified that the Authority performs a risk assessment whilst the Commission should perform the risk management and take the ultimate decision on an active substance. Provisions should be included to ensure transparency of the evaluation process.
- (11) For ethical reasons, the assessment of an active substance or a plant protection product should not be based on tests or studies involving the deliberate administration of the active substance or plant protection product to humans with the purpose of determining a human No Observed Effect Level of an active substance. Similarly,

⁴ 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).

toxicological studies carried out on humans should not be used to lower the safety margins for active substances or plant protection products.

- (12) To speed up the approval of active substances, strict deadlines should be established for the different procedural steps.
- (13) In the interest of safety, the approval period for active substances should be limited in time. The approval period should be proportional to the possible risks inherent in the use of such substances. Experience gained from the actual use of plant protection products containing the substances concerned and any developments in science and technology should be taken into account when any decision regarding the renewal of an approval is taken. After the first renewal, such substances should only be reviewed further where there are indications that they no longer meet the requirements of this Regulation.
- (14) The possibility of amending or withdrawing the approval of an active substance in cases where the criteria for approval are no longer satisfied **or where compliance with Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy⁵ should be provided for.**
- (15) The evaluation of an active substance may reveal that it presents considerably less of a risk than other substances. In order to favour the inclusion of such a substance in plant protection products, it is appropriate to identify such substances and to facilitate the placing on the market of plant protection products containing them.
- (16) Certain substances which are not predominantly used as a plant protection product may be of value for plant protection, but the economic interest of applying for approval may be limited. Therefore, specific provisions should ensure that such substances, as far as their risks are acceptable, may also be approved for plant protection use.
- (17) Some active substances may only be acceptable when extensive risk mitigation measures are taken. Such substances **of particular concern, which are approved,** should be identified at Community level **as candidates for substitution.** Member States should regularly re-examine whether plant protection products containing such active substances can be replaced by plant protection products containing active substances which require less risk mitigation.
- (18) In addition to active substances, plant protection products may contain safeners or synergists for which similar rules should be provided. The technical rules necessary for the review of such substances should be established. Substances currently on the market should only be reviewed after those provisions have been established.
- (19) Plant protection products may also contain co-formulants. It is appropriate to provide a list of co-formulants which should not be included in plant protection products.

⁵ OJ L 327, 22.12.2000, p. 1. Directive as amended by Decision (EC) No 2455/2001/EC (OJ L 331, 15.12.2001, p. 1).

- (20) Plant protection products containing active substances can be formulated in many ways and used on a variety of crops, under different agricultural, ecological and climatic conditions. Authorisations for plant protection products should therefore be granted by Member States.
- (21) The provisions governing authorisation must ensure a high standard of protection. In particular, when granting authorisations of plant protection products, the objective of protecting human or animal health and the environment should take priority over the objective of improving plant production. Therefore, it should be demonstrated, before plant protection products are placed on the market, that they present a clear benefit for plant production and do not have any harmful effect on human or animal health, **including that of vulnerable groups**, or any unacceptable influence on the environment.
- (22) In the interest of predictability, efficiency and consistency, criteria, procedures and conditions for the authorisation of plant protection products should be harmonised, account being taken of the general principles of protection of human and animal health and the environment.
- (23) The active substances contained in a plant protection product can be produced by different manufacturing processes, leading to differences in specifications. Such differences may have safety implications. For efficiency reasons, a harmonised procedure at Community level should be provided for the assessment of those differences.
- (24) To avoid ~~any unnecessary~~ duplication of work, to reduce the administrative burden for industry and for Member States and to **facilitate** ~~ensure~~ more harmonised availability of plant protection products, authorisations granted by one Member State should be accepted by other Member States where ecological and climatic conditions are comparable. Therefore, the European Union should be divided in authorisation zones with comparable conditions in order to facilitate such mutual recognition.
- (25) The economic interest for industry to apply for an authorisation is limited in certain uses. In order to ensure that diversification of agriculture and horticulture is not jeopardised by the lack of availability of plant protection products, specific rules should be established for minor uses.
- (26) In exceptional cases, **Member States** should be permitted to authorise plant protection products not complying with the conditions provided for in this Regulation, where it is necessary to do so because of a danger or threat to plant production **and ecosystems** which cannot be contained by any other means. Such **temporary** authorisations should be reviewed at Community level.
- (27) To promote innovation, special rules should be established permitting the use of plant protection products in experiments even where they have not yet been authorised.
- (28) In order to ensure a high level of protection of human health and the environment, plant protection products should be used properly having regard to the principles of integrated pest management. The Council shall include in the statutory management requirement referred to in Annex III of Regulation (EC) No 1782/2003 the principles of integrated pest management, including good plant protection practice and good

environmental practice. A transitional period should therefore be foreseen to allow Member States to put in place the necessary structures to enable users of plant protection products to apply the principles of integrated pest management.

- (29) A system of exchange of information should be established. Member States should make available to each other, the Authority and the Commission the particulars and scientific documentation submitted in connection with applications for authorisation of plant protection products.
- (30) Adjuvants may be used to increase the efficacy of a plant protection product. Their placing on the market or use should be forbidden where they contain a co-formulant which has been prohibited.
- (31) Studies represent a major investment. This investment should be protected in order to stimulate research. For this reason, studies lodged by one applicant with a Member State should be protected against use by another applicant. This protection should, however, be limited in time in order to allow competition. It should also be limited to studies which are genuinely necessary for regulatory purposes, to avoid applicants artificially extending the period of protection by submitting new studies which are not necessary.
- (32) Rules should be laid down to avoid duplication of tests and studies. In particular, repetition of studies involving vertebrates should be prohibited. In this context, there should be an obligation to allow access to studies on vertebrates **and other studies that may prevent animal testing** on reasonable terms. In order to allow operators to know what studies have been carried out by others, Member States should keep a list of such studies even where they are not covered by the above system of compulsory access. **The development of non-animal in vitro test methods should be promoted in order to replace animal studies currently in use. Testing on vertebrate animals for the purposes of this Regulation should be undertaken only as a last resort.**
- (33) As different rules are applied by Member States, the Authority or the Commission in relation to access to and confidentiality of documents, it is appropriate to clarify the provisions concerning access to information contained in the documents in the possession of these authorities and the confidentiality of these documents. **Such clarification should also cover the availability to the public of studies and data relevant for toxicological and ecotoxicological assessment of plant protection products.**
- (34) Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations⁶ applies to the classification, packaging and labelling of pesticides. However, to further improve the protection of users of plant protection products, **of residents and bystanders who could be exposed to pesticides from crop-spraying,** of consumers of plants and plant products and of the environment, further specific

⁶ OJ L 200, 30.7.1999, p. 1. Directive as last amended by Commission Directive 2006/8/EC (OJ L 19, 24.1.2006, p. 12).

rules are appropriate which take account of the specific conditions of use of plant protection products.

- (35) To ensure that advertisements do not mislead users of plant protection products **or the public**, it is appropriate to provide rules on the advertising of those products.
- (36) Provisions on record keeping and information about the use of plant protection products should be established in order to raise the level of protection of human and animal health and the environment by ensuring the traceability of potential exposure, to increase the efficiency of monitoring and control and to reduce the costs of monitoring water quality.
- (37) Provisions on control and inspection arrangements with regard to the marketing and use of plant protection products should ensure correct, safe and harmonised implementation of the requirements laid down in this Regulation in order to achieve a high level of protection of both human and animal health and the environment.
- (38) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules⁷ provides for control measures for the use of plant protection products at all stages of the production of food, including record keeping on the use of plant protection products. Similar rules should apply to the storage and use of plant protection products not covered by Regulation (EC) No 882/2004.
- (39) Close coordination should be ensured with other Community legislation, in particular Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residues levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC⁸, and Community legislation on the protection of workers and anyone concerned with the contained use and deliberate release of genetically modified organisms.
- (40) It is necessary to establish procedures for the adoption of emergency measures in situations where an approved active substance, a safener, a synergist or a plant protection product is likely to constitute a serious risk to human or animal health or the environment.
- (41) Member States should lay down rules on penalties applicable to infringements of this Regulation and should take the measures necessary to ensure that they are implemented.
- (42) General civil and criminal liability in the Member States of the manufacturer and, where applicable, of the person responsible for placing the plant protection product on the market or using it should remain applicable.
- (43) Member States should have the possibility of recovering the costs of the procedures associated with the application of the Regulation from those seeking to place, or

⁷ OJ L 165, 30.4.2004, p. 1. Corrected version in OJ L 191, 28.5.2004, p. 1.

⁸ OJ L 70, 16.3.2005, p. 1.

placing, plant protection products on the market and from those applying for the approval of active substances, safeners or synergists.

- (44) Member States should designate the necessary national authorities.
- (45) The Commission should facilitate the application of this Regulation. Therefore, it is appropriate to provide for the necessary financial resources and the possibility of amending certain provisions of the Regulation in the light of experience or of developing technical notes for guidance.
- (46) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁹. It is appropriate to adopt purely technical, administrative or urgent measures using the advisory committee procedure.
- (46a) Power should be conferred on the Commission in particular to establish implementing measures for the procedures of renewal and review of active substances and a programme of work for the gradual review of synergists and safeners on the market when the regulation will enter into force, to adopt data requirements for safeners and synergists, to amend the criteria for approving low risk active substances, to adopt rules on research and development of new plant protection products, to adopt an implementing regulation setting out provisions for the control and to amend the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.**
- (46b) On grounds of efficiency, the normal time-limits for the regulatory procedure with scrutiny should be curtailed for the adoption of a Regulation to renew or not to renew the approval of an active substance, and for the extension of approval period due to the duration of the procedure.**

⁹ OJ L 184, 17.7.1999, p. 23.

(46c) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to use the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC where it concludes that the criteria for approval are no longer satisfied and a regulation to withdraw or amend the approval of the substance to be adopted.

(47) Certain provisions of Directive 91/414/EEC should remain applicable during the transitional period,

HAVE ADOPTED THIS REGULATION:

CHAPTER I GENERAL PROVISIONS

Article 1

*Subject matter **and purpose***

1. This Regulation lays down rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the Community.
2. This Regulation lays down both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants.
3. **The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment.**
4. **This Regulation reflects the precautionary principle in ensuring that substances or products placed on the market do not adversely affect human health or the environment.**
5. **The purpose of this Regulation is furthermore to harmonise the rules on the placing on the market of plant protection products in order to harmonise the availability of plant protection products between farmers in different Member States.**

Article 2

Scope

1. This Regulation shall apply to products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:

- (a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for hygiene reasons rather than for the protection of plants or plant products;
- (b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient;
- (c) preserving plant products, insofar as such substances or products are not subject to special Community provisions on preservatives;
- (d) destroying undesired plants or parts of plants, except algae;
- (e) checking or preventing undesired growth of plants, except algae.

These products are referred to hereinafter as 'plant protection products'.

2. This Regulation shall apply to substances, including micro-organisms and viruses, having general or specific action against harmful organisms or on plants, parts of plants or plant products, hereinafter 'active substances'.
3. This Regulation shall apply to the following:
 - (a) substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the preparation on certain plants, hereinafter 'safeners';
 - (b) substances or preparations which, while showing no or only weak activity in the sense of paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product, hereinafter 'synergists';
 - (c) substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, hereinafter 'co-formulants';
 - (d) substances or preparations which consist of co-formulants or preparations containing one or more co-formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product for the purpose of changing its properties or effects, hereinafter 'adjuvants'.

Article 3
Definitions

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

(1) 'residues'

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, breakdown or reaction products;

(2) 'substances'

Chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process **used**;

(3) 'preparations'

Mixtures composed of two or more substances intended for use as a plant protection product or as an adjuvant;

(4) '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 present risks of such an effect.

Such substances include, but are not limited to, substances classified as dangerous in accordance with Directive 67/548/EEC¹⁰, 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 Directive 1999/45/EC;

Any substance which has an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects should be regarded as a substance of concern.

(5) 'plants'

Live plants and live parts of plants, including fresh fruit, vegetables and seeds;

(6) 'plant products'

Products in unprocessed state or having undergone only simple preparation, such as milling, drying or pressing, derived from plants, but excluding plants as defined in point (5);

¹⁰ OJ 196, 16.8.1967, p. 1.

(7) 'harmful organisms'

Any species, strain or biotype belonging to the animal or plant kingdom or pathogenic agent injurious to plants or plant products;

(7a) **'low risk.'**

Of a nature considered inherently unlikely to cause an adverse effect on humans, animals or the environment;

(8) 'animals'

Animals belonging to species normally domesticated, fed, kept or consumed by humans;

(9) 'placing on the market'

The holding of a plant protection product for the purpose of sale within the Community, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves. Release for free circulation 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;

(9a) **'parallel trade'**

The introduction in a Member State of a plant protection product originating from a Member State where the product has been authorised with the intention of placing it on the market in the Member State of destination where the plant protection product or an identical reference product has been authorised.

(10) 'authorisation of a plant protection product'

Administrative act by which the competent authority of a Member State authorises the placing on the market of a plant protection product in its territory;

(11) 'producer'

A person who manufactures active substances, safeners, synergists, co-formulants, plant protection products or adjuvants on his own, or who contracts this manufacturing to another party, or a person designated by the manufacturer as his sole representative for the purpose of compliance with this Regulation;

(12) 'letter of access'

A document by which the owner of data protected under this Regulation agrees to the use of such data by the competent authority for the purpose of granting an authorisation of a plant protection product or an approval of an active substance, synergist or safener for the benefit of another person;

(13) 'environment'

Waters (including ground, surface, transitional and coastal), soil, air, land, wild species of fauna and flora, and any interrelationship between them, and any relationship with other living organisms;

(13b) **'vulnerable groups of the population'**

Persons needing specific consideration when assessing the acute and chronic health effects of plant protection products. These include pregnant and nursing women, the unborn, infants and children, the elderly, people who are ill and those taking medication, workers and residents subject to high pesticide exposure;

(14) 'integrated pest management'

Careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep plant protection products and other forms of intervention to levels that are economically justified and reduce or minimise risks to human health and the environment. Integrated pest management emphasises the growth of a healthy crop with the least possible disruption to agro-ecosystems **and encourages natural pest control mechanisms"**;

(14a) 'non-chemical methods of plant protection'

Pest control and management techniques that imply the use of non chemical methods for plant protection (e.g. crop rotation, physical and mechanical pest control, natural predators management);

(15) 'micro-organisms'

Any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material;

(16) 'genetically modified micro-organisms'

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 Council¹¹;

(17) 'zone'

Group of Member States, as defined in Annex I, for which it is assumed that the agricultural, plant health and environmental (including climatic) conditions are relatively similar;

¹¹ OJ L 106, 17.4.2001, p. 1.

(18) 'Good Plant Protection Practice'

Practice whereby the treatments with plant protection products applied to a given crop, in conformity with the conditions of their authorised uses, are selected, dosed and timed to ensure optimum efficacy with the minimum quantity necessary, taking due account of local conditions and of the possibilities for cultural and biological control **and giving consideration to non-chemical methods of plant protection and pest and crop management;**

(19) 'Good Environmental Practice'

Practice in plant protection which includes the handling and application of plant protection products in a way which only contaminates the environment with the smallest amount practicable;

(20) 'Good Laboratory Practice'

Practice as defined by Directive 2004/10/EC¹²;

(21) 'Data protection'

A test or study report is covered by data protection where its owner has the right to prevent it being used for the benefit of another person;

(21a) 'Rapporteur Member State'

The Member State which undertakes the task of evaluating an active substance, safener or synergist;

(21b) 'Tests and studies'

Investigation or experiment whose purpose is to determine the properties and behaviour of an active substance or of plant protection products, predict exposure to active substances and/or their relevant metabolites, determine safe levels of exposure and establish conditions for the safe use of plant protection products.

¹² OJ L 50, 20.2.2004, p. 44.

CHAPTER II

Active substances, safeners, synergists and co-formulants

SECTION 1

ACTIVE SUBSTANCES

SUBSECTION 1

REQUIREMENTS AND CONDITIONS FOR APPROVAL

Article 4

Approval criteria for active substances

1. An active substance shall be approved in accordance with Annex II, if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance will fulfil the conditions provided for in paragraphs 2 and 3.
2. The residues of the plant protection products, consequent on application consistent with good plant protection practice, shall meet the following requirements:
 - (a) they shall not have any harmful effects on human health, including vulnerable groups, or animal health, taking into account known cumulative and synergistic effects when the methods to assess such effects are available, or on ground water;
 - (b) they shall not have any unacceptable effect on the environment;
 - (c) for residues which are of toxicological or environmental significance, there shall be **standardised** methods in general use for measuring them, **which are sufficiently sensitive**;
3. The use of the plant protection products, consequent on application consistent with good plant protection practice and having regard to ~~normal~~ **realistic** conditions of use, shall meet the following requirements:
 - (a) it shall be sufficiently effective;
 - (b) it shall have no immediate or delayed harmful effect on human **health, including that of vulnerable groups,** or animal health, directly or through drinking water, food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the methods to assess such effects are available; or on groundwater;

- (c) it shall not have any unacceptable effects on plants or plant products;
 - (d) it shall not cause unnecessary suffering and pain to vertebrates to be controlled;
 - (e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations:
 - (i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, drinking water, groundwater, air and soil, **taking into account locations distant from its use following long-range environmental transport;**
 - (ii) its impact on non-target species; **including on the behaviour of those species;**
 - (iii) its impact on biodiversity **and the ecosystem.**
4. For approval of an active substance, paragraphs 1, 2 and 3 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.
5. In relation to human health, no data collected on humans shall be used to lower the safety margins resulting from tests or studies on animals.

Article 5 *First approval*

First approval shall be for a period not exceeding ten years.

Article 6 *Conditions and restrictions*

Approval may be subject to conditions and restrictions including:

- (a) the minimum degree of purity of the active substance;
- (b) the nature and maximum content of certain impurities;
- (c) restrictions arising from the evaluation of the information referred to in Article 8 taking account of the agricultural, plant health and environmental, including climatic, conditions in question;
- (d) type of preparation;
- (e) manner **and conditions** of application;
- (f) submission of further confirmatory information to Member States and to the European Food Safety Authority, hereinafter 'the Authority', where new requirements are established during the evaluation process as a result of new scientific and technical knowledge;

- (g) designation of categories of users, such as professional and non-professional;
- (h) designation of places where plant protection products containing the active substance may be authorised according to specific conditions;
- (i) the need to impose risk mitigation measures and monitoring after use;
- (j) any other particular conditions that result from the evaluation of information made available in the context of this Regulation.

SUBSECTION 2

APPROVAL PROCEDURE

Article 7 *Application*

1. An application for the approval of an active substance or for an amendment to the conditions of an approval shall be submitted by the producer of the active substance to a Member State (hereinafter referred to as ‘rapporteur Member State’) together with a complete and a summary dossier, as provided for in Article 8(1) and (2), or a letter of access to such dossiers or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in Article 4.

A joint application may be submitted by an association of producers designated by the producers for the purpose of compliance with this Regulation.

2. Within 14 days of receiving the application, the rapporteur Member State shall send the applicant a written acknowledgement, stating the date of receipt.
3. When submitting his application, the applicant may, pursuant to Article 60, request certain parts of the dossiers referred to in paragraph 1 to be kept confidential. He shall explain for each document or each part of a document why it is to be considered as confidential.

He shall at the same time submit any claims for data protection pursuant to Article 56.

After giving the applicant the possibility to submit comments on the decision it plans to adopt, the rapporteur Member State shall decide what information is to be kept confidential. It shall inform the applicant and the Authority of its decision.

Article 8
Dossiers

1. The summary dossier shall include the following:
 - (a) Data with respect to one or more representative uses on a widely grown crop in each zone of at least one plant protection product containing the active substance, demonstrating that the requirements of Article 4 are met; where the data submitted do not cover all zones or concern a crop which is not widely grown, justification for this approach;
 - (b) for each point of the data requirements for the active substance referred to in Article 75(1)(b), the summaries and results of tests and studies, the name of their owner and of the person or institute that has carried out the tests and studies;
 - (c) for each point of the data requirements for the plant protection product referred to in Article 75(1)(b), the summaries and results of tests and studies, the name of their owner and of the person or institute that carried out the tests and studies, relevant to the assessment of the criteria referred to in Article 4 for one or more plant protection products which are representative of the uses referred to in point (a), taking into account the fact that data gaps in the dossier, as provided for in paragraph 2, resulting from the proposed limited range of representative uses of the active substance, may lead to restrictions in the approval;
 - (ca) for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplicative testing on vertebrate animals;**
 - (d) a checklist demonstrating that the dossier provided for in paragraph 2 is complete;
 - (e) the reasons why the test and study reports submitted are necessary for first approval of the active substance or for amendments to the conditions of the approval;
 - (f) an assessment of all information submitted.
2. The complete dossier shall contain the full text of the individual test and study reports concerning all the information referred to in points (b) and (c) of paragraph 1. **No** tests or studies involving the deliberate administration of the active substance or the plant protection product to humans **shall be performed.**

3. The format of the summary dossier and the complete dossier shall be established in accordance with the procedure referred to in Article 76(2).

The data requirements referred to in Article 8(1) shall be defined in Regulations adopted in accordance with the procedure referred to in Article 76(2), incorporating the requirements for active substances and plant protection products in Annexes II and III to Directive 91/414/EEC ~~with any necessary modifications~~. **The Commission shall define similar data requirements shall be defined for safeners and synergists within 5 years of the entry into force of this Regulation** ~~in accordance with the procedure referred to in Article 76(3).~~

The measures referred to in the third subparagraph, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a).

- 3(a) **All scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health and the environment and published within the last five years before the date of dossier submission shall be added by the applicant to the dossier.**

Article 9 *Admissibility of the application*

1. Within 30 days of receiving the application, the rapporteur Member State shall check whether the dossiers submitted with the application contain all the elements provided for in Article 8, using the checklist referred to in Article 8(1)(d).
2. Where one or more of the elements provided for in Article 8 are missing, the Member State shall inform the applicant, setting a time period **not exceeding six months** for their submission. **Article 7 (3) shall apply.**

Where at the end of that period, the applicant has not submitted the missing elements, the rapporteur Member State shall inform the applicant that the application is inadmissible.

A new application for the same substance may be submitted at any time.

3. Where the dossiers submitted with the application contain all the elements provided for in Article 8, the rapporteur Member State shall notify the applicant, the Commission, the other Member States and the Authority of the admissibility of the application and start assessing the active substance.

After receiving that notification, the applicant shall immediately forward the summary dossier and the complete dossier to the other Member States, the Authority and the Commission.

Article 10
Access to the summary dossier

The Authority shall without delay make the summary dossier referred to in Article 8(1) available to the public, excluding any information which is confidential under Article 60.

Article 11
Draft assessment report

1. Within twelve months of the date of the notification provided for in the first subparagraph of Article 9(3), the rapporteur Member State shall prepare and submit to the Authority a report (hereafter called “draft assessment report”) assessing whether the active substance can be expected to meet the requirements of Article 4.

Where the Member State needs additional information, it shall set a time period for the applicant to supply it. In that case, the twelve months period shall be extended by the additional time period granted by the Member State. **The additional time period shall not exceed six months and shall cease at the moment when the additional information is received by the Rapporteur Member State which shall inform the Commission and the Authority. When supplying additional information, the applicant shall at the same time submit any claims for data protection pursuant to Article 56. Article 7(3) shall apply.**

The Member State may consult the Authority.

2. The format of the draft assessment report shall be established in accordance with the procedure referred to in Article 76(2).

Article 12
Conclusion by the Authority

1. The Authority shall circulate the draft assessment report received from the rapporteur Member State to the applicant, the other Member States and the Commission.

It shall make it available to the public, after giving the applicant two weeks to request, pursuant to Article 60, that certain parts of the draft assessment report be kept confidential.

The Authority shall allow a period of ninety days for the submission of written comments.

Where appropriate, the Authority shall organise a consultation of experts, including experts from the rapporteur Member State.

2. The Authority shall adopt a conclusion on whether the active substance can be expected to meet the requirements of Article 4 within ninety days of the end of the period provided for in paragraph 1 of this Article **with due justification, including a reference to the consideration of any public comments**, and communicate it to the applicant, the Member States and the Commission. **The conclusion shall be published by the Authority on its website.**

Where appropriate, the Authority shall address in its conclusion the risk mitigation options identified in the draft assessment report.

3. Where the Authority needs additional information, it shall set a time period **not exceeding ninety days**, for the applicant to supply it **to the Authority and the rapporteur Member State** ~~In that case, the ninety-day period provided for in paragraph 2 shall be extended by the additional period granted by the Authority, which~~ **It shall inform the Commission and the Member States.**

The rapporteur Member State shall assess the additional information and submit it to the Authority without delay and at the latest within sixty days after the receipt of the additional information. In that case the ninety-day period provided for in paragraph 2 shall be extended by an additional period which shall cease at the moment when the additional assessment is received by the Authority.

The Authority may ask the Commission to consult a Community reference laboratory, designated pursuant to Regulation (EC) No 882/2004 for the purposes of verifying whether the analytical method for the determination of the residues proposed by the applicant is satisfactory and meets the requirements of Article 29(1)(f) of this Regulation. The applicant shall, if requested by the Community reference laboratory, provide samples and analytical standards.

4. The Authority shall establish the format for its conclusion which shall include details on the procedure of the evaluation and the properties of the active substance concerned.

Article 13 *Approval Regulation*

1. Within six months of receiving the conclusion provided for in Article 12(2) from the Authority, the Commission shall present a report, (hereinafter referred to as “the review report”, to the Committee referred to in Article 76(1), taking into account the draft assessment report by the Rapporteur Member State under Article 11 and the conclusion of the Authority under Article 12.

The applicant shall be given **the opportunity** ~~the possibility~~ to submit comments on the review report.

2. On the basis of the review report provided for in paragraph 1, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) of Regulation (EC) No 178/2002 are relevant, a Regulation shall be adopted in accordance with the procedure referred to in Article 76(3), providing that:
 - (a) an active substance is approved, subject to conditions and restrictions, as referred to in Article 6, where appropriate;
 - (b) an active substance is not approved; or
 - (c) the conditions of the approval are amended.
3. The Commission shall maintain **an updated** list of approved active substances **and their review reports and publish them on its website**.

SUBSECTION 3 RENEWAL AND REVIEW

Article 14 Renewal of approval

1. On application the approval of an active substance shall be renewed where it is established that the criteria referred to in Article 4 are satisfied.

Article 4 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

Such renewal of the approval may include conditions and restrictions, as referred to in Article 6.
2. The renewal shall be for an unlimited period of time.

Article 15 Application for renewal

1. The application provided for in Article 14 shall be submitted by a producer of the active substance to a Member State, with a copy to the other Member States, the Commission and the Authority, no later than three years before the expiry of the first approval.

2. When applying for renewal, the applicant shall identify new data he intends to submit and demonstrate that they are necessary, because of data requirements or criteria which were not applicable on first approval of the active substance or because his request is for an amended approval. He shall at the same time submit a timetable of any new and ongoing studies.

The applicant shall identify, giving reasons, the parts of the information submitted that are to be kept confidential in accordance with Article 60.

Article 16
Access to the application for renewal

The Authority shall, without delay, make available to the public the information provided by the applicant under Article 15, excluding any information declared confidential under Article 60.

Article 17
Extension of approval period for the duration of the procedure

Where for reasons beyond the control of the applicant it appears that the approval is likely to expire before a decision has been taken on renewal, a Regulation shall be adopted ~~in accordance with the procedure referred to in Article 76(3)~~, postponing the expiry for a period sufficient to examine the application. In particular, such a Regulation shall be adopted where applicants could not give the three years' notice required under Article 15(1) because the active substance was included in Annex I to Directive 91/414/EEC for a duration which expired less than three years after the date of application of this Regulation.

The length of that period shall be established on the basis of the following:

- (a) the time needed to provide the information requested;
- (b) the time needed to complete the procedure;
- (c) the need to ensure the establishment of a coherent programme of work, as provided for in Article 18.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3b).

Article 18
Programme of work

The Commission may establish a programme of work grouping together similar active substances. This programme may require interested parties to submit all the necessary data to the Commission, the Authority and the Member States within a period provided for in the programme.

The programme shall include the following:

- (a) the procedures concerning the submission and assessment of applications for renewal of approvals;
- (b) the necessary data to be submitted **including measures to avoid or minimise animal testing, in particular the use of non-animal test methods and intelligent testing strategies;**
- (c) the time periods for submission of such data;
- (d) rules on the submission of new information;
- (e) rules on requests for confidentiality in accordance with Article 60.

Article 19 *Implementing measures*

~~A Regulation, adopted in accordance with the procedure referred to in Article 76(3), shall set out~~ **The Commission shall adopt a Regulation setting out** the provisions necessary for the implementation of the renewal and review procedure, including, where relevant, the implementation of a programme of work, as provided for in Article 18.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a).

Article 20 *Renewal Regulation*

1. **The Commission shall adopt a** ~~A Regulation shall be adopted in accordance with the procedure referred to in Article 76(3),~~ providing that:
 - (a) the approval of an active substance is renewed, where appropriate, subject to conditions and restrictions; or
 - (b) the approval of an active substance is not renewed.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3b).

2. Where the reasons for not renewing the approval permit it, the Regulation referred to in paragraph 1 shall provide for a grace period for using up stocks of the plant protection products concerned, which **shall not exceed one year.**
- 2a. **In the event of a withdrawal of the approval or if the approval is not renewed because of immediate concerns for human health or animal health or the environment, the plant protection products concerned shall be disposed of immediately.**

Article 21
Review of approval

1. The Commission may review the approval of an active substance at any time.

Where it considers that there are indications that the substance no longer satisfies the criteria provided for in Article 4, or further information required in accordance with point (f) of Article 6 has not been provided, it shall inform the Member States, the Authority and the producer of the active substance, setting a time period for the producer to submit its comments.

Such review shall also be carried out where there are indications that the achievement of the objectives established in accordance with Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may be compromised.

2. The Commission may ask the Authority for an opinion, or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within 3 months of the request.
3. Where the Commission concludes that the criteria referred to in Article 4 are no longer satisfied, or the further information required in accordance with point (f) of Article 6 has not been provided, **it shall adopt** a Regulation to withdraw or amend the approval.

That Regulation, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 76(3c). ~~shall be adopted in accordance with the procedure referred to in Article 76(3).~~

Article 20(2) shall apply.

- 3a. **Where the Commission evaluation concludes that the objectives of reducing pollution from priority substances established in accordance with Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC cannot be met, it shall adopt a Regulation to withdraw or amend the approval.**

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 76(3c).

SUBSECTION 4 DEROGATIONS

Article 22 *Low risk active substances*

1. By way of derogation from Article 5, an active substance complying with the criteria provided for in Article 4 shall be approved for a period not exceeding 15 years, where it may be expected that plant protection products containing that substance will pose only a low risk to human and animal health and the environment, as provided for in Article 46(1).

1(a) The derogation provided for in paragraph 1 shall not apply to any active substance

(a) classified in accordance with Directive 67/548/EEC as or which meets the criteria to be classified as such:

- **carcinogenic**
- **mutagenic**
- **toxic for reproduction**
- **very toxic**
- **toxic**
- **sensitising**
- **explosive,**

(b) which is qualified as :

- **persistent with a half- life of more than 60 days**
- **endocrine disrupters**
- **bioaccumulative and non readily-degradable**

1(b) The Commission may review and if necessary specify the criteria for approving an active substance as a low risk substance.

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a).

2. Article 4(4) and Articles 6 to 21 shall apply.

Article 23
Approval criteria for basic substances

1. Basic substances shall be approved in accordance with paragraphs 2 to 6. By way of derogation from Article 5, the approval shall be for an unlimited period of time. For the purpose of those paragraphs, a basic substance is an active substance which
 - (a) is not predominantly used as a plant protection product but
 - (b) nevertheless has some use as a plant protection product, either directly or in a product consisting of the substance and a simple diluent,
 - (c) is not a substance of concern, and
 - (d) is not directly marketed for use as a plant protection product.

1(a) For the purpose of this Regulation, an active substance which fulfils the criteria of a foodstuff as defined in Article 2 of Regulation (EC) N° 178/2002 shall be considered as a basic substance.

2. By way of derogation from Article 5, a basic substance shall be approved where any relevant evaluations carried out in accordance with other Community legislation, regulating the use of that substance for purposes other than as a plant protection product, show that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment.
3. An application for the approval of a basic substance shall be submitted by any interested party or by a Member State to the Commission.

The application shall be accompanied by the following information:

- (a) any evaluations carried out in accordance with other Community legislation regulating the use of the substance; or
 - (b) information indicating that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment.
4. The Commission may ask the Authority for an opinion, or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within 3 months of the request.
5. Articles 6 and 13 shall apply.
6. The Commission may review the approval of a basic substance at any time.

Where it considers that there are indications that the substance no longer satisfies the criteria provided for in paragraphs 1 and 2 it shall inform the Member States, the Authority and the interested party, setting a time period for their comments to be submitted.

The Commission shall ask the Authority for an opinion, or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within 3 months of the request.

Where the Commission concludes that the criteria referred to in paragraph 1 are no longer satisfied, **it shall adopt** a Regulation to withdraw or amend the approval.

That Regulation, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 76(3c). ~~shall be adopted in accordance with the procedure referred to in Article 76(3).~~

Article 20(2) shall apply.

Article 24

Approval criteria for candidates for substitution

1. By way of derogation from Article 5 and Article 14(2), an active substance complying with the criteria provided for in Article 4 shall be approved for a period not exceeding seven years, where other already approved active substances are significantly less toxic for consumers or operators or present significantly fewer risks for the environment. The assessment shall take account of the criteria laid down in point 4 of Annex II.

Such a substance is referred to hereinafter as a ‘candidate for substitution’.

2. Article 4(4) and Articles 6 to 21 shall apply.

SECTION 2

SAFENERS AND SYNERGISTS

Article 25

Approval of safeners and synergists

1. A safener or synergist shall be approved, where it complies with Article 4.
- 1a. **By way of derogation from Article 4(4), for approval of a safener or synergist, Article 4(1), (2), and (3) shall be deemed to be satisfied where this has been established with respect to one or more representative uses of the safener or synergists with at least one plant protection product.**
2. Articles 5 to 21 shall apply.

Article 26
Safeners and synergists already on the market

Within 5 years of the entry into force of this Regulation, a Regulation shall be adopted ~~in accordance with the procedure referred to in Article 76(3)~~ establishing a programme of work for the gradual review of synergists and safeners on the market when that Regulation enters into force. The regulation shall include the establishment of data requirements, **including measures to avoid or minimise animal testing**, notification, evaluation, assessment and decision-making procedures. It shall require interested parties to submit all the necessary data to the Commission, the Authority and the Member States within a specified time period.

Those measures, designed to amend non-essential elements of this Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a).

SECTION 3
UNACCEPTABLE CO-FORMULANTS

Article 27
Prohibition

1. A co-formulant shall be prohibited where it has been established that:
 - (a) **the co-formulant or** its residues, consequent on application consistent with good plant protection practice and **with realistic conditions of use**, have a harmful effect on human or animal health or on groundwater or an unacceptable effect on the environment; or
 - (b) its use, consequent on application consistent with good plant protection practice and having regard to realistic ~~normal~~ conditions of use, has a harmful effect on human or animal health or an unacceptable effect on plants, plant products or the environment.
2. Co-formulants prohibited pursuant to paragraph 1 shall be included in Annex III.

Those measures, designed to amend non-essential elements of this Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a).

CHAPTER III

Plant protection products

SECTION 1

AUTHORISATION

SUBSECTION 1

REQUIREMENTS AND CONTENTS

Article 28

Authorisation for placing on the market and use

1. A plant protection product shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with this Regulation.
2. By way of derogation from paragraph 1, no authorisation shall be required in the following cases:
 - (a) use of plant protection products containing exclusively one or more basic substances;
 - (b) placing on the market and use of plant protection products for research or development purposes in accordance with Article 51;
 - (c) production, storage or movement of a plant protection product intended for use in another Member State, provided that the product is authorised in that Member State and that the Member State of production, storage or movement has put in place inspection requirements to ensure that the plant protection product is not used in its territory.

Article 29

Requirements

1. A plant protection product shall only be authorised where it complies with the following requirements:
 - (a) its active substances, safeners and synergists have been approved;

- (b) where its active substance, safener or synergist is produced by a person or in accordance with a manufacturing process other than that specified in the dossier on the basis of which that substance, safener or synergist was approved, the active substance, safener or synergist contained in the plant protection product does not deviate significantly from the specification included in the Regulation approving that substance, safener or synergist and has no more harmful effects within the meaning of Article 4(2) and (3), due to its impurities, than if it had been produced in accordance with the manufacturing process specified in that dossier;
 - (c) its co-formulants have not been prohibited under Article 27;
 - (ca) its formulation is such that user exposure or other risks are limited as much as possible without compromising the functioning of the product;**
 - (d) in the light of current scientific and technical knowledge, it complies with the requirements provided for in Article 4(3);
 - (e) the nature and quantity of its active substances, safeners and synergists and, where appropriate, any toxicologically, ecotoxicologically or environmentally significant impurities and co-formulants can be determined by appropriate methods;
 - (f) its residues, resulting from authorised uses, and which are of toxicological, ecotoxicological or environmental significance, can be determined by appropriate **standardised** methods in general use, **which are sufficiently sensitive;**
 - (g) its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;
 - (h) for feed and food crops, where appropriate, the maximum residue levels for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with Regulation (EC) No 396/2005.
2. By way of derogation from point (a) of paragraph 1, a Member State may, during a period of 5 years following the adoption of the programme of work referred to in Article 26 authorise the placing on the market in its territory of plant protection products containing synergists and safeners which are not approved, but which are included in that programme.
 3. The applicant shall demonstrate that the requirements provided for in paragraph 1 are met.
 4. Compliance with the requirements set out in point (b) and points (d) to (g) of paragraph 1 shall be established by official or officially recognised tests and analyses carried out under agricultural, plant health and environmental conditions relevant to the use of the plant protection product in question and representative of the conditions prevailing in the zone where the product is intended to be used.

5. ~~With respect to point (e) of paragraph 1, harmonised methods may be adopted in accordance with the procedure referred to in Article 76(3).~~ **The Commission may adopt harmonised methods with respect to point (e) of paragraph 1.**

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a).

6. Uniform principles for evaluation and authorisation of plant protection products shall be defined in Regulations adopted in accordance with the procedure referred to in Article 76(2), incorporating the requirements in Annex VI to Directive 91/414/EEC with any necessary modifications.

Article 30

*Contents **of the authorisation***

1. The authorisation shall define the crops on which and the purposes for which the plant protection product may be used.
2. The authorisation shall set out the requirements relating to the placing on the market and use of the plant protection product. Those requirements shall **as a minimum** include:
 - (a)** the conditions of use necessary to comply with the conditions and requirements provided for in the Regulation approving the active substances, safeners and synergists.
 - (b)** ~~authorisation shall include~~ a classification of the plant protection product for the purpose of Directive 1999/45/EC;
 - (c) the maximum dose per hectare in each application;**
 - (d) the period between the last application and harvest;**
 - (e) the number of applications per year.**
3. The requirements referred to in paragraph 2 may include:
 - (a) a restriction of the product with respect to the distribution and use of the plant protection product to protect the health of the distributors, users and workers concerned;
 - (b) the obligation to inform any neighbours who could be exposed to the spray drift before the product is used and who have requested to be informed.

Article 31
Duration

1. The period of authorisation shall be laid down in the authorisation. The duration of an authorisation shall be set for as long as all active substances, safeners and synergists contained in the plant protection product are approved.
2. Authorisations may be granted for shorter periods to synchronise the re-evaluation of similar products for the purposes of a comparative assessment of products containing candidates for substitution as provided for in Article 48.
3. After renewal of the approval of an active substance, safener or synergist contained in the plant protection product, an additional authorisation period of nine months shall be granted to allow the examination as provided for in Article 42 to be carried out.

SUBSECTION 2
PROCEDURE

Article 32
Application for authorisation

1. A person who wishes to place a plant protection product on the market shall apply for an authorisation, in person or via a representative, to each Member State where the plant protection product is intended to be placed on the market.
2. The application shall include the following:
 - (a) a list of the zones and the Member States where the applicant has made an application;
 - (b) a proposal as to which Member State the applicant expects to evaluate the application in the zone concerned;
 - (c) a certified copy of any authorisations already granted for that plant protection product in a Member State.
3. The application shall be accompanied by the following:
 - (a) for the plant protection product concerned, a complete and a summary dossier for each point of the data requirements of the plant protection product;
 - (b) for each active substance, safener and synergist contained in the plant protection product, a complete and a summary dossier for each point of the data requirements of the active substance, safener and synergist; and

- (c) for each test or study involving vertebrate animals, a justification of the steps taken to avoid **animal testing and** duplicative testing **on vertebrate animals**;
 - (d) the reasons why the test and study reports submitted are necessary for first authorisation or for amendments to the conditions of the authorisation.
4. When submitting his application, the applicant may, pursuant to Article 60, request that certain parts of the dossiers referred to in paragraph 3 are to be kept confidential. He shall explain for each document or each part of a document why it is to be considered as confidential.

He shall at the same time submit any claims for data protection pursuant to Article 56(3).

After giving the applicant the possibility to submit comments on the decision it plans to adopt, the rapporteur Member State shall decide what information is to be kept confidential. It shall inform the applicant and the Authority of its decision

5. Where requested by the Member State the applicant shall submit his application in the national or official languages of that Member State or one of those languages.

On request, the applicant shall provide the Member **States involved in the assessment** with samples of the plant protection product and analytical standards of its ingredients.

5a. The format of the application forms may be established in accordance with the procedure referred to in Article 76 (2).

*Article 33
Exemption*

1. Applicants shall be exempted from supplying the test and study reports referred to in Article 32(3) where they demonstrate that they have been granted access in accordance with Article 56, 58 or 59 or that any data protection period has expired.
2. However, applicants to whom paragraph 1 applies shall provide the following information:
- (a) the information needed to identify the active substance, safener or synergist, where they have been approved, and to establish whether the conditions for approval are met and comply with Article 29(1)(b), where appropriate;
 - (b) the data needed to demonstrate that the plant protection product has comparable effects to the plant protection product for which they show access to the protected data.

Article 34
Member State examining the application

The application shall be examined by the Member State proposed by the applicant, unless another Member State in the same zone agrees to examine it. The Member State which will examine the application shall inform the applicant. **It shall give all Member States in the same zone the opportunity to submit comments.**

At the request of the Member State examining the application, the other Member States in the same zone to which an application has been submitted shall cooperate to ensure a fair division of the workload.

The other Member States within the zone to which an application has been submitted shall refrain from proceeding with the file pending assessment by the Member State examining the application.

Article 35
Examination

1. The Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge.

It shall apply the uniform principles for evaluation and authorisation of plant protection products, referred to in Article 29(6), to establish whether the plant protection product meets the requirements provided for in Article 29, where used in accordance with Article 52, and under all realistic ~~normal~~ conditions of use, and the consequences of its use under the authorised conditions.

The Member State examining the application shall make available its assessment to the other Member States within the same zone to which an application has been made.

2. The Member States concerned shall grant or refuse authorisations accordingly on the basis of the conclusions of the assessment of the Member State examining the application as provided for in Articles 30 and 31. The Member States shall authorise the plant protection product concerned under the same conditions, including classification for the purpose of Directive 1999/45/EC, as the Member State examining the application.
3. By way of derogation from paragraph 2 and subject to Community law, additional conditions may be imposed with respect to the requirements referred to in Article 30(3).

Article 36
Time period for examination

1. The Member State examining the application shall decide within twelve months of receiving it whether the requirements for authorisation are met.

Where the Member State needs additional information, it shall set a time period **not exceeding six months** for the applicant to supply it. In that case, the twelve-months period shall be extended by the additional time period granted by the Member State ~~which may not exceed six months~~.

2. The time-limits provided for in paragraph 1 shall be suspended while applying the procedure set out in Article 37.
3. For an application for authorisation of a plant protection product containing an active substance not yet approved, Member States shall start the evaluation as soon as it has received the draft assessment report referred to in Article 12(1). In such case the Member State shall decide on the application at the latest within six months of the active substance being approved.

Article 37
Assessment of equivalence under Article 29(1)(b)

1. Where it is necessary to establish whether a plant protection product complies with Article 29(1)(b), this shall be assessed by the Member State which acted as rapporteur for the active substance, safener or synergist as referred to in Article 7(1), hereafter called the rapporteur Member State. The applicant shall submit all necessary data to that Member State.
2. After giving the applicant the opportunity to submit his comments, which the applicant shall also communicate to the Member State examining the application, the rapporteur Member State shall adopt a conclusion which it shall communicate to the Commission, the other Member States and the applicant.
3. Where the Member State examining the application for authorisation does not agree with the conclusion of the rapporteur Member State, it shall inform the applicant, the other Member States and the Commission stating its reasons.

The Member State examining the application for authorisation and the rapporteur Member State shall try to reach agreement on whether Article 29(1)(b) is complied with. They shall provide the applicant with an opportunity to submit his comments.

4. Where the Member States concerned do not reach agreement within 90 days the Member State examining the application for authorisation shall submit the matter to the Commission. A decision on whether the conditions referred to in Article 29(1)(b) are complied with shall be adopted in accordance with the procedure referred to in Article 76(2). The 90-day period begins on the date on which the Member State examining the application for authorisation informed the rapporteur Member State that it does not agree with the conclusion of the latter, in accordance with paragraph 3.

Before such a decision is adopted, the Commission may ask the Authority for an opinion, or for scientific or technical assistance which shall be provided within three months of the request.

5. Detailed rules for the implementation of paragraphs 1 to 4 may be established in accordance with the procedure referred to in Article 76(3), after consultation of the Authority.

Article 38

Reporting and exchange of information on applications for authorisation

1. Member States shall compile a file on each application. Each file shall contain the following:
 - (a) a copy of the application;
 - (b) a report containing information on the evaluation of and decision on the plant protection product;
 - (c) a record of the administrative decisions taken by the Member State concerning the application and the documentation provided for in Article 32(3) together with a summary of the latter.
2. **To facilitate the decision making process referred to in Article 35(2), Member States having granted an authorisation, shall without delay, make available to the other Member States, the Authority and the Commission a file containing the documentation provided for in points (a), (b) and (c) of paragraph 1 of this Article.**
3. On request, applicants shall provide a copy of the documentation to be submitted with an application pursuant to Article 32(2) and Article 33 to Member States, the Authority and the Commission.

SUBSECTION 3

MUTUAL RECOGNITION OF AUTHORISATIONS

Article 39 *Mutual recognition*

1. The holder of an authorisation may apply for an authorisation for the same plant protection product and for the same use in another Member State under the mutual recognition procedure, provided for in this subsection, in the following cases:
 - (a) the authorisation was granted by a Member State (reference Member State) which belongs to the same zone; or
 - (b) the authorisation was granted by a Member State for use in greenhouses or as post-harvest treatment, regardless of the zone to which the reference Member State belongs.
2. Mutual recognition shall not apply to plant protection products containing a candidate for substitution.

Article 40 *Authorisation*

1. The Member State to which an application under Article 39 is submitted shall authorise the plant protection product concerned under the same conditions, including classification for the purpose of Directive 1999/45/EC, as the reference Member State.
2. By way of derogation from paragraph 1 and subject to Community law, additional conditions may be imposed with respect to the requirements referred to in Article 30(3).

Article 41 *Procedure*

1. The application shall be accompanied by:
 - (a) a certified copy of the authorisation granted by the reference Member State;
 - (b) a formal statement that the plant protection product is identical to that authorised by the reference Member State;
 - (c) a summary of the dossier as required in Article 32(3).
- (ca) at the request of the Member State a complete dossier as required in Article 32(3).**

2. The Member State to which an application under Article 39 is submitted shall decide on the application within 90 days.

SUBSECTION 4

RENEWAL, AMENDMENT AND WITHDRAWAL

Article 42

Renewal of authorisation

1. An authorisation shall be renewed upon application by the authorisation holder, provided that the conditions provided for in Article 29 are still satisfied.

The application shall be submitted at the latest one year before the expiry of the authorisation except where applicants cannot comply with this deadline because the active substance in question was included in Annex I to Directive 91/414/EEC for a duration which expired less than a year after the date of application of this Regulation.

2. The application shall be accompanied by the following information:

- (a) a copy of the authorisation of the plant protection product,
- (b) a report on the results of monitoring, where the authorisation was subject to monitoring.

3. Within three months of renewal of the approval of an active substance, safener or synergist contained in the plant protection product, the applicant shall submit the following information:

- (a) any new information **referred to in the renewal Regulation, as mentioned in Article 20, or** required as a result of amendments in data requirements or criteria;
- (b) justification that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted **or necessary to amend the conditions of the authorisation**;
- (c) any information required to demonstrate that the plant protection product meets the requirements set out in the Regulation on the renewal of the approval of the active substance, safener or synergist contained in it.

4. Member States shall check that all plant protection products containing the active substance, safener or synergist concerned comply with any conditions and restrictions provided for in the Regulation renewing the approval under Article 20.

The Member State which acted as rapporteur for the active substance, safener or synergist shall coordinate performance of the compliance check and assessment of the results. The compliance check shall be performed within the time period set in the Regulation on the renewal of the approval.

5. Guidelines on the organisation of compliance checks may be established in accordance with the procedure referred to in Article 76(2).
6. Member States shall decide on the renewal of the authorisation at the latest nine months after the renewal of the approval of the active substance, safener or synergist contained in it.
7. Where, for reasons beyond the control of the holder of the authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Member State in question shall extend the authorisation for the period necessary to complete the examination and adopt a decision on the renewal.

Article 43

Withdrawal or amendment of an authorisation

1. Member States may review an authorisation at any time where there are indications that a requirement referred to in Article 29 is no longer satisfied.
- 1a. **A Member State shall review an authorisation where it concludes that the objectives of Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may not be achieved.**
2. Where a Member State intends to withdraw or amend an authorisation, it shall inform the authorisation holder and give him the possibility to submit comments.

The Member State may ask the authorisation holder to submit further information.
3. The Member State shall withdraw or amend the authorisation, as appropriate, where:
 - (a) the requirements referred to in Article 29 are not or are no longer satisfied;
 - (b) false or misleading information was supplied concerning the facts on the basis of which the authorisation was granted;
 - (c) a condition included in the authorisation has not been met;**(ca) on the basis of developments in scientific and technical knowledge, the manner of use and amounts used can be modified without affecting the effectiveness.**
4. Where a Member State withdraws or amends an authorisation in accordance with paragraph 3, it shall immediately inform the holder of the authorisation, the other Member States, the Authority and the Commission. The other Member States belonging to the same zone shall withdraw or amend the authorisation accordingly. Article 45 shall apply where appropriate.

Article 44

Withdrawal or amendment of an authorisation at the request of the authorisation holder

1. An authorisation may be withdrawn or amended at the request of the holder of the authorisation, who shall state the reasons for his request.
2. Amendments may only be granted where it is established that the requirements of Article 29 continue to be satisfied.

Article 45

Grace period

Where a Member State withdraws or amends an authorisation or does not renew it, it may grant a grace period for the disposal, storage, placing on the market and use of existing stocks.

Where the reasons for withdrawal, amendment or not renewing the authorisation permit, grace periods for using up stocks of the plant protection products concerned shall be such that they do not interfere with the normal period of use of the plant protection product.

SUBSECTION 5 SPECIAL CASES

Article 46

Placing on the market and use of low-risk plant protection products

1. Where all the active substances contained in a plant protection product are substances as referred to in Article 22 ('low-risk active substances'), that product shall, by way of derogation from Article 29, be authorised as a low-risk plant protection product provided it meets the following requirements:
 - (a) the low-risk active substances, safeners and synergists contained in it have been approved under Chapter II;
 - (b) it does not contain a substance of concern;
 - (c) it is sufficiently effective;
 - (d) it does not cause unnecessary pain and suffering to vertebrates to be controlled;
 - (e) it complies with Article 29(1)(b), (c) and (e) to (h).

These products are referred to hereinafter as 'low-risk plant protection products'.

2. An applicant for authorisation of a low-risk plant protection product shall demonstrate that the requirements set out in paragraph 1 are met and shall accompany the application with a complete and summary dossier for each point of the data requirements of the active substance and the plant protection product.
3. The Member State shall decide within 90 days on whether to approve an application for authorisation of a low-risk plant protection product.

The period shall be 60 days where an authorisation has already been granted for the same low-risk plant protection product by another Member State located in the same zone.

Where the Member State needs additional information, it shall set a time limit **not exceeding six months** for the applicant to supply it. In that case, the 90-day period shall be extended by the additional time limit granted by the Member State.

4. Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

Article 47

Placing on the market and use of plant protection products containing a genetically modified micro-organism

1. A plant protection product which contains a micro-organism falling within the scope of Directive 2001/18/EC shall be examined in respect of the genetic modification in accordance with that Directive, in addition to the assessment under this Chapter.

An authorisation under this Regulation shall not be granted for such a plant protection product unless written consent, as referred to in Article 19 of Directive 2001/18/EC, has been granted for it.

2. Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

Article 48

Comparative assessment of plant protection products containing candidates for substitution

1. Member States shall not authorise **for use in a given crop** a plant protection product containing a candidate for substitution where a comparative assessment weighing up the risks and benefits, as set out in Annex IV, shows that:
 - (a) for the uses specified in the application an authorised plant protection product or a non-chemical control or prevention method **with comparable effectiveness is** already **authorised** ~~exists which~~ **and** is significantly safer for human or animal health or the environment;

- (b) the substitution by plant protection products or non-chemical control or prevention methods referred to in point (a) does not present significant economic or practical disadvantages;
 - (c) the chemical diversity of the active substances where relevant, or methods and practices of crop management and pest prevention are adequate to minimise the occurrence of resistance in the target organism.
2. By way of derogation from paragraph 1, a plant protection product containing a candidate for substitution shall be authorised without comparative assessment in cases where it is necessary to acquire experience first through using that product in practice.
- Such authorisations shall be granted for a period not exceeding three years.
3. Member States shall repeat the comparative assessment provided for in paragraph 1 regularly and at the latest four years after authorisation or renewal of the authorisation was granted.
- Based on the results of that comparative assessment, Member States shall maintain, withdraw or amend the authorisation.
4. Where a Member State decides to withdraw or amend an authorisation pursuant to paragraph 3, that withdrawal or amendment shall take effect four years after the decision of the Member State or at the end of the approval period of the candidate for substitution where that period ends earlier.
5. Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

Article 49

Extension of authorisations for minor uses

- 1. For the purpose of this Article, minor use of a plant protection product in a particular Member State means the use of that product on a crop which is not widely grown in that Member State or on a widely grown crop to meet an exceptional need.
- 2. The authorisation holder, official or scientific bodies involved in agricultural activities or professional agricultural organisations and professional users may ask for the authorisation of a plant protection product already authorised in the Member State concerned to be extended to minor uses not yet covered by that authorisation.
- 3. Member States shall extend the authorisation provided that:
 - (a) the intended use is minor in nature;
 - (b) the conditions referred to in Article 4(3)(b), (d) and (e) and Article 29(1)(h) are satisfied;

- (c) the extension is in the public interest;
 - (d) the documentation and information to support an extension of use has been submitted by the persons or bodies referred to in paragraph 2.
4. The extension may take the form of an amendment to the existing authorisation or may be a separate authorisation, according to the administrative procedures of the Member State concerned.

Extensions on the basis of this Article shall be separately identified.

5. When Member States grant an extension of authorisation for a minor use, they shall inform the authorisation holder and request him to change the labelling accordingly.

Where the authorisation holder declines, the Member States shall ensure that users are fully and specifically informed as to instructions for use, by means of an official publication or an official website.

6. Member States shall establish and regularly update a list of minor uses. **This list shall be made available to the public through official websites of the Member States.**
7. Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.

Article 49a
Parallel trade

1. **A plant protection product that is authorised in one Member State (Member State of origin) may, subject to an application for a parallel trade permit, be introduced, placed on the market and used in another Member State (Member State of introduction), if this Member State determines that the plant protection product is identical in specification and content of the active substances, safeners and synergists, in type of the formulation and in composition to a plant protection product already authorised in the Member State of introduction (reference product). The application shall be submitted to the regulatory authority in the Member State of introduction (competent authority).**
2. **From receiving a complete application a parallel trade permit shall be granted within 45 working days. The parallel trade permit shall be granted automatically if the Member State of introduction has not adopted an explicit decision on the request within the period defined in the first sentence of this paragraph. The Member State of introduction may seek information from the Member State of origin if it has no other way of establishing whether the plant protection product is identical as defined in this Article. Member States shall duly cooperate to provide each other with the necessary information. The period defined in the first sentence of this paragraph is extended by 10 working days whenever a request for information is sent to the competent authority of the Member State of origin. The Member State of introduction shall inform the applicant of this request.**

3. Active substances, safeners and synergists shall be considered as identical in terms of paragraph 1 if:
- (a) they have been manufactured by the same company or by an associated undertaking or under licence according to the same manufacturing process; or
 - (b) they are found to have either the same specification or specifications under the procedure referred to in Article 37.
4. The plant protection product to be introduced and the reference product are identical in composition in terms of paragraph 1 if:
- (a) the co-formulants are identical in all respects; or
 - (b) the different co-formulants have no more harmful effects within the meaning of Article 4 (3) with due regard, in particular, to differences which may exist in conditions relating to agriculture, plant health and the environment, in particular climatic conditions, relevant to the use of the product.
5. The criteria and the procedures for evaluating to what extent the compositions are identical may be described in detail in accordance with the procedure referred to in Article 76 (3).
6. The application for a parallel trade permit shall include the following:
- (a) In case of an application for a plant protection product for which no parallel trade permit has yet been granted
 - Member State of origin
 - name and address of the applicant
 - name to be given to the plant protection product to be distributed in the Member State of introduction
 - name and registration number of the plant protection product in the Member State of origin
 - name and address of the authorisation holder in the Member State of origin
 - original instructions for use with which the plant protection product to be introduced is distributed in the Member State of origin if it is considered as necessary for the examination by the competent authority. The competent authority may require a translation of the relevant parts of the original instructions for use.
 - name and registration number of the reference product

- name of the authorisation holder of the reference product
 - a draft label for the product intended to be placed on the market
 - a sample of the product which is intended to be introduced if it is considered as necessary by the competent authority
- (b) In case of an application for a plant protection products for which a parallel trade permit has already been granted:
- Member State of origin
 - name and address of the applicant
 - name to be given to the plant protection product to be distributed in the Member State of introduction
 - name of the identical product that already received a parallel permit
 - name and registration number of the reference product
 - name of the authorisation holder of the reference product
 - a draft label for the product intended to be placed on the market
- (c) In case of an application for a plant protection product for the personal use of the applicant, for which a parallel trade permit has already been granted, and which is not the subject of any commercial transaction after being imported:
- Member State of origin
 - name and address of the applicant
 - name of the identical product that already received a parallel permit
 - name and registration number of the reference product
 - name of the authorisation holder of the reference product
 - a declaration from the applicant that he will respect the conditions of use applicable for the reference product

7. The applicant for a first parallel trade permit may demonstrate by means of all available and accessible information that the plant protection product intended to be introduced is identical in terms of paragraph 3, 4 and 5 to the reference product.

8. A plant protection product for which a parallel trade permit has been issued is to be placed on the market and used in accordance with the provisions of the authorisation of the reference product.
9. The parallel trade permit is valid for the duration of authorisation of the reference product. If the authorisation holder of the reference product applies for a withdrawal of authorisation in accordance with Article 44 (1) and the requirements of Article 29 are still fulfilled, the validity of the parallel trade permit will expire by the date on which the authorisation of the reference product would normally have expired.
10. Without prejudice to specific provisions in this Article, Articles 43-45, 52, 53 (4), 54 and Chapter VI – X shall apply to parallel traded plant protection products *mutatis mutandis*.
11. Without prejudice to Article 43 a parallel trade permit may be withdrawn if the authorisation of the introduced plant protection product is withdrawn in the Member State of origin because of safety or efficacy reasons.
12. Where, with regard to the criteria provided for in paragraphs 3, 4 and 5 the assessment carried out by the Member State of introduction shows that the product intended to be introduced is not identical in terms of paragraph 3, 4 or 5 to the reference product, the Member State of introduction may only grant the authorisation required for placing on the market and use in accordance with Article 28.
13. The provisions of this Article do not apply to plant protection products which are authorised in the Member State of origin according Article 50 or 51.

SUBSECTION 6 DEROGATIONS

Article 50

Agricultural emergency situation

Emergency situations in plant protection

1. By way of derogation from Article 28, in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger to plant health which cannot be contained by any other reasonable means.

The Member State concerned shall immediately inform the other Member States and the Commission of the measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety.

2. The Commission may ask the Authority for an opinion, or for scientific or technical assistance.

The Authority shall provide its opinion or the results of its work to the Commission within one month of the request.

3. If necessary, a decision shall be taken, in accordance with the procedure referred to in Article 76(3), as to
 - (a) whether the treated crop may be safely marketed, and
 - (b) whether and under what conditions the Member State
 - (i) may extend the duration of the measure or repeat it; or
 - (ii) shall withdraw or amend its measure.
4. Paragraphs 1 to 3 shall not apply to plant protection products containing or composed of genetically modified micro-organisms.

Article 51 *Research and development*

1. By way of derogation from Article 28, experiments or tests for research or development purposes involving the release into the environment of an unauthorised plant protection product may be carried out if the Member State in whose territory the experiment or test is to be carried out has assessed the available data and granted an authorisation for trial purposes. The authorisation may limit the quantities to be used and the areas to be treated and may impose further conditions to prevent any harmful effects on human or animal health or any unacceptable adverse effect on the environment, such as the need to prevent entry into the food chain of feed and food containing residues unless a relevant provision has already been established under Regulation (EC) No 396/2005.

The Member State may authorise a programme of experiments or tests in advance or require an authorisation for each experiment or test.

2. An application shall be submitted to the Member State in whose territory the experiment or test is to be conducted, together with a dossier containing all the available data to permit an assessment of possible effects on human or animal health or the possible impact on the environment.
3. An authorisation for trial purposes shall not be granted for experiments or tests involving the release into environment of a genetically modified micro-organism unless such release has been accepted under Directive 2001/18/EC.
4. **The Commission may adopt detailed rules for the application of this Article, in particular the maximum quantities of plant protection products that may be released during experiments or tests and the minimum data to be submitted in accordance with paragraph 2.**

Those measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a). ~~may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a).~~

SECTION 2 USE AND INFORMATION

Article 52 Use of plant protection products

Plant protection products shall be used properly.

Proper use shall include compliance with the conditions established in accordance with Article 30 and specified on the labelling, and application of the principles of good plant protection practice as well as, whenever possible, the principles of integrated pest management and good environmental practice.

At the latest by 1 January 2014 proper use of plant protection products shall comply with the principles of integrated pest management, including good plant protection practice and good environmental practise.

Detailed rules for the application of this Article including minimum requirements for these principles may be adopted in accordance with the procedure referred to in Article 76(2).

Article 53 Information on potentially harmful effects

1. The holder of an authorisation for a plant protection product shall immediately notify the Member States that granted an authorisation of any new information concerning that plant protection product, or an active substance, safener or synergist contained in the plant protection product, which suggests that the plant protection product has harmful effects which might mean that the plant protection product or the active substance, safener or synergist no longer complies with the criteria set out in Articles 29 and 4 respectively.

In particular, potentially harmful effects of that plant protection product, or of residues of an active substance, safener or synergist contained in it, on human or animal health or on groundwater, or their potentially unacceptable effects on plants or plant products or the environment shall be notified.

To this end the authorisation holder shall record and report all suspected adverse reactions in humans **and in animals** related to the use of the plant protection product.

The obligation to notify shall include relevant information on decisions or assessments by public bodies which authorise plant protection products or active substances in third countries.

2. The notification shall include an assessment of whether and how the new information means that the plant protection product or the active substance, safener or synergist no longer comply with the requirements set out in Article 29 and Article 4 respectively.
3. **Without prejudice to the right of Member States to adopt interim protective measures,** the first Member State which granted an authorisation within each zone shall evaluate the information received and inform the other Member States, belonging to the same zone, where it decides to withdraw or amend the authorisation under Article 43.

It shall inform the other Member States, the Authority and the Commission where it considers that the conditions of the approval of the active substance, safener or synergist contained in the plant protection product are no longer fulfilled and propose that the approval be withdrawn or the conditions amended.
4. The holder of an authorisation for a plant protection product shall report annually to the competent authority of **each** Member State which authorised his plant protection product any available information relating to the lack of expected efficacy, the development of resistance and to any unexpected effect on plants, plant products or the environment.

Article 54
Obligation to keep information available

1. Member States shall keep information electronically available to the public on plant protection products authorised or withdrawn in accordance with this Regulation, containing at least:
 - (a) the name or business name of the holder of the authorisation,
 - (b) the trade name of the product,
 - (c) the type of preparation,
 - (d) the name and amount of each active substance, safener or synergist which it contains,
 - (e) the use or uses for which it is intended,
 - (f) where relevant, the reasons for withdrawal of an authorisation.
2. The information referred to in paragraph 1 shall be readily accessible and updated at least once every three months.
3. In accordance with the procedure referred to in Article 76(2), a standardised information system may be set up to facilitate the application of paragraphs 1 and 2.

CHAPTER IV ADJUVANTS

Article 55

Placing on the market and use of adjuvants

An adjuvant shall not be placed on the market or used if it contains a co-formulant which has been prohibited in accordance with Article 27.

CHAPTER V DATA PROTECTION AND DATA SHARING

Article 56

Data protection

1. Test and study reports shall benefit from data protection under the conditions laid down in this Article.

The protection applies to test and study reports submitted to a Member State by an applicant for authorisation under this Regulation (hereinafter called ‘the first applicant’), provided that those test and study reports were

- (a) necessary for the authorisation or an amendment of an authorisation in order to allow the use on another crop, and
- (b) certified as compliant with the principles of Good Laboratory Practice or Good Experimental Practice in accordance with the data requirements for plant protection products referred to in Article 8(1)(c).

Where a report is protected, it may not be used, by the Member State which received it, for the benefit of other applicants for plant protection products, except as provided in paragraph 2, in Article 59 or in Article 77.

The period of data protection is ten years starting at the date of the first authorisation in that Member State, except as provided in paragraph 2, in Article 59 or in Article 77. That period is extended to 12 years for plant protection products covered by Article 46.

A study shall not be protected if it was only necessary for the renewal or review of an authorisation.

Data protection shall also apply to tests and study reports submitted to a Member State in accordance with Article 49 for the purpose of an extension of an authorization for a minor use.

- 1(a). **The data protection period referred to in paragraph 1 shall be prolonged for each extension for authorisation for a minor use as defined in Article 49 (1) if the application for such an authorisation is made by the authorisation holder at the latest 5 years after the date of the first authorisation in that Member State. The data protection period shall be prolonged by three months for each extension granted for minor use on the condition that each of these minor uses is identified by a different code number in Annex I to Regulation (EC) No 396/2005. The data protection period may be prolonged by a maximum of three years.**
2. Paragraph 1 shall not apply:
- (a) to test and study reports for which the applicant has submitted a letter of access; or
 - (b) where any period of data protection granted for the test and study reports concerned in relation to another plant protection product has expired.
3. Data protection under paragraph 1 shall only be granted where the first applicant has claimed data protection at the time of submitting the dossier or **further information submitted in accordance with Article 36 (1)** and has provided to the Member State concerned for each test or study report the following information:
- (a) justification that the test and study reports submitted are necessary for the first authorisation, or for the amendment of the authorisation of a plant protection product;
 - (b) confirmation that any period of data protection granted for the test or study report has not expired.

Article 57
List of test and study reports

1. For each active substance, safener and synergist, rapporteur Member States shall keep, and make available to any interested party upon request, a list of the test and study reports necessary for first approval, amendment of approval conditions or renewal of the approval.
2. For each plant protection product which they authorise, Member States shall keep and make available to any interested party upon request:
- (a) a list of the test and study reports necessary for first authorisation, amendment of the authorisation conditions or renewal of the authorisation; and
 - (b) a list of test and study reports for which protection is claimed under Article 56 and any justifications submitted in accordance with that Article.
3. The lists provided for in paragraphs 1 and 2 shall include information on whether those test and study reports were certified as compliant with the principles of Good Laboratory Practice or with the principles of Good Experimental Practice.

Article 58
General rules on avoidance of duplicative testing

1. Any persons intending to seek an authorisation for a plant protection product shall, before carrying out tests or studies, enquire of the competent authority of the Member State to which they intend to make an application whether an authorisation has already been granted in that Member State for a plant protection product containing the same active substance, safener or synergist. Such enquiry shall include consultation of the information available pursuant to ~~Article~~ **Articles 54 and 57.**

The prospective applicant shall submit all data regarding the identity and impurities of the active substance he proposes to use. The enquiry shall be supported by evidence that the prospective applicant intends to apply for an authorisation.

2. The competent authority of the Member State, where satisfied that the prospective applicant intends to apply for an authorisation, **or the renewal or review thereof,** shall provide him with the name and address of the holder or holders of previous relevant authorisations and shall at the same time inform the holders of the authorisations of the name and address of the applicant.
3. The prospective applicant for the authorisation and the holder or holders of relevant authorisations shall take all reasonable steps to reach agreement on the sharing of any test and study reports protected under Article 56 that are required by the applicant for authorisation of a plant protection product.

Article 59
Sharing of tests and studies involving vertebrate animals

1. Tests and studies involving vertebrate animals **or tests and studies that may prevent animal testing** shall not be repeated for the purposes of this Regulation. Any person intending to perform **such** tests and studies ~~involving vertebrate animals~~ shall take the necessary measures to verify that those tests and studies have not already been performed or initiated, **in particular by consulting the information referred to in Articles 10, 12 and 54.**
2. The prospective applicant and the holder or holders of the relevant authorisations shall make every effort to ensure that they share tests and studies involving vertebrate animals **or tests and studies that may prevent animal testing.** The costs of sharing the test and study reports shall be determined in a fair, transparent and non-discriminatory way. The prospective applicant is only required to share in the costs of information he is required to submit to meet the authorisation requirements.
3. Where the prospective applicant and the holder or holders of the relevant authorisations of plant protection products containing the same active substance, safener or synergist cannot reach agreement on the sharing of test and study reports involving vertebrate animals **or on tests and studies that may prevent animal testing,** the prospective applicant shall inform the competent authority of the Member State. The two parties shall nevertheless agree which courts have jurisdiction for the purpose of the second subparagraph.

The failure to reach agreement, as provided in paragraph 2, shall not prevent the competent authority of the Member State from using **such** test and study reports ~~involving vertebrate animals~~ for the purpose of the application of the prospective applicant. The holder or holders of the relevant authorisation shall have a claim on the prospective applicant for an equal share of the costs incurred by him, which shall be enforceable before the courts of a Member State, as designated by the parties under the first subparagraph. Those courts shall have regard to the principles in paragraph 2.

CHAPTER VI

PUBLIC ACCESS TO INFORMATION

Article 60 *Confidentiality*

1. A person claiming under Articles 7(3), 12(1), 15(2), 16 or 32(4) that information submitted by that person under this Regulation is to be treated as confidential shall provide a verifiable justification to show that the disclosure of the information might undermine his commercial interests, as referred to in the first indent of Article 4(2) of Regulation (EC) No 1049/2001 of the European Parliament and of the Council¹³, or any interest protected by Article 4(1) of that Regulation.
- 1(a). An opportunity to comment shall be given to the applicant as on the confidentiality of such data.**
2. As regards the commercial interests referred to in paragraph 1, only the following elements shall be considered confidential:
 - (a) the method of manufacture;
 - (b) the specification of purity of the active substance except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant;
 - (c) information on the complete composition of a plant protection product.
3. This Article is without prejudice to Directive 2003/4/EC of the European Parliament and of the Council¹⁴.

¹³ OJ L 145, 31.5.2001, p. 43.

¹⁴ OJ L 41, 14.2.2003, p. 26.

CHAPTER VII

PACKAGING, LABELLING AND ADVERTISING OF PLANT PROTECTION PRODUCTS AND ADJUVANTS

Article 61

Packaging and presentation

1. Plant protection products and adjuvants that may be mistaken for food, drink or feed shall be packaged in such a way as to minimise the likelihood of such a mistake being made.
2. Plant protection products and adjuvants available to the general public that may be mistaken for food, drink or feed shall contain components to discourage or prevent their consumption.
3. Article 9 of Directive 1999/45/EC shall also apply to plant protection products and adjuvants not covered by that Directive.

Article 62

Labelling

1. The labelling of plant protection products shall comply with the requirements set out in a Regulation adopted in accordance with the procedure referred to in Article 76(2).

That Regulation shall also contain standard phrases for special risks and safety precautions which supplement the phrases provided for by Directive 1999/45/EC. It shall incorporate **the requirements of Article 16 of Directive 91/414/EEC and** the text of the Annexes IV and V to **that** Directive 91/414/EEC with any necessary modifications.
2. Member States may require samples or mock-ups of the packaging and drafts of labels and leaflets to be submitted **for examination before an authorisation is granted.**
3. Where a Member State considers that additional phrases are necessary to protect human or animal health or the environment, it shall notify the other Member States and the Commission forthwith and shall forward the additional phrase or phrases and the reasons for these requirements.

Such phrases shall be included in the Regulation referred to in paragraph 1.

Pending that inclusion, the Member State may require the use of the additional phrase or phrases.

Article 63
Advertising

1. **For the purpose of this Article, advertisement is any means of promoting the sale or use of plant protection products to anyone other than the authorisation holder, the person placing the plant protection product on the market and their agents.**
- 1a. Every advertisement for a plant protection product shall be accompanied by the sentences ‘Use plant protection products safely. Always read the label and product information before use’. These sentences shall be clearly distinguishable in relation to the whole advertisement. The words ‘plant protection products’ may be replaced by a more precise description of the product-type, such as fungicide, insecticide or herbicide.
2. The advertisement shall not include information which could be misleading as regards possible risks to human or animal health or to the environment, such as the terms ‘low risk’, ‘non-toxic’ or ‘harmless’.
- 2a. **Member States may prohibit or restrict the advertising of plant protection products in certain media, subject to the provisions of the Treaty.**

CHAPTER VIII CONTROLS

Article 64
Record keeping

1. Producers, suppliers, distributors and professional users of plant protection products shall keep records of the plant protection products they produce, store or use.

They shall make the relevant information contained in these records available to the competent authority on request. They shall also keep this information available for neighbours or the drinking water industry who request access to it.
- 1a. **Producers of plant protection products shall undertake post-registration monitoring. They shall notify the competent authorities of any relevant information and keep the information available to relevant stakeholders on request.**
2. Authorisation holders shall provide the competent authorities of the Member States with all data relating to the volume of sales of plant protection products.
3. Implementing measures to ensure the uniform application of paragraphs 1 and 2 may be adopted in accordance with the procedure referred to in Article 76(3).

Article 65
Monitoring and controls

Member States shall carry out official controls in order to enforce compliance with this Regulation. **These controls shall include controls on the farm, in order to verify compliance with use restrictions. Member States** They shall finalise and transmit to the Commission, a report on the scope and the results of these controls within six months of the end of the year to which the reports relate.

Commission experts shall carry out general and specific audits in the Member States for purposes of verifying the official controls carried out by the Member States.

A Regulation, ~~shall be adopted in accordance with the procedure referred to in Article 76(3),~~ **shall setting** out provisions for the controls on the production, packaging, labelling, storage, transport, marketing, formulation and use of plant protection products. That Regulation shall contain provisions equivalent to Articles 1 to 13, 26, 27(1), 27(4)(a) and (b) and 27(5) to (12), 28, 29, 32 to 45, 51, 53, 54, 66 and to Annexes I, II, III, VI, and VII to Regulation (EC) No 882/2004. It shall also contain provisions concerning the collection of information and reporting on suspected poisonings and shall detail the information to be made available in response to medical demand.

Those measures, designed to amend non-essential elements of this Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a).

CHAPTER IX
EMERGENCIES

Article 66
Emergency measures

Where it is clear that an approved substance, safener, synergist or co-formulant or a plant protection product which has been authorised in accordance with this Regulation 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, measures to restrict or prohibit the use and/or sale of that substance or product shall be taken immediately in accordance with the procedure referred to in Article 76(3), either at the own initiative of the Commission or at the request of a Member State. Before taking such measures the Commission shall examine the evidence and may request an opinion from the Authority. The Commission may set a time limit within which such an opinion shall be provided.

Article 67
Emergency measures in cases of extreme urgency

By way of derogation from Article 66, the Commission may provisionally adopt the measures referred to in Article 66 after consulting the Member State or Member States concerned and informing the other Member States.

As soon as possible, and at the latest after 10 working days, those measures shall be confirmed, amended, revoked or extended in accordance with the procedure referred to in Article 76(3).

Article 68
Other emergency measures

1. Where a Member State officially informs the Commission of the need to take emergency measures, and no action has been taken in accordance with Articles 66 or 67, the Member State may adopt interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.
2. Within 30 working days, the Commission shall put the matter before the Committee referred to in Article 76(1) in accordance with the procedure provided for in Article 76(3) with a view to the extension, amendment or abrogation of the national interim protective measure.
3. The Member State may maintain its national interim protective measures until Community measures have been adopted.

CHAPTER X

ADMINISTRATIVE AND FINANCIAL PROVISIONS

Article 69
Penalties

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 rules and any subsequent amendment to the Commission without delay.

Article 70
Civil and criminal liability

The granting of authorisation and any other measures in conformity with this Regulation shall be without prejudice to general civil and criminal liability in the Member States of the producer and, where applicable, of the person responsible for placing the plant protection product on the market or using it.

Article 71
Fees and charges

1. Member States may recover the costs associated with any work they carry out arising from obligations under this Regulation, by means of fees or charges.
2. Member States shall ensure that the fee or charge referred to in paragraph 1:
 - (a) is established in a transparent manner; and
 - (b) corresponds to the actual cost of the work involved.

The fee or charge may include a scale of fixed charges based on average costs for the work referred to in paragraph 1.

Article 72
Member State authority

1. Each Member State shall designate a competent authority or authorities to carry out the obligations of the Member States as defined in this Regulation.
2. Each Member State shall designate a coordinating national authority to coordinate and ensure all the necessary contacts with applicants, other Member States, the Commission and the Authority.
3. Each Member State shall give the details concerning its national competent authority or authorities to the Commission, the Authority and the coordinating national authorities of the other Member States and inform them of any modifications thereof.
4. The Commission shall publish and keep updated on its website a list of the authorities referred to in paragraphs 1 and 2.

Article 73
Expenditure by the Commission

1. The Commission may incur expenditure for activities contributing to the aims of this Regulation including the organisation of the following:
 - (a) development of a harmonised system, including an appropriate database, for gathering and storing all information concerning active substances, safeners, synergists, co-formulants, plant protection products and adjuvants and for making such information available to the Member States, producers and other interested parties;
 - (b) performance of studies needed to prepare and develop further legislation on the placing on the market and use of plant protection products and adjuvants;
 - (c) performance of studies needed to harmonise procedures, decision-making criteria and data requirements;
 - (d) coordination, if necessary by electronic means, of cooperation between Member States, the Authority and the Commission and measures to facilitate work sharing;
 - (e) development and maintenance of a coordinated electronic submission and evaluation system aimed at promoting electronic document exchange and work sharing between the applicants, the Member States, the Authority and the Commission;
 - (f) development of guidance to facilitate the day-to-day implementation of this Regulation;
 - (g) travel and subsistence expenses that Member States' experts incur as a result of the Commission appointing them to assist its experts in the framework of control activities laid down under Article 65;
 - (h) training of control staff;
 - (i) financing of other measures needed to ensure application of the Regulation adopted under Article 65.
2. The appropriations required under paragraph 1 shall be subject to authorisation by the budgetary authority each financial year.

Article 74
Guidance documents

The Commission may, in accordance with the procedure referred to in Article 76(2), adopt or amend technical and other guidance documents for the implementation of this Regulation. The Commission may ask the Authority to prepare or to contribute to such guidance documents.

Article 75
Amendments and implementing measures

1. The following **measures, designed to amend non-essential elements of this Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 76(3a)**, ~~shall be adopted in accordance with the procedure referred to in Article 76(3):~~
 - (a) amendments to the Annexes, taking into account current scientific and technical knowledge;
 - (b) the Regulations on data requirements for active substances and for plant protection products, as referred to in Article 8(1)(b) and (c), **including measures to avoid or minimise animal testing, in particular the use of non-animal testing methods and intelligent testing strategies**, taking into account scientific and technical knowledge;
 - (c) amendments to the Regulation on uniform principles for evaluation and authorisation of plant protection products, as referred to in Article 29(6), taking into account scientific and technical knowledge;
 - (d) amendments to the Regulation containing the requirements of the labelling of plant protection products as referred to in Article 62(1).
2. **The measures needed to implement this Regulation shall be adopted in accordance with the procedure referred to in Article 76(3).**
3. In accordance with the procedure referred to in Article 76(2), a Regulation shall be adopted containing the list of active substances included in Annex I to Directive 91/414/EEC. Those substances shall be deemed to have been approved under this Regulation.

Article 76
Committee

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, as established by Article 58 of Regulation (EC) No 178/2002, hereinafter referred to as “the Committee”.
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.
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.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3a. Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3b. Where reference is made to this paragraph, Article 5a paragraphs 1 to 4 and 5 (b) and Article 7 of the Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The time limits down in Article 5a(3)(c), 4(b) and 4(e) of Decision 1999/468/EC shall be set at two months, one month and two months respectively.

3c. Where reference is made to this paragraph, Article 5a (1), (2) (4) and 6 and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. The Committee shall adopt its Rules of Procedure.

Chapter XI

Transitional and final provisions

Article 77

Transitional measures

1. Directive 91/414/EEC (“the Directive”) shall continue to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before the date of application of this Regulation.

On the basis of the examination carried out under the Directive, a Regulation on the approval of such a substance shall be adopted in accordance with Article 13(2) of this Regulation.

2. Article 13(1) to (4) of the Directive and Annexes II and III to the Directive shall continue to apply with respect to active substances included in Annex I to the Directive and to active substances approved in accordance with paragraph 1:

- For a period of five years from the date of their inclusion or approval, for active substances covered by Article 8(2) of the Directive.
- For a period of ten years from the date of their inclusion or approval, for active substances which were not on the market two years after the date of notification of the Directive.
- For a period of five years from the date of the renewal of the inclusion or renewal of the approval, for active substances whose inclusion in Annex I to the Directive expires at the latest two years after the date of publication of this Regulation. This provision shall only apply to data necessary for the renewal of the approval and which were certified as compliant with the principles of Good Laboratory practice at the latest two years after the publication of Regulation.

3. Where Article 13 of the Directive applies by virtue of paragraph 1 or paragraph 2, it shall be subject to any special rules concerning the Directive laid down in the Act of Accession by which a Member State joined the Community.
4. For active substances for which the first approval expires at the latest three years after the entry into force of this Regulation, the application provided for in Article 14 shall be submitted by a producer of the active substance to a Member State, with a copy to the other Member States, the Commission and the Authority, no later than two years before the expiry of the first approval.
5. Applications for authorisations of plant protection products under Article 4 of the Directive which are pending in the Member States on the date of application of this Regulation shall be decided on the basis of national law in force on that date.

After that decision, this Regulation shall apply.

6. Products labelled in accordance with Article 16 of the Directive may continue to be placed on the market for four years from the date of application of this Regulation.

Article 78

Derogation for safeners and synergists

By way of derogation from Article 28(1), a Member State may, for a period of five years following the adoption of the programme referred to in Article 26 authorise the placing on the market in its territory of plant protection products containing safeners and synergists which have not been approved, where they are included in that programme.

Article 79

Repeal

Directives 79/117/EEC and 91/414/EEC, as amended by the acts listed in Annex V, are repealed with effect from the date of application of this Regulation, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directives set out in that Annex.

References to the repealed Directives shall be construed as references to this Regulation.

Article 80

Entry into force and application

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

The Commission shall within 18 months after its entry into force adopt the following Regulations:

- A Regulation containing the list of the active substances already approved at the moment of publication of that Regulation
- A Regulation on data requirements for active substances, as referred to in Article 8(1)(b)
- A Regulation on data requirements for plant protection products, as referred to in Article 8(1)(c)
- A Regulation on uniform principles for risk assessment for plant protection products, as referred to in Article 35
- A Regulation containing the requirements of the labelling of plant protection products as referred to in Article 62(1).

It shall apply from 18 months from that date on which it enters into force. [*OFFICE OF PUBLICATIONS: INSERT DATE ... AFTER PUBLICATION*]

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

Definition of zones for the authorisation of plant protection products

Zone A – North

The following Member States belong to this zone:

Denmark, Estonia, Latvia, Lithuania, Finland, Sweden

Zone B – Centre

The following Member States belong to this zone:

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

Zone C – South

The following Member States belong to this zone:

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

ANNEX II

Procedure and criteria for the approval of active substances, safeners and synergists pursuant to Chapter II

1. Evaluation

- 1.1. During the process of evaluation and decision-making provided for in Articles 4 to 21, the rapporteur Member State and the Authority shall cooperate with applicants to resolve any questions on the dossier quickly or to identify at an early stage any additional studies necessary for the evaluation of the dossier, including information to eliminate the need for a restriction of the approval, 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 Regulation.
- 1.2. The evaluation by the Authority and the rapporteur Member State must be based on scientific principles and be made with the benefit of expert advice.
- 1.3. During the process of evaluation and decision-making provided for in Articles 4 to 21, Member States and the Authority shall take into consideration any further guidance developed in the framework of the Standing Committee on the Food Chain and Animal Health for the purposes of refining, where relevant, the risk assessments.

2. General decision-making criteria

- 2.1. Article 7(1) shall only be considered as complied with, where, on the basis of the dossier submitted, authorisation in at least one Member State is expected to be possible for at least one plant protection product containing that active substance for at least one of the representative uses.

2.2. Submission of further information

In principle an active substance shall only be approved where a complete dossier is submitted.

In exceptional cases an active substance may be approved even though certain information is still to be submitted where:

- (a) the data requirements have been amended or refined after the submission of the dossier or;
- (b) the information is considered to be confirmatory in nature, as required to increase the confidence in the decision.

In such cases the additional information shall be submitted to the rapporteur Member State for evaluation within a deadline set by the Commission. The Member State shall report to the Commission on the results of the assessment.

2.3. Restrictions on approval

Restrictions on approval, where necessary, may 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 the applicant.

Where the rapporteur Member State considers that the dossier provided lacks certain information, to the effect that the active substance could only be approved subject to restrictions, it shall contact the applicant at an early stage to obtain more information which may possibly enable these restrictions to be removed.

3. Criteria for the approval of an active substance

3.1. Dossier

The dossiers submitted pursuant to Article 7(1) shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).

In the case of an active substance for which the limited range of representative uses includes use on feed or food crops or leads indirectly to residues in food or feed, the dossier submitted pursuant to Article 7(1) shall contain the information necessary to carry out a risk assessment and for enforcement purposes.

The dossier shall in particular:

- (a) permit any residue of concern to be defined;
- (b) reliably predict the residues in food and feed, including succeeding crops;
- (c) reliably predict, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing;
- (d) permit a Maximum Residue Level (MRL) to be defined for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals;
- (e) permit, where relevant, concentration or dilution factors due to processing and/or mixing to be defined;

The dossier submitted pursuant to Article 7(1) shall be sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.

3.2. Efficacy

An active substance shall only be approved where it has been established for a limited range of representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic ~~normal~~ conditions of use is sufficiently effective. This requirement shall be evaluated in the light of the uniform principles for evaluation and authorisation of plant protection products referred to in the second paragraph of Article 35.

3.3. Toxic relevance of breakdown products

Where the limited range of representative uses includes use on food or feed crops, the documentation submitted shall be sufficient to permit the establishment of the toxicological relevance of breakdown products that were not present in the animals used in the test or studies performed on the active substance but which are formed in or on treated plants, as a result of processing or are found in studies performed on livestock animals.

3.4. Composition of the active substance

3.4.1. The specification shall define the minimum degree of purity, the identity and maximum content of impurities, and where relevant of isomers / diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.

3.4.2. The specification shall be in compliance with the relevant FAO specification where such specification exists. However where necessary for reasons of protection of human or animal health or the environment, stricter specifications may be adopted.

3.5. Methods of analysis

3.5.1. The methods of analysis of the active substance as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance as manufactured, shall have been validated and shown to be sufficiently specific, linear, accurate and precise.

3.5.2. The method of analysis in environmental matrices, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

3.5.3. The evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 35.

3.6. Impact on human health

- 3.6.1. Where relevant, an ADI, AOEL and ARfD shall be established. When establishing such values **an appropriate** safety margin **of at least 100** shall be ensured taking into account the type and severity of effects and the vulnerability of specific groups of the population.
- 3.6.2. An active substance shall only be approved, if, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements for the active substances and the plant protection products 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 mutagen category 1 or 2 unless the exposure of humans to that active substance in a plant protection product, under realistic proposed conditions of use is negligible **because the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance concerned on food and feed do not exceed the limit of determination using the most sensitive methods.**
- 3.6.3. An active substance shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances and the plant protection products 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 1 or 2 unless the exposure of humans to that active substance in a plant protection product, under realistic proposed conditions of use is negligible **because the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance concerned on food and feed do not exceed the limit of determination using the most sensitive methods.**
- 3.6.4. An active substance shall only be approved, if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances and the plant protection products 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 1 or 2 unless the exposure of humans to that active substance in a plant protection product, under realistic proposed conditions of use is negligible **because the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance concerned on food and feed do not exceed the limit of determination using the most sensitive methods.**

3.6.5. An active substance shall only be approved, if, on the basis of the assessment of Community or internationally agreed test guidelines it is not considered to have endocrine disrupting properties that may be of toxicological significance in humans unless the exposure of humans to that active substance in a plant protection product, under realistic proposed conditions of use, is negligible **because the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance concerned on food and feed do not exceed the limit of determination using the most sensitive methods.**

3.7. Fate and behaviour in the environment

3.7.1. An active substance shall only be approved where it is not considered to be a persistent organic pollutant.

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 non-target species, high toxicity or ecotoxicity; 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.

3.7.2. An active substance shall only be approved if it is not considered to be a persistent, bioaccumulating and toxic (PBT) substance.

A substance that fulfils all three of the criteria of the sections below is a PBT substance.

3.7.2.1. Persistence

An active substance fulfils the persistence criterion where:

- the half-life in marine water is higher than 60 days, or
- the half-life in fresh or estuarine water is higher than 40 days, or
- the half-life in marine sediment is higher than 180 days, or
- the half-life in fresh or estuarine water sediment is higher than 120 days, or
- the half-life in soil is higher than 120 days.

Assessment of persistency in the environment shall be based on available half-life data collected under appropriate conditions, which shall be described by the applicant.

3.7.2.2. Bioaccumulation

An active substance fulfils the bioaccumulation criterion where the bioconcentration factor (BCF) is higher than 2000.

Assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from both freshwater and marine water species can be used.

3.7.2.3. Toxicity

An active substance fulfils the toxicity criterion where:

- the long-term no-observed effect concentration (NOEC) for marine or freshwater organisms is less than 0.01 mg/l, or
- the substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or
- there is other evidence of chronic toxicity, as identified by the classifications: T, R48 or Xn, R48 pursuant to Directive 67/548/EEC.

3.7.3. An active substance shall not be considered as complying with Article 4 where it is very persistent, very bioaccumulating (vPvB).

A substance that fulfils both of the criteria of the sections below is a vPvB substance.

3.7.3.1. Persistence

An active substance fulfils the very persistence criterion where:

- the half-life in marine, fresh- or estuarine water is higher than 60 days, or
- the half-life in marine, fresh- or estuarine water sediment is higher than 180 days, or
- the half-life in soil is higher than 180 days.

3.7.3.2. Bioaccumulation

An active substance fulfils the very bioaccumulative criterion where the bioconcentration factor is greater than 5000.

3.8. Ecotoxicology

3.8.1. An active substance shall only be considered as complying with Article 4 if the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 35 under realistic proposed conditions of use of a plant protection product containing the active substance. The assessment must take into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance is expected to affect adversely by the intended use.

3.8.2. An active substance shall only be considered as complying with Article 4 if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may be of toxicological significance on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product, under realistic proposed conditions of use is negligible.

3.9. Residue definition

An active substance shall only be approved if, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.

4. Criteria for approval as a candidate for substitution

An active substance shall be approved as a candidate for substitution pursuant to Article 24 where **any of the following conditions are met :**

- its ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances;
- it meets two of the criteria to be considered as a PBT substance;
- **its leaching behaviour presents a high potential risk to groundwater;**
- there are reasons for concern linked to the nature of the critical effects **(such as neurotoxic or immunotoxic effects)** which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, even with very restrictive risk management measures (such as extensive personal protective equipment or very large buffer zones);
- it contains a significant proportion of non-active isomers.

ANNEX III

List of co-formulants which are not accepted for inclusion in plant protection products

ANNEX IV

Comparative assessment pursuant to Article 48

1. Conditions for comparative assessment

A comparative assessment shall be performed by Member States when evaluating an application for authorisation for a plant protection product containing an active substance approved as a candidate for substitution.

Where refusal or withdrawal of an authorisation of a plant protection product in favour of an alternative plant protection product is considered (hereinafter 'substitution'), the alternative must, in the light of scientific and technical knowledge, show significantly lower risk to health or the environment. An assessment of the alternative plant protection product shall be performed to demonstrate whether it can be used with similar effect on the target organism and without significant economic and practical disadvantages to the user or not.

Further conditions for refusal or withdrawal of an authorisation are:

- (a) substitution shall be applied only where the chemical diversity of the active substances, **where relevant, or methods and practices of crop management and pest prevention are** sufficient to minimise the occurrence of resistance in the target organism;
- (b) substitution shall be applied only to active substances which, where used in authorised plant protection products, present a significantly higher level of risk to human health or the environment;
- (c) substitution shall be applied only after allowing for the possibility, where necessary, of acquiring experience from use in practice, where not already available.

2. Significant difference in risk

A significant difference in risk, **especially for health risks**, shall be identified on a case-by-case basis by the competent authorities, **taking into account known cumulative and synergistic effects, where the methods to assess such effects are available**. The properties of the active substance, and the possibility of exposure of different population subgroups (professional or non-professional users, bystanders, workers, residents, specific vulnerable groups or consumers) directly or indirectly through food, feed, water or the environment shall be taken into account. Other factors such as the stringency of imposed restrictions on use and prescribed personal protective equipment must also be considered.

For the environment, a factor of at least 10 between the Predicted Environmental Concentration (PEC) and the Predicted No Effect Concentration (PNEC) ratios of different active substances is considered a significant difference in risk.

3. Significant practical or economic disadvantages

Significant practical or economic disadvantage to the user is defined as a major quantifiable impairment of working practices or business activity leading to inability to maintain sufficient control of the target organism. Such a major impairment might be, for example, where no technical facilities for the use of the alternative substance(s) are available or economically feasible.

Where a comparative assessment indicates that restrictions/prohibitions of use of a plant protection product could cause such disadvantage, then this will be taken into account in the decision-making process. This situation must be substantiated.

ANNEX V

Repealed Directives and their successive amendments

A. Directive 91/414/EEC

Acts amending Directive 91/414/EEC	Deadline for transposition
Directive 93/71/EEC	3 August 1994
Directive 94/37/EC	31 July 1995
Directive 94/79/EC	31 January 1996
Directive 95/35/EC	30 June 1996
Directive 95/36/EC	30 April 1996
Directive 96/12/EC	31 March 1997
Directive 96/46/EC	30 April 1997
Directive 96/68/EC	30 November 1997
Directive 97/57/EC	1 October 1997
Directive 2000/80/EC	1 July 2002
Directive 2001/21/EC	1 July 2002
Directive 2001/28/EC	1 August 2001
Directive 2001/36/EC	1 May 2002
Directive 2001/47/EC	31 December 2001
Directive 2001/49/EC	31 December 2001
Directive 2001/87/EC	31 March 2002
Directive 2001/99/EC	1 January 2003
Directive 2001/103/EC	1 April 2003
Directive 2002/18/EC	30 June 2003
Directive 2002/37/EC	31 August 2003

Directive 2002/48/EC	31 December 2002
Directive 2002/64/EC	31 March 2003
Directive 2002/81/EC	30 June 2003
Directive 2003/5/EC	30 April 2004
Directive 2003/23/EC	31 December 2003
Directive 2003/31/EC	30 June 2004
Directive 2003/39/EC	30 September 2004
Directive 2003/68/EC	31 March 2004
Directive 2003/70/EC	30 November 2004
Directive 2003/79/EC	30 June 2004
Directive 2003/81/EC	31 January 2005
Directive 2003/82/EC	30 July 2004
Directive 2003/84/EC	30 June 2004
Directive 2003/112/EC	30 April 2005
Directive 2003/119/EC	30 September 2004
Regulation (EC) No 806/2003	-
Directive 2004/20/EC	31 July 2005
Directive 2004/30/EC	30 November 2004
Directive 2004/58/EC	31 August 2005
Directive 2004/60/EC	28 February 2005
Directive 2004/62/EC	31 March 2005
Directive 2004/66/EC	1 May 2004
Directive 2004/71/EC	31 March 2005
Directive 2004/99/EC	30 June 2005
Directive 2005/2/EC	30 September 2005

Directive 2005/3/EC	30 September 2005
Directive 2005/25/EC	28 May 2006
Directive 2005/34/EC	30 November 2005
Directive 2005/53/EC	31 August 2006
Directive 2005/54/EC	31 August 2006
Directive 2005/57/EC	31 October 2006
Directive 2005/58/EC	31 May 2006
Directive 2005/72/EC	31 December 2006
Directive 2006/5/EC	31 March 2007
Directive 2006/6/EC	31 March 2007
Directive 2006/10/EC	30 September 2006
Directive 2006/16/EC	31 January 2007
Directive 2006/19/EC	30 September 2006
Directive 2006/39/EC	31 July 2007

B. Directive 79/117/EEC

Acts amending Directive 79/117/EEC	Deadline for transposition
Directive 83/131/EEC	1 October 1984
Directive 85/298/EEC	1 January 1986
Directive 86/214/EEC	-
Directive 86/355/EEC	1 July 1987
Directive 87/181/EEC	1 January 1988 and 1 January 1989
Directive 87/477/EEC	1 January 1988
Directive 89/365/EEC	31 December 1989
Directive 90/335/EEC	1 January 1991
Directive 90/533/EEC	31 December 1990 and 30 September 1990
Directive 91/118/EEC	31 March 1992
Regulation (EC) No 807/2003	-
Regulation (EC) No 850/2004	-

FINANCIAL STATEMENT

1. NAME OF THE PROPOSAL :

Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market.

2. ABM / ABB FRAMEWORK

Policy Area(s) concerned: Health and Consumer Protection

Activity/Activities: Plant health, Food Safety, Animal Health, Animal Welfare and Protection of the Environment

3. BUDGET LINES

3.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B..A lines)) including headings :

17.01.04.01 Plant health measures expenditure on administrative management.

3.2. Duration of the action and of the financial impact:

Open ended

3.3. Budgetary characteristics (*add rows if necessary*) :

Budget line	Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
17.01.04.01	Comp/	D	NO	NO	NO	NO [2]

4. SUMMARY OF RESOURCES

4.1. Financial Resources

4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Section no.		Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
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Operational expenditure¹⁵

Commitment Appropriations (CA)	8.1	a	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Payment Appropriations (PA)		b	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Administrative expenditure within reference amount¹⁶

Technical & administrative assistance (NDA)	8.2.4	c	1.0	1.0	1.0	1.0	1.0	1.0	6.0
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TOTAL REFERENCE AMOUNT

Commitment Appropriations		a+c	1.0	1.0	1.0	1.0	1.0	1.0	6.0
Payment Appropriations		b+c	1.0	1.0	1.0	1.0	1.0	1.0	6.0

Administrative expenditure not included in reference amount¹⁷

Human resources and associated expenditure (NDA)	8.2.5	d	1.348	1.348	1.348	1.348	1.348	1.348	8.088
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	8.2.6	e	0.85	0.85	0.85	0.85	0.85	0.85	5.10

Total indicative financial cost of intervention

TOTAL CA including cost of Human Resources		a+c+d+e	3.198	3.198	3.198	3.198	3.198	3.198	19.188
TOTAL PA including cost of Human Resources		b+c+d+e	3.198	3.198	3.198	3.198	3.198	3.198	19.188

¹⁵ No expenditure foreseen.

¹⁶ Expenditure within article 17 01 04 01.

¹⁷ Expenditure within chapter 17 01 01.

Co-financing details

If the proposal involves co-financing by Member States, or other bodies (please specify which), an estimate of the level of this co-financing should be indicated in the table below (additional lines may be added if different bodies are foreseen for the provision of the co-financing):

EUR million (to 3 decimal places)

Co-financing body		Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
.....	f							
TOTAL CA including co-financing	a+c +d+ e+f							

4.1.2. Compatibility with Financial Programming

- ☒ Proposal is compatible with existing financial programming.
- ☐ Proposal will entail reprogramming of the relevant heading in the financial perspective.
- ☐ Proposal may require application of the provisions of the Interinstitutional Agreement¹⁸ (i.e. flexibility instrument or revision of the financial perspective).

4.1.3. Financial impact on Revenue

- ☒ Proposal has no financial implications on revenue
- ☐ Proposal has financial impact – the effect on revenue is as follows:

NB: *All details and observations relating to the method of calculating the effect on revenue should be shown in a separate annex.*

¹⁸ See points 19 and 24 of the Interinstitutional agreement.

EUR million (to one decimal place)

Budget line	Revenue	Prior to action [Year n-1]	Situation following action					
			[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5] ¹⁹
	a) Revenue in absolute terms							
	b) Change in revenue	Δ						

(Please specify each revenue budget line involved, adding the appropriate number of rows to the table if there is an effect on more than one budget line.)

4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.

Annual requirements	Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later
Total number of human resources	13	13	13	13	13	13

5. CHARACTERISTICS AND OBJECTIVES

Details of the context of the proposal are required in the Explanatory Memorandum. This section of the Legislative Financial Statement should include the following specific complementary information:

5.1. Need to be met in the short or long term

In order to assure proportionality of the implementing measures that will be taken in the framework of the proposed regulation, the following instruments are therefore needed:

The Legislation on placing plant protection products on the market is harmonised within the EU. Decisions on active substances are taken at EU level; decisions on plant protection products (products used by the farmers) are taken by Member States, based on uniform criteria and data requirements.

Presently there are about 500 active substances under examination for approval at EU level (inclusion in a positive list). Such a list has to be managed continuously. The proposal provides for obligatory zonal mutual recognition which has to be coordinated. Reinforced control measures require continuous follow-up.

¹⁹ Additional columns should be added if necessary i.e. if the duration of the action exceeds 6 years.

The following instruments are foreseen in the framework of the proposed Regulation:

- (a) the development of a harmonised system, including an appropriate database, for gathering and storing all information concerning active substances, safeners, synergists, co-formulants, plant protection products and adjuvants and for making such information available to the competent authorities, producers and other interested parties;
- (b) the performance of studies necessary for the preparation and development of further legislation on the placing on the market and use of plant protection products and adjuvants;
- (c) the performance of studies necessary to harmonise procedures, decision-making criteria and data requirements;
- (d) coordination, if necessary by electronic means, of the cooperation between Member States, the Authority and the Commission and measures to facilitate work sharing;
- (e) the development and maintenance of a coordinated electronic submission and evaluation system aimed at promoting electronic document exchange and work sharing between the applicants, the Member States, the Authority and the Commission;
- (f) development of guidance to facilitate the day-to-day implementation of this Regulation;
- (g) measures to ensure the application of the control measures such as training of control staff, travel and subsistence expenses that Member States' experts incur as a result of the Commission appointing them to assist its experts in the framework of control activities

5.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy

The data and information obtained will help in assuring:

- effective protection of plants
- protection of human health (consumers, users of plant protection products) and the environment
- a harmonised and predictable legal environment for industry

5.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework

Assure that the use of plant protection products does not lead to unacceptable risks for the user, the consumer or the environment and at the same time does not impose unnecessary burden to the industry by ensuring an appropriate functioning of the internal market for plant protection products.

5.4. Method of Implementation (indicative)

Show below the method(s)²⁰ chosen for the implementation of the action.

X Centralised Management

X Directly by the Commission

↑ Indirectly by delegation to:

↑ Executive Agencies

↑ Bodies set up by the Communities as referred to in art. 185 of the Financial Regulation

↑ National public-sector bodies/bodies with public-service mission

↑ ***Shared or decentralised management***

↑ With Member states

↑ With Third countries

↑ ***Joint management with international organisations (please specify)***

6. MONITORING AND EVALUATION

6.1. Monitoring system

The number of active substances approved, of plant protection products authorised in Member States of the same zone and the implementation of the legislation by Member States.

Evaluation

6.1.1. Ex-ante evaluation

The proposed measure is an amendment of an existing Directive. An intensive stakeholder consultation has taken place. Main points which during the consultation were identified as deserving an in-depth discussion are covered by the impact assessment. Other points which bring consistency with other EU policies or optimise existing policies are included to improve the current system.

²⁰

If more than one method is indicated please provide additional details in the "Relevant comments" section of this point.

6.1.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)

6.1.3. Terms and frequency of future evaluation

The Commission will perform an ongoing evaluation to monitor the need to propose implementing measures.

Indicators include the duration of the evaluation procedure, the availability of plant protection products in different zones and the availability of low risk plant protection products. A procedure allowing to adopt implementing measures is foreseen in the Regulation.

In addition, the effectiveness, efficiency and relevance of the measure will be evaluated in accordance with a timetable, which allows the results of the evaluation to be used for the decision-making on the modification or renewal of the Regulation.

7. ANTI-FRAUD MEASURES

Full application of internal control standards No 14, 15, 16, 18, 19, 20, 21.

The Commission shall ensure that, when actions financed under the present programme are implemented, the financial interests of the Community are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and by the recovery of the amounts unduly paid and, if irregularities are detected, by effective, proportional and dissuasive penalties, in accordance with Council Regulations (EC Euratom) No 2988/95 and (Euratom, EC) No 2185/96, and with Regulation (EC) No 1073/1999 of the European Parliament and of the Council.

8. DETAILS OF RESOURCES

8.1. Objectives of the proposal in terms of their financial cost

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	Type of output	Av. cost	Year n		Year n+1		Year n+2		Year n+3		Year n+4		Year n+5 and later		TOTAL	
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost
OPERATIONAL OBJECTIVE No.1																
TOTAL COST																

8.2 Administrative Expenditure

8.2.1. Number and type of human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources (number of posts/FTEs)					
		Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5
Officials or temporary staff ²¹ (17 01 01)	A*/AD	7 existing 2 new	7 existing 2 new	7 existing 2 new	7 existing 2 new	7 existing 2 new	7 existing 2 new
	B*, C*/AST	4	4	4	4	4	4
Staff financed ²² by art. XX 01 02							
Other staff ²³ financed by art. XX 01 04/05							
TOTAL		13	13	13	13	13	13

8.2.2. Description of tasks deriving from the action

Examination of technical reports from Industry, Member States, the European Food Safety Authority and preparation of decisions on substances

Control of the implementation by Member States of the measures foreseen in the Regulation

Preparation of legislation to harmonise data requirements, criteria, control measures

Examination of technical and financial reports, preparations of commitments and pass to payment

²¹ Cost of which is NOT covered by the reference amount.

²² Cost of which is NOT covered by the reference amount.

²³ Cost of which is included within the reference amount.

8.2.3. Sources of human resources (statutory)

(When more than one source is stated, please indicate the number of posts originating from each of the sources)

- ☐ Posts currently allocated to the management of the programme to be replaced or extended
- ☐ Posts pre-allocated within the APS/PDB exercise for year n
- X Posts to be requested in the next APS/PDB procedure
- ☐ Posts to be redeployed using existing resources within the managing service (internal redeployment)
- ☐ Posts required for year n although not foreseen in the APS/PDB exercise of the year in question

8.2.4. Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management)

EUR million (to 3 decimal places)

Budget line (number and heading)	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later	TOTAL
1. Technical and administrative assistance (including related staff costs)							
Executive agencies ²⁴							
Other technical and administrative assistance							
– <i>intra muros</i>							
– <i>extra muros.</i> <i>As mentioned in point 5.01 this will involve the development of a harmonised system, the performance of studies, coordination, control measures etc.</i>	1.0	1.0	1.0	1.0	1.0	1.0	6.0
Total Technical and administrative assistance	1.0	1.0	1.0	1.0	1.0	1.0	6.0

²⁴

Reference should be made to the specific legislative financial statement for the Executive Agency(ies) concerned.

8.2.5. Financial cost of human resources and associated costs not included in the reference amount

EUR million (to 3 decimal places)

Type of human resources	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later
Officials and temporary staff (XX 01 01)	1.188	1.188	1.188	1.188	1.188	1.188
Staff financed by Art XX 01 02 (auxiliary, END, contract staff, etc.) (specify budget line)	0.160	0.160	0.160	0.160	0.160	0.160
Total cost of Human Resources and associated costs (NOT in reference amount)	1.348	1.348	1.348	1.348	1.348	1.348

Calculation– ***Officials and Temporary agents***

Reference should be made to Point 8.2.1, if applicable

11 officials x 0.108

Calculation– ***Staff financed under art. XX 01 02***

Reference should be made to Point 8.2.1, if applicable

2 END x 0.08

8.2.6 Other administrative expenditure not included in reference amount

EUR million (to 3 decimal places)

	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later	TOTAL
XX 01 02 11 01 – Missions	0.20	0.20	0.20	0.20	0.20	0.20	1.2
XX 01 02 11 02 – Meetings & Conferences	0.50	0.50	0.50	0.50	0.50	0.50	3.0
XX 01 02 11 03 – Committees ²⁵ Standing Committee on the Food Chain and Animal Health	0.15	0.15	0.15	0.15	0.15	0.15	0.90
XX 01 02 11 04 – Studies & consultations							
XX 01 02 11 05 - Information systems							
2. Total Other Management Expenditure (XX 01 02 11)							
3. Other expenditure of an administrative nature (specify including reference to budget line)							
Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)	0.85	0.85	0.85	0.85	0.85	0.85	5.10

Calculation - ***Other administrative expenditure not included in reference amount***

100 missions with a unit cost of 2000 € are foreseen, including in particular to follow the evaluations performed by the European Food Safety Authority and to assist in the coordination of Member State activities.

The organisation of meetings to prepare the necessary implementing measures and 1 conference to discuss major problems of principle.

6 Meetings of the Standing Committee (unit cost 25.000 €) are foreseen every year.

The needs for human and administrative resources shall be covered within the allocation granted to the managing DG in the framework of the annual allocation procedure.

²⁵

Specify the type of committee and the group to which it belongs.