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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 21 October 2009

concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37(2), Article 95 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Having regard to the opinion of the Committee of the Regions [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [4] provides for rules governing plant protection products and the active substances contained in those products.

(2) Following the progress report presented by the Commission under Directive 91/414/EEC, the European Parliament by its Resolution of 30 May 2002 [5] and the Council in its Conclusions of 12 December 2001 asked the Commission to review Directive 91/414/EEC 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, that Directive 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 substances [6].

(5) To simplify application of the new act and to ensure consistency throughout the Member States, it should take the form of a Regulation.

(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 however 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.

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[1] OJ C 175, 27.7.2007, p. 44.
[2] OJ C 146, 30.6.2007, p. 48.
[3] Opinion of the European Parliament of 23 October 2007 (OJ C 263 E, 16.10.2008, p. 181), Council Common Position of 15 September 2008 (OJ C 266 E, 21.10.2008, p. 1) and European Parliament Position of 13 January 2009 (not yet published in the Official Journal). Council Decision of 24 September 2009.
[4] OJ L 230, 19.8.1991, p. 1.
[5] OJ C 187 E, 7.8.2003, p. 173.
[6] OJ L 33, 8.2.1979, p. 36.

(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 Community 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 this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.

(9) In order to remove as far as possible obstacles to trade in plant protection products existing due to the different levels of protection in the Member States, this Regulation should also lay down harmonised rules for the approval of active substances and the placing on the market of plant protection products, including the rules on the mutual recognition of authorisations and on parallel trade. The purpose of this Regulation is thus to increase the free movement of such products and availability of these products in the Member States.

(10) 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 effects on the environment. In order to achieve the same level of protection in all Member States, the decision on acceptability or non-acceptability of such substances should be taken at Community level on the basis of harmonised criteria. These criteria should be applied for the first approval of an active substance under this Regulation. For active substances already approved, the criteria should be applied at the time of renewal or review of their approval.

(11) The development of non-animal test methods should be promoted in order to produce safety data relevant to humans and to replace animal studies currently in use.

(12) 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 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1] (the Authority). It should be clarified that the Authority performs a risk assessment whilst the Commission should perform the risk management role and take the final decision on an active substance. Provisions should be included to ensure the transparency of the evaluation process.

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

(14) To speed up the approval of active substances, strict deadlines should be established for the different procedural steps.

(15) In the interest of safety, the approval period for active substances should be limited in time. The approval period should be proportionate 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. The renewal of the approval should be for a period not exceeding 15 years.

(16) 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 policy [2] is compromised, should be provided for under certain conditions.

(17) 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. Incentives should be given for the placing on the market of low-risk plant protection products.

[1] OJ L 31, 1.2.2002, p. 1.
[2] OJ L 327, 22.12.2000, p. 1.

(18) Certain substances which are not predominantly used as plant protection products 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.

(19) Some active substances with certain properties should be identified at Community level as candidates for substitution. Member States should regularly examine plant protection products containing such active substances with the aim of replacing them by plant protection products containing active substances which require less risk mitigation or by non-chemical control or prevention methods.

(20) In certain Member States non-chemical control or prevention methods, which are significantly safer for human and animal health and for the environment, have been established and generally applied for certain uses. In exceptional cases Member States should also be able to apply the comparative assessment when granting authorisation for plant protection products.

(21) 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 evaluation of such substances should be established. Substances currently on the market should only be evaluated after those rules have been established.

(22) 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.

(23) Plant protection products containing active substances can be formulated in many ways and used on a variety of plants and plant products, under different agricultural, plant health and environmental (including climatic) conditions. Authorisations for plant protection products should therefore be granted by Member States.

(24) 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 and 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 effects on the environment.

(25) 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.

(26) Where the decision on approval cannot be finalised within the period provided for due to reasons not falling under the responsibility of the applicant, Member States should be able to grant the provisional authorisations for a limited period in order to facilitate the transition to the approval procedure provided for under this Regulation. In the light of the experience gained from the approval of the active substances under this Regulation, the provisions on provisional authorisations should cease to apply or be extended after the period of five years, if necessary.

(27) 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.

(28) Good administrative cooperation between Member States should be increased during all steps of the authorisation procedure.

(29) The principle of mutual recognition is one of the means of ensuring the free movement of goods within the Community. To avoid any duplication of work, to reduce the administrative burden for industry and for Member States and to provide for more harmonised availability of plant protection products, authorisations granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. Therefore, the Community should be divided into zones with such comparable conditions in order to facilitate such mutual recognition. However, environmental or agricultural circumstances specific to the territory of one or more Member States might require that, on application, Member States recognise or amend an authorisation issued by another Member State, or refuse to authorise the plant protection product in their territory, where justified as a result of specific environmental or agricultural circumstances or where the high level of protection of both human and animal health and the environment required by this Regulation cannot be achieved. It should also be possible to impose appropriate conditions having regard to the objectives laid down in the National Action Plan adopted in accordance with Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve a sustainable use of pesticides [1].

[1] See page 71 of this Official Journal.

(30) The economic incentive for industry to apply for an authorisation is limited for 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.

(31) Where identical plant protection products are authorised in different Member States, a simplified procedure for granting a parallel trade permit should be provided for in this Regulation, in order to facilitate the trade between Member States of such products.

(32) 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 or ecosystems which cannot be contained by any other reasonable means. Such temporary authorisations should be reviewed at Community level.

(33) Community seeds legislation provides for free movement of seeds within the Community but does not contain a specific provision concerning seeds treated with plant protection products. Such a provision should therefore be included in this Regulation. If treated seeds constitute a serious risk to human or animal health or to the environment, Member States should have the possibility of taking protective measures.

(34) 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.

(35) To ensure a high level of protection of human and animal health and the environment, plant protection products should be used properly, in accordance with their authorisation, having regard to the principles of integrated pest management and giving priority to non-chemical and natural alternatives wherever possible. The Council should include in the statutory management requirement referred to in Annex III to Council Regulation (EC) No 1782/2003 of 29 September 2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers [1], the principles of integrated pest management, including good plant protection practice and non-chemical methods of plant protection and pest and crop management.

(36) In addition to this Regulation and Directive 2009/128/EC, a thematic strategy on the sustainable use of pesticides was adopted. In order to achieve coherence between these instruments, the user should know from the product label where, when and under what circumstances a plant protection product may be used.

(37) A system of exchange of information should be established. Member States should make available to each other, the Commission and the Authority the particulars and scientific documentation submitted in connection with applications for authorisation of plant protection products.

(38) 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. The technical rules necessary for the authorisation should be established.

(39) Studies represent a major investment. This investment should be protected in order to stimulate research. For this reason, tests and studies, other than those involving vertebrate animals, which will be subject to obligatory data sharing, 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. Business operators, in particular small and medium sized enterprises, should have the same opportunities in respect of market access.

(40) The use of non-animal test methods and other risk assessment strategies should be promoted. Animal testing for the purposes of this Regulation should be minimised and tests on vertebrates should be undertaken as a last resort. In accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes [2], tests on vertebrate animals must be replaced, restricted or refined. Therefore, rules should be laid down to avoid duplicative testing and duplication of tests and studies on vertebrates should be prohibited. For the purpose of developing new plant protection products, there should be an obligation to allow access to studies on vertebrates on reasonable terms and the results and the costs of tests and studies on animals should be shared. 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.

[1] OJ L 270, 21.10.2003, p. 1.

[2] OJ L 358, 18.12.1986, p. 1.

(41) As different rules are applied by Member States, the Commission and the Authority 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.

(42) 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 preparations [1] applies to the classification, packaging and labelling of plant protection products. However, to improve further the protection of users of plant protection products, of consumers of plants and plant products and of the environment, further specific rules are appropriate which take account of the specific conditions of use of plant protection products.

(43) To ensure that advertisements do not mislead users of plant protection products or the public, it is appropriate to lay down rules on the advertising of those products.

(44) 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.

(45) 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.

(46) 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 rules [2] 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 on monitoring and controls relating to the storage and use of plant protection products not covered by Regulation (EC) No 882/2004 should be adopted by the Commission. The bureaucratic burden on farmers should be as limited as possible.

(47) The measures provided for in this Regulation should apply without prejudice to other Community legislation, in particular Directive 2009/128/EC, Directive 2000/60/EC, Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin [3] and Community legislation on the protection of workers and anyone concerned with the contained use and deliberate release of genetically modified organisms.

(48) 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.

(49) 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.

(50) 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.

(51) Member States should have the possibility of recovering the costs of the procedures associated with the application of this Regulation from those seeking to place, or placing, plant protection products or adjuvants on the market and from those applying for the approval of active substances, safeners or synergists.

(52) Member States should designate the necessary national competent authorities.

(53) 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 this Regulation in the light of experience or of developing technical notes for guidance.

(54) 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 Commission [4].

[1] OJ L 200, 30.7.1999, p. 1.
[2] OJ L 165, 30.4.2004, p. 1.
[3] OJ L 70, 16.3.2005, p. 1.
[4] OJ L 184, 17.7.1999, p. 23.

(55) In particular, the Commission should be empowered to adopt harmonised methods to determine the nature and quantity of active substances, safeners and synergists, and where appropriate of relevant impurities and co-formulants, and maximum quantities of plant protection products to be released, and to adopt Regulations concerning labelling requirements, controls and rules for adjuvants, establishing a work programme for safeners and synergists, including their data requirements, postponing the expiry of the approval period, extending the date for provisional authorisations, setting the information requirements for parallel trade and on inclusion of co-formulants, as well as amendments to the Regulations on data requirements and on uniform principles for evaluation and authorisation and to 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 with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(56) On grounds of efficiency, the normal time limits for the regulatory procedure with scrutiny should be curtailed for the adoption of a Regulation postponing the expiry of the approval period for a period sufficient to examine the application.

(57) Furthermore, it is appropriate to transfer certain current provisions set out in the Annexes to Directive 91/414/EEC into separate legal instruments to be adopted by the Commission within 18 months after the entry into force of this Regulation. Since these current provisions should be, as a first step, transferred into new legal instruments and thus be adopted without any substantial modification, the advisory procedure is the most appropriate.

(58) It is also appropriate to use the advisory procedure to adopt some purely technical measures, in particular technical guidelines in view of their non-binding character.

(59) 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 and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.

4. The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.

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 reasons of hygiene 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, in so far as such substances or products are not subject to special Community provisions on preservatives;

(d) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants;

(e) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants.

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

2. This Regulation shall apply to substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as '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 plant protection product on certain plants, referred to as 'safeners';

(b) substances or preparations which, while showing no or only weak activity as referred to in paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product, referred to as '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, referred to as '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 and which enhance its effectiveness or other pesticidal properties, referred to as 'adjuvants'.

Article 3

Definitions

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

1. 'residues' means one or more substances present in or on plants or plant products, edible animal products, drinking water or elsewhere in the environment and resulting from the use of a plant protection product, including their metabolites, breakdown or reaction products;

2. 'substances' means chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;

3. 'preparations' means mixtures or solutions composed of two or more substances intended for use as a plant protection product or as an adjuvant;

4. 'substance of concern' means 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 meeting the criteria to be classified as hazardous in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures [1], 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;

5. 'plants' means live plants and live parts of plants, including fresh fruit, vegetables and seeds;

6. 'plant products' means products of plant origin in an unprocessed state or having undergone only simple preparation, such as milling, drying or pressing, but excluding plants;

7. 'harmful organisms' means any species, strain or biotype belonging to the animal kingdom or plant kingdom or pathogenic agent injurious to plants or plant products;

8. 'non-chemical methods' means alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques such as those referred to in point 1 of Annex III to Directive 2009/128/EC, or physical, mechanical or biological pest control methods;

9. 'placing on the market' means the holding 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, but not the return to the previous seller. Release for free circulation into the territory of the Community shall constitute placing on the market for the purposes of this Regulation;

10. 'authorisation of a plant protection product' means an 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' means a person who manufactures plant protection products, active substances, safeners, synergists, co-formulants 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;

[1] OJ L 353, 31.12.2008, p. 1.

12. 'letter of access' means an original document by which the owner of data protected under this Regulation agrees to the use of such data under the specific terms and conditions 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 applicant;

13. 'environment' means waters (including ground, surface, transitional, coastal and marine), sediment, soil, air, land, wild species of fauna and flora, and any interrelationship between them, and any relationship with other living organisms;

14. 'vulnerable groups' means 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 and workers and residents subject to high pesticide exposure over the long term;

15. 'micro-organisms' means any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material;

16. 'genetically modified organisms' means organisms in which the genetic material has been altered within the meaning of Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms [1];

17. 'zone' means a group of Member States as defined in Annex I.

    For the purpose of use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment the zone means all zones defined in Annex I;

18. 'good plant protection practice' means a practice whereby the treatments with plant protection products applied to given plants or plant products, in conformity with the conditions of their authorised uses, are selected, dosed and timed to ensure acceptable efficacy with the minimum quantity necessary, taking due account of local conditions and of the possibilities for cultural and biological control;

19. 'good laboratory practice' means a practice as defined in point 2.1 of Annex I to Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances [2];

20. 'good experimental practice' means a practice in accordance with the provisions of European and Mediterranean Plant Protection Organisation (EPPO) Guidelines 181 and 152;

21. 'data protection' means the temporary right of the owner of a test or study report to prevent it being used for the benefit of another applicant;

22. 'rapporteur Member State' means the Member State which undertakes the task of evaluating an active substance, safener or synergist;

23. 'tests and studies' means investigations or experiments 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;

24. 'authorisation holder' means any natural or legal person holding an authorisation of a plant protection product;

25. 'professional user' means a professional user as defined in Article 3(1) of Directive 2009/128/EC;

26. 'minor use' means use of a plant protection product in a particular Member State on plants or plant products which are:

    (a) not widely grown in that Member State; or

    (b) widely grown, to meet an exceptional plant protection need;

27. 'greenhouse' means a walk-in, static, closed place of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of plant protection products into the environment.

    For the purpose of this Regulation, closed places of plant production where the outer shell is not translucent (for example, for production of mushrooms or witloof) are also considered as greenhouses;

[1] OJ L 106, 17.4.2001, p. 1.

[2] OJ L 50, 20.2.2004, p. 44.

28. 'post-harvest treatment' means treatment of plants or plant products after harvest in an isolated space where no run-off is possible, for example in a warehouse;

29. 'biodiversity' means variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this variability may include diversity within species, between species and of ecosystems;

30. 'competent authority' means any authority or authorities of a Member State responsible for carrying out the tasks established under this Regulation;

31. 'advertisement' means a 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) by printed or electronic media;

32. 'metabolite' means any metabolite or a degradation product of an active substance, safener or synergist, formed either in organisms or in the environment.

A metabolite is deemed relevant if there is a reason to assume that it has intrinsic properties comparable to the parent substance in terms of its biological target activity, or that it poses a higher or comparable risk to organisms than the parent substance or that it has certain toxicological properties that are considered unacceptable. Such a metabolite is relevant for the overall approval decision or for the definition of risk mitigation measures;

33. 'impurity' means any component other than the pure active substance and/or variant which is present in the technical material (including components originating from the manufacturing process or from degradation during storage).

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 meet the requirements provided for in paragraphs 2 and 3.

The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.

2. The residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

(a) they shall not have any harmful effects on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater;

(b) they shall not have any unacceptable effect on the environment.

For residues which are of toxicological, ecotoxicological, environmental or drinking water relevance, there shall be methods in general use for measuring them. Analytical standards shall be commonly available.

3. A plant protection product, consequent on application consistent with good plant protection practice and having regard to 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 (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority 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 where the scientific methods accepted by the Authority to assess such effects are available:

(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;

(ii) its impact on non-target species, including on the ongoing behaviour of those species;

(iii) its impact on biodiversity and the ecosystem.

4. The requirements of paragraphs 2 and 3 shall be evaluated in the light of uniform principles as referred to in Article 29(6).

5. 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.

6. 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.

7. By way of derogation from paragraph 1, where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.

This derogation shall not apply to active substances which are or have to be classified in accordance with Regulation (EC) No 1272/2008, as carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A.

Member States may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control that serious danger to plant health in their territory.

At the same time, they shall draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods, and shall without delay transmit that plan to the Commission.

Article 5

First approval

First approval shall be for a period not exceeding 10 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, the Commission and the European Food Safety Authority, (the Authority), where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge;

(g) designation of categories of users, such as professional and non-professional;

(h) designation of areas where the use of plant protection products, including soil treatment products, containing the active substance may not be authorised or where the use may be authorised under 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, (the rapporteur Member State), together with a summary and a complete dossier as provided for in Article 8(1) and (2) 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.

The application shall be examined by the Member State proposed by the applicant, unless another Member State agrees to examine it.

2. Assessment of an application may be performed by a number of Member States together under a co-rapporteur system.

3. When submitting the application, the applicant may pursuant to Article 63 request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

Member States shall assess the confidentiality requests. Upon a request for access to information, the rapporteur Member State shall decide what information is to be kept confidential.

4. When submitting the application the applicant shall at the same time join a complete list of tests and studies submitted pursuant to Article 8(2) and a list of any claims for data protection pursuant to Article 59.

5. When assessing the application the rapporteur Member State may at any time consult the Authority.

Article 8

Dossiers

1. The summary dossier shall include the following:

(a) information 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 approval criteria provided for in Article 4 are met; where the information submitted does 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, 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, 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 provided for in Article 4(2) and (3) 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 of this Article, resulting from the proposed limited range of representative uses of the active substance, may lead to restrictions in the approval;

(d) for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies on vertebrate animals;

(e) a checklist demonstrating that the dossier provided for in paragraph 2 of this Article is complete in view of the uses applied for;

(f) 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;

(g) where relevant, a copy of an application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;

(h) 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. It shall not contain any reports of tests or studies involving the deliberate administration of the active substance or the plant protection product to humans.

3. The format of the summary dossier and the complete dossier shall be established in accordance with the advisory procedure referred to in Article 79(2).

4. The data requirements referred to in paragraphs 1 and 2 shall contain the requirements for active substances and plant protection products as set out in Annexes II and III to Directive 91/414/EEC and laid down in Regulations adopted in accordance with the advisory procedure referred to in Article 79(2) without any substantial modifications. Subsequent amendments to these Regulations shall be adopted in accordance with Article 78(1)(b).

5. Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier.

Article 9

Admissibility of the application

1. Within 45 days of receiving the application, the rapporteur Member State shall send the applicant a written acknowledgement, stating the date of receipt, and check whether the dossiers submitted with the application contain all the elements provided for in Article 8, using the checklist referred to in point (e) of Article 8(1). It shall also check the requests for confidentiality referred to in Article 7(3) and the complete lists of tests and studies submitted pursuant to Article 8(2).

2. Where one or more of the elements provided for in Article 8 are missing, the rapporteur Member State shall inform the applicant, setting a period for their submission. Such period shall be a maximum of 3 months.

Where at the end of that period, the applicant has not submitted the missing elements, the rapporteur Member State shall inform the applicant, the other Member States and the Commission 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 other Member States, the Commission 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 dossiers as provided for in Article 8 to the other Member States, the Commission and the Authority, including the information about those parts of the dossiers in respect of which confidentiality has been requested as referred to in Article 7(3).

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 in respect of which confidential treatment has been requested and justified pursuant to Article 63, unless there is an overriding public interest in its disclosure.

Article 11

Draft assessment report

1. Within 12 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 Commission, with a copy to the Authority, a report, referred to as the 'draft assessment report', assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4.

2. The draft assessment report shall also include where relevant, a proposal to set maximum residue levels.

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

Where, pursuant to Article 4(1), the assessment establishes that the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are not satisfied, the draft assessment report shall be limited to those parts of the assessment.

3. Where the rapporteur Member State needs additional studies or information, it shall set a period in which the applicant must supply those studies or that information. In that case, the 12-month period shall be extended by the additional period granted by the rapporteur Member State. The additional period shall be of a maximum of 6 months and shall cease at the moment when the additional information is received by the rapporteur Member State. It shall inform the Commission and the Authority accordingly.

Where at the end of the additional period, the applicant has not submitted the additional studies or information, the rapporteur Member State shall inform the applicant, the Commission and the Authority and shall state the missing elements in the assessment included in the draft assessment report.

4. The format of the draft assessment report shall be established in accordance with the advisory procedure referred to in Article 79(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 and the other Member States at the latest 30 days after its receipt. It shall ask the applicant to circulate an update of the dossier where applicable to the Member States, the Commission and the Authority.

The Authority shall make the draft assessment report available to the public, after giving the applicant two weeks to request, pursuant to Article 63, that certain parts of the draft assessment report be kept confidential.

The Authority shall allow a period of 60 days for the submission of written comments.

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

Within 120 days of the end of the period provided for the submission of written comments, the Authority shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents available at the time of application on whether the active substance can be expected to meet the approval criteria provided for in Article 4 and shall communicate it to the applicant, the Member States and the Commission and shall make it available to the public. In the event of a consultation as provided for in this paragraph, the 120-day period shall be extended by 30 days.

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 period of a maximum of 90 days for the applicant to supply it to the Member States, the Commission and the Authority.

The rapporteur Member State shall assess the additional information and submit it to the Authority without delay and at the latest within 60 days after receipt of the additional information. In that case the 120-day period provided for in paragraph 2 shall be extended by a 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 in Article 29(1)(g) of this Regulation. The applicant shall, if requested by the Community reference laboratory, provide samples and analytical standards.

4. The conclusion of the Authority shall include details concerning the evaluation procedure and the properties of the active substance concerned.

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

6. The time limits for the Authority's opinion on applications concerning maximum residue levels set out in Article 11 and for decisions on applications concerning maximum residue levels set out in Article 14 of Regulation (EC) No 396/2005 shall be without prejudice to the time limits laid down in this Regulation.

7. Where the conclusion of the Authority is adopted within the time limit set out in paragraph 2 of this Article, extended by any additional period set in accordance with paragraph 3, the provisions of Article 11 of Regulation (EC) No 396/2005 shall not apply and the provisions of Article 14 of that Regulation shall apply without delay.

8. Where the conclusion of the Authority is not adopted within the time limit set out in paragraph 2 of this Article, extended by any additional period set in accordance with paragraph 3, the provisions of Articles 11 and 14 of Regulation (EC) No 396/2005 shall apply without delay.

Article 13

Approval Regulation

1. Within six months of receiving the conclusion from the Authority, the Commission shall present a report, referred to as 'the review report', and a draft Regulation to the Committee referred to in Article 79(1), taking into account the draft assessment report by the rapporteur Member State and the conclusion of the Authority.

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

2. On the basis of the review report, 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 regulatory procedure referred to in Article 79(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. Where the approval provides for the submission of further confirmatory information as referred to in Article 6(f), the Regulation shall provide the time limit to submit the information to the Member States, the Commission and the Authority.

The rapporteur Member State shall assess the additional information and submit its assessment to the other Member States, the Commission and the Authority without delay and at the latest six months after the receipt of the additional information.

4. Approved active substances shall be included in the Regulation referred to in Article 78(3) containing the list of active substances already approved. The Commission shall maintain a list of approved active substances electronically available to the public.

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 approval criteria provided for 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 of the approval shall be for a period not exceeding 15 years. The renewal of approval of active substances covered by Article 4(7) shall be for a period not exceeding five years.

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 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 at the time of the last approval of the active substance or because his request is for an amended approval. The applicant 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 he requests to be kept confidential in accordance with Article 63 and at the same time any data protection claims pursuant to Article 59.

Article 16

Access to the information for renewal

The Authority shall, without delay, make available to the public the information provided by the applicant under Article 15, excluding any information in respect of which confidential treatment has been requested and justified pursuant to Article 63, unless there is an overriding public interest in its disclosure.

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 decision shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), postponing the expiry of the approval period for that applicant for a period sufficient to examine the application.

A Regulation postponing the expiry for a period sufficient to examine the application shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(5) where an applicant 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 before 14 June 2014.

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) where appropriate, the need to ensure the establishment of a coherent work programme, as provided for in Article 18.

Article 18

Work programme

The Commission may establish a work programme grouping together similar active substances setting priorities on the basis of safety concerns for human and animal health or the environment and taking into account, as far as possible, the need for an effective control and resistance management of target pest. The programme may require interested parties to submit all the necessary data to the Member States, the Commission and the Authority 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 minimise animal testing, in particular the use of non-animal test methods and intelligent testing strategies;

(c) the periods for submission of such data;

(d) rules on the submission of new information;

(e) period for assessment and decision making;

(f) the allocation of evaluation of active substances to Member States, taking into account a balance in the responsibilities and work to be done among Member States acting as rapporteurs.

Article 19

Implementing measures

A Regulation, adopted in accordance with the regulatory procedure referred to in Article 79(3), shall set out the provisions necessary for the implementation of the renewal procedure, including, where relevant, the implementation of a work programme, as provided for in Article 18.

Article 20

Renewal Regulation

1. A Regulation shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), providing that:

(a) the approval of an active substance is renewed, subject to conditions and restrictions where appropriate; or

(b) the approval of an active substance is not renewed.

2. Where the reasons for not renewing the approval do not concern the protection of health or the environment, the Regulation referred to in paragraph 1 shall provide for a grace period not exceeding six months for the sale and distribution, and in addition a maximum of one year for the disposal, storage, and use of existing stocks of the plant protection products concerned. The grace period for the sale and distribution shall take into account the normal period of use of the plant protection product but the total grace period shall not exceed 18 months.

In the case of a withdrawal of the approval or if the approval is not renewed because of the immediate concerns for human health or animal health or the environment, the plant protection products concerned shall be withdrawn from the market immediately.

3. Article 13(4) shall apply.

Article 21

Review of approval

1. The Commission may review the approval of an active substance at any time. It shall take into account the request of a Member State to review, in the light of new scientific and technical knowledge and monitoring data, the approval of an active substance, including where, after the review of the authorisations pursuant to Article 44(1), 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 is compromised.

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

2. The Commission may ask the Member States and the Authority for an opinion, or for scientific or technical assistance. The Member States may provide their comments to the Commission within three months from the date of the request. The Authority shall provide its opinion or the results of its work to the Commission within three months of the date of the request.

3. Where the Commission concludes that the approval criteria provided for in Article 4 are no longer satisfied, or the further information required in accordance with Article 6(f) has not been provided, a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3).

Article 13(4) and Article 20(2) shall apply.

Subsection 4

Derogations

Article 22

Low-risk active substances

1. An active substance complying with the criteria provided for in Article 4 shall be approved for a period not exceeding 15 years by way of derogation from Article 5, where it is considered a low-risk active substance and 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 47(1).

2. Articles 4 and 6 to 21 and point 5 of Annex II shall apply. Low-risk active substances shall be listed separately in the Regulation referred to in Article 13(4).

3. The Commission may review and if necessary specify new criteria for approving an active substance as low-risk active substance in accordance with Article 78(1)(a).

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.

For the purpose of paragraphs 2 to 6, a basic substance is an active substance which:

(a) is not a substance of concern; and

(b) does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and

(c) is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and

(d) is not placed on the market as a plant protection product.

For the purpose of this Regulation, an active substance which fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 shall be considered as a basic substance.

2. By way of derogation from Article 4, 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 for 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. By way of derogation from Article 7 an application for the approval of a basic substance shall be submitted by a Member State or by any interested party to the Commission.

The application shall be accompanied by the following information:

(a) any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other Community legislation regulating the use of the substance; and

(b) other relevant information on its possible effects on human or animal health or the environment.

4. 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 date of the request.

5. Articles 6 and 13 shall apply. Basic substances shall be listed separately in the Regulation referred to in Article 13(4).

6. The Commission may review the approval of a basic substance at any time. It may take into account the request of a Member State to review the approval.

Where the Commission considers that there are indications that the substance no longer satisfies the criteria provided for in paragraphs 1 to 3 it shall inform the Member States, the Authority and the interested party, setting a 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 three months of the date of the request.

Where the Commission concludes that the criteria referred to in paragraph 1 are no longer satisfied, a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3).

Article 24

Candidates for substitution

1. An active substance complying with the criteria provided for in Article 4 shall be approved, for a period not exceeding seven years, as a candidate for substitution if it meets one or more of the additional criteria laid down in point 4 of Annex II. By way of derogation from Article 14(2), the approval may be renewed once or more for periods not exceeding seven years.

2. Without prejudice to paragraph 1, Articles 4 to 21 shall apply. Candidates for substitution shall be listed separately in the Regulation referred to in Article 13(4).

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.

2. Articles 5 to 21 shall apply.

3. Similar data requirements to those referred to in Article 8(4) shall be defined for safeners and synergists in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Article 26

Safeners and synergists already on the market

By 14 December 2014, a Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4) establishing a work programme 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 minimise animal testing, notification, evaluation, assessment and decision-making procedures. It shall require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a specified period.

SECTION 3

Unacceptable co-formulants

Article 27

Co-formulants

1. A co-formulant shall not be accepted for inclusion in a plant protection product where it has been established that:

(a) its residues, consequent on application consistent with good plant protection practice, and having regard to 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 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 which are not accepted for inclusion in a plant protection product pursuant to paragraph 1 shall be included in Annex III in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

3. The Commission may review co-formulants at any time. It may take into account relevant information provided by Member States.

4. Article 81(2) shall apply.

5. Detailed rules for the implementation of this Article may be established in accordance with the regulatory procedure referred to in Article 79(3).

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 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 54;

(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;

(d) production, storage or movement of a plant protection product intended for use in a third country provided that the Member State of production, storage or movement has put in place inspection requirements to ensure that the plant protection product is exported from its territory;

(e) placing on the market and use of plant protection products for which a parallel trade permit has been granted in accordance with Article 52.

Article 29

Requirements for the authorisation for placing on the market

1. Without prejudice to Article 50 a plant protection product shall only be authorised where following the uniform principles referred to in paragraph 6 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 different source, or by the same source with a change in the manufacturing process and/or manufacturing location:

(i) the specification, pursuant to Article 38, does not deviate significantly from the specification included in the Regulation approving that substance, safener or synergist; and

(ii) the active substance, safener or synergist 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 the dossier that supported the approval;

(c) its co-formulants are not included in Annex III;

(d) its technical formulation is such that user exposure or other risks are limited as much as possible without compromising the functioning of the product;

(e) in the light of current scientific and technical knowledge, it complies with the requirements provided for in Article 4(3);

(f) the nature and quantity of its active substances, safeners and synergists and, where appropriate, any toxicologically, ecotoxicologically or environmentally relevant impurities and co-formulants can be determined by appropriate methods;

(g) its residues, resulting from authorised uses, and which are of toxicological, ecotoxicological or environmental relevance, can be determined by appropriate methods in general use in all Member States, with appropriate limits of determination on relevant samples;

(h) its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;

(i) for plants or plant products to be used as feed or food, 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. The applicant shall demonstrate that the requirements provided for in points (a) to (h) of paragraph 1 are met.

3. Compliance with the requirements set out in point (b) and points (e) to (h) 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.

4. With respect to point (f) of paragraph 1, harmonised methods may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

5. Article 81 shall apply.

6. Uniform principles for evaluation and authorisation of plant protection products shall contain the requirements set out in Annex VI to Directive 91/414/EEC and shall be laid down in Regulations adopted in accordance with the advisory procedure referred to in Article 79(2) without any substantial modifications. Subsequent amendments to these Regulations shall be adopted in accordance with Article 78(1)(c).

Following these principles, interaction between the active substance, safeners, synergists and co-formulants shall be taken into account in the evaluation of plant protection products.

Article 30

Provisional authorisations

1. By way of derogation from Article 29(1)(a), Member States may authorise for a provisional period not exceeding 3 years, the placing on the market of plant protection products containing an active substance not yet approved, provided that:

(a) the decision on approval could not be finalised within a period of 30 months from the date of admissibility of the application, extended by any additional period set in accordance with Article 9(2), Article 11(3) or Article 12(2) or (3); and

(b) pursuant to Article 9 the dossier on the active substance is admissible in relation to the proposed uses; and

(c) the Member State concludes that the active substance can satisfy the requirements of Article 4(2) and (3) and that the plant protection product may be expected to satisfy the requirements of Article 29(1)(b) to (h); and

(d) maximum residue levels have been established in accordance with Regulation (EC) No 396/2005.

2. In such cases the Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorisation, giving at least the information provided for in Article 57(1).

3. The provisions laid down in paragraphs 1 and 2 shall apply until 14 June 2016. If necessary, that time limit may be extended in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Article 31

Contents of authorisations

1. The authorisation shall define plants or plant products and non-agricultural areas (for example railways, public areas, storage rooms) 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 the conditions of use necessary to comply with the conditions and requirements provided for in the Regulation approving the active substances, safeners and synergists.

The authorisation shall include a classification of the plant protection product for the purpose of Directive 1999/45/EC. Member States may provide that authorisation holders shall classify or update the label without undue delay following any change to the classification and labelling of the plant protection product in accordance with Directive 1999/45/EC. In such cases, they shall immediately inform the competent authority thereof.

3. The requirements referred to in paragraph 2 shall also include where applicable:

(a) the maximum dose per hectare in each application;

(b) the period between the last application and harvest;

(c) the maximum number of applications per year.

4. The requirements referred to in paragraph 2 may include the following:

(a) a restriction with respect to the distribution and use of the plant protection product in order to protect the health of the distributors, users, bystanders, residents, consumers or workers concerned or the environment, taking into consideration requirements imposed by other Community provisions; such restriction shall be indicated on the label;

(b) the obligation before the product is used to inform any neighbours who could be exposed to the spray drift and who have requested to be informed;

(c) indications for proper use according to the principles of Integrated Pest Management referred to in Article 14 of and Annex III to Directive 2009/128/EC;

(d) designation of categories of users, such as professional and non-professional;

(e) the approved label;

(f) the interval between applications;

(g) the period between the last application and consumption of the plant product where applicable;

(h) the re-entry interval;

(i) the packaging size and material.

Article 32

Duration

1. The period of authorisation shall be laid down in the authorisation.

Without prejudice to Article 44, the duration of an authorisation shall be set for a period not exceeding 1 year from the date of expiry of the approval of the active substances, safeners and synergists contained in the plant protection product and thereafter for as long as the active substances, safeners and synergists contained in the plant protection product are approved.

This period shall allow the examination as provided for in Article 43 to be carried out.

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 50.

Subsection 2

Procedure

Article 33

Application for authorisation or amendment of an authorisation

1. An applicant who wishes to place a plant protection product on the market shall apply for an authorisation or amendment of an authorisation himself, or through 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 intended uses in each zone as indicated in Annex I and the Member States where the applicant has made or intends to make an application;

(b) a proposal as to which Member State the applicant expects to evaluate the application in the zone concerned. In the case of an application for use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment, only one Member State shall be proposed, which evaluates the application taking account of all zones. In this case the applicant shall send the summary or complete dossier as referred to in Article 8 to other Member States on request;

(c) where relevant, a copy of any authorisations already granted for that plant protection product in a Member State;

(d) where relevant, a copy of any conclusion of the Member State assessing equivalence as referred to in Article 38(2).

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;

(c) for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplication of tests and studies 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;

(e) where relevant a copy of the application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information;

(f) where relevant for an amendment of an authorisation an assessment of all information submitted in accordance with point (h) of Article 8(1);

(g) a draft label.

4. When submitting the application, the applicant may pursuant to Article 63, request certain information, including certain parts of the dossier, to be kept confidential and shall physically separate that information.

The applicant shall at the same time submit the complete list of studies submitted pursuant to Article 8(2) and a list of test and study reports for which any claims for data protection pursuant to Article 59 are requested.

Upon a request for access to information the Member State examining the application shall decide what information is to be kept confidential.

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.

6. On request, the applicant shall provide the Member State with samples of the plant protection product and analytical standards of its ingredients.

Article 34

Exemption from the submission of studies

1. Applicants shall be exempted from supplying the test and study reports referred to in Article 33(3) where the Member State to which an application is made has the test and study reports concerned and the applicants demonstrate that they have been granted access in accordance with Article 59, 61 or 62 or that any data protection period has expired.

2. However, applicants to whom paragraph 1 applies shall provide the following information:

(a) all necessary data for the identification of the plant protection product including its complete composition as well as a declaration that no unacceptable co-formulants are used;

(b) 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 point (b) of Article 29(1), where appropriate;

(c) on the request of the concerned Member State, 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 35

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.

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.

Where an application has been made in more than one zone, Member States evaluating the application shall agree on the evaluation of data which are not related to the environmental and agricultural conditions.

Article 36

Examination for authorisation

1. The Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application. It shall give all Member States in the same zone the opportunity to submit comments to be considered in the assessment.

It shall apply the uniform principles for evaluation and authorisation of plant protection products, referred to in Article 29(6), to establish, as far as possible, whether the plant protection product meets the requirements provided for in Article 29 in the same zone, where used in accordance with Article 55, and under realistic conditions of use.

The Member State examining the application shall make available its assessment to the other Member States within the same zone. The format of the assessment report shall be established in accordance with the advisory procedure referred to in Article 79(2).

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 31 and 32.

3. By way of derogation from paragraph 2 and subject to Community law, appropriate conditions may be imposed with respect to the requirements referred to in Article 31(3) and (4) and other risk mitigation measures deriving from specific conditions of use.

Where the concerns of a Member State relating to human or animal health or the environment cannot be controlled by the establishment of the national risk mitigation measures referred to in the first subparagraph, a Member State may refuse authorisation of the plant protection product in its territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment.

That Member State shall immediately inform the applicant and the Commission of its decision and provide a technical or scientific justification therefor.

Member States shall provide for the possibility of challenging a decision refusing the authorisation of such products before national courts or other instances of appeal.

Article 37

Period for examination

1. The Member State examining the application shall decide within 12 months of receiving it whether the requirements for authorisation are met.

Where the Member State needs additional information, it shall set a period for the applicant to supply it. In that case, the 12-month period shall be extended by the additional period granted by the Member State. That additional period shall be a maximum of 6 months and shall cease at the moment when the additional information is received by the Member State. Where at the end of that period the applicant has not submitted the missing elements, the Member State shall inform the applicant that the application is inadmissible.

2. The time limits provided for in paragraph 1 shall be suspended during the application of the procedure set out in Article 38.

3. For an application for authorisation of a plant protection product containing an active substance not yet approved, the Member State examining the application shall start the evaluation as soon as it has received the draft assessment report referred to in Article 12(1). In case the application concerns the same plant protection product and the same uses as contained in the dossier referred to in Article 8, the Member State shall decide on the application at the latest within six months of the active substance being approved.

4. The other Member States concerned shall at the latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the Member State examining the application decide on the application as referred to in Article 36(2) and (3).

Article 38

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

1. Where it is necessary to establish for an active substance, safener or synergist whether a different source or, for the same source a change of the manufacturing process and/or manufacturing location complies with point (b) of Article 29(1), 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) unless the Member State examining the application as referred to in Article 35 agrees to assess the equivalence. The applicant shall submit all necessary data to the Member State assessing equivalence.

2. After giving the applicant the opportunity to submit comments, which the applicant shall also communicate to the rapporteur Member State or the Member State examining the application as the case may be, the Member State assessing equivalence shall prepare a report on equivalence within 60 days from receiving the application and shall communicate the report to the Commission, the other Member States and the applicant.

3. In the case of a positive conclusion on equivalence and where no objection to this conclusion has been raised, point (b) of Article 29(1) shall be considered to be complied with. However, where a Member State examining the application does not agree with the conclusion of the rapporteur Member State or vice versa, it shall inform the applicant, the other Member States and the Commission stating its reasons.

The Member States concerned shall try to reach agreement on whether point (b) of Article 29(1) is complied with. They shall provide the applicant with an opportunity to submit comments.

4. Where the Member States concerned do not reach agreement within 45 days, the Member State assessing equivalence shall submit the matter to the Commission. A decision on whether the conditions referred to in point (b) of Article 29(1) are complied with shall be adopted in accordance with the regulatory procedure referred to in Article 79(3). The 45-day period begins on the date on which the Member State examining the application for authorisation informed the rapporteur Member State or vice versa 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 3 months of the request.

5. Detailed rules and procedures for the implementation of paragraphs 1 to 4 may be established in accordance with the regulatory procedure referred to in Article 79(3), after consultation of the Authority.

Article 39

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; the format of the report shall be established in accordance with the advisory procedure referred to in Article 79(2);

(c) a record of the administrative decisions taken by the Member State concerning the application and of the documentation provided for in Article 33(3) and Article 34 together with a summary of the latter;

(d) the approved label, where applicable.

2. On request, Member States shall, without delay, make available to the other Member States, the Commission and the Authority a file containing the documentation provided for in points (a) to (d) of paragraph 1.

3. On request, applicants shall provide a copy of the documentation to be submitted with an application pursuant to Article 33(3) and Article 34 to Member States, the Commission and the Authority.

4. Detailed rules for the implementation of paragraphs 2 and 3 may be established in accordance with the regulatory procedure referred to in Article 79(3).

Subsection 3

Mutual recognition of authorisations

Article 40

Mutual recognition

1. The holder of an authorisation granted in accordance with Article 29 may apply for an authorisation for the same plant protection product, the same use and under the comparable agricultural practices 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;

(b) the authorisation was granted by a Member State (reference Member State) which belongs to a different zone provided that the authorisation for which the application was made is not used for the purpose of mutual recognition in another Member State within the same zone;

(c) the authorisation was granted by a Member State for use in greenhouses, or as post-harvest treatment, or for treatment of empty rooms or containers used for storing plant or plant products, or for seed treatment, regardless of the zone to which the reference Member State belongs.

2. Where a plant protection product is not authorised in a Member State because no application for an authorisation has been submitted in that Member State, official or scientific bodies involved in agricultural activities or professional agricultural organisations may apply, with the consent of the authorisation holder, for an authorisation for the same plant protection product, the same use and under the same agricultural practices in that Member State under the mutual recognition procedure referred to in paragraph 1. In that case the applicant must demonstrate that the use of such a plant protection product is of general interest for the Member State of introduction.

Where the authorisation holder refuses its consent, the competent authority of the Member State concerned may accept the application, on grounds of public interest.

Article 41

Authorisation

1. The Member State to which an application under Article 40 is submitted shall, having examined the application and the accompanying documents referred to in Article 42(1), as appropriate with regard to the circumstances in its territory, authorise the plant protection product concerned under the same conditions as the Member State examining the application, except where Article 36(3) applies.

2. By way of derogation from paragraph 1, the Member State may authorise the plant protection product where:

(a) an authorisation under point (b) of Article 40(1) was applied for;

(b) it contains a candidate of substitution;

(c) Article 30 has been applied; or

(d) it contains a substance approved in accordance with Article 4(7).

Article 42

Procedure

1. The application shall be accompanied by the following:

(a) a copy of the authorisation granted by the reference Member State as well as a translation of the authorisation into an official language of the Member State receiving the application;

(b) a formal statement that the plant protection product is identical to that authorised by the reference Member State;

(c) a complete or summary dossier as required in Article 33(3) when requested by the Member State;

(d) an assessment report of the reference Member State containing information on the evaluation and decision on the plant protection product.

2. The Member State to which an application under Article 40 is submitted shall decide on the application within 120 days.

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

Subsection 4

Renewal, withdrawal and amendment

Article 43

Renewal of authorisation

1. An authorisation shall be renewed upon application by the authorisation holder, provided that the requirements referred to in Article 29 are still met.

2. Within 3 months from the 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) a copy of the authorisation of the plant protection product;

(b) any new information required as a result of amendments in data requirements or criteria;

(c) evidence 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 approval;

(d) 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 therein;

(e) a report on the monitoring information, where the authorisation was subject to monitoring.

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

The Member State referred to in Article 35 within each zone shall coordinate the compliance check and assessment of the information submitted for all Member States within that zone.

4. Guidelines on the organisation of compliance checks may be established in accordance with the advisory procedure referred to in Article 79(2).

5. Member States shall decide on the renewal of the authorisation of a plant protection product at the latest 12 months after the renewal of the approval of the active substance, safener or synergist contained therein.

6. 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 44

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.

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 or 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;

(d) on the basis of developments in scientific and technical knowledge, the manner of use and amounts used can be modified; or

(e) the authorisation holder fails to comply with the obligations resulting from this Regulation.

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 Commission and the Authority. The other Member States belonging to the same zone shall withdraw or amend the authorisation accordingly taking into account national conditions and risk mitigation measures except for cases where the second, third or fourth subparagraphs of Article 36(3) have been applied. Article 46 shall apply where appropriate.

Article 45

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 referred to in Article 29 continue to be met.

3. Article 46 shall apply where appropriate.

Article 46

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 non-renewal of the authorisation are not related to the protection of human and animal health or the environment, the grace period shall be limited and shall not exceed 6 months for the sale and the distribution and an additional maximum of 1 year for the disposal, storage, and use of existing stocks of the plant protection products concerned.

Subsection 5

Special cases

Article 47

Placing on the market of low-risk plant protection products

1. Where all the active substances contained in a plant protection product are low-risk active substances as referred to in Article 22, that product shall be authorised as a low-risk plant protection product provided no specific risk mitigation measures are needed following a risk assessment. This plant protection product shall also meet 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 points (b), (c) and (f) to (i) of Article 29(1).

These products are referred to 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 submit with the application a complete and a 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 120 days whether to approve an application for authorisation of a low-risk plant protection product.

Where the Member State needs additional information, it shall set a time limit for the applicant to supply it. In that case, the period specified shall be extended by the additional time limit granted by the Member State.

The additional period shall be of a maximum of 6 months and shall cease at the moment when the additional information is received by the Member State. Where at the end of that period the applicant has not submitted the missing elements, the Member State shall inform the applicant that the application is inadmissible.

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

Article 48

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

1. A plant protection product which contains an 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 49

Placing on the market of treated seeds

1. Member States shall not prohibit placing on the market and use of seeds treated with plant protection products authorised for that use in at least one Member State.

2. Where there are substantial concerns that treated seeds as referred to in paragraph 1 are likely to constitute a serious risk to human or animal health or to 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 such treated seeds shall be taken immediately in accordance with the regulatory procedure referred to in Article 79(3). 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.

3. Articles 70 and 71 shall apply.

4. Without prejudice to other Community legislation concerning the labelling of seeds, the label and documents accompanying the treated seeds shall include the name of the plant protection product with which the seeds were treated, the name(s) of the active substance(s) in that product, standard phrases for safety precautions as provided for in Directive 1999/45/EC and risk mitigation measures set out in the authorisation for that product where appropriate.

Article 50

Comparative assessment of plant protection products containing candidates for substitution

1. 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. Member States shall not authorise or shall restrict the use of a plant protection product containing a candidate for substitution for use on a particular crop where the comparative assessment weighing up the risks and benefits, as set out in Annex IV, demonstrates that:

(a) for the uses specified in the application an authorised plant protection product, or a non-chemical control or prevention method, already exists which 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; and

(d) the consequences on minor use authorisations are taken into account.

2. By way of derogation from Article 36(2) Member States may in exceptional cases also apply the provisions of paragraph 1 of this Article when evaluating an application for authorisation of a plant protection product not containing a candidate for substitution or a low-risk active substance, if a non-chemical control or prevention method exists for the same use and it is in general use in that Member State.

3. 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 once for a period not exceeding five years.

4. For plant protection products containing a candidate for substitution Member States shall perform the comparative assessment provided for in paragraph 1 regularly and at the latest at renewal or amendment of the authorisation.

Based on the results of that comparative assessment, Member States shall maintain, withdraw or amend the authorisation.

5. Where a Member State decides to withdraw or amend an authorisation pursuant to paragraph 4, that withdrawal or amendment shall take effect 3 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.

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

Article 51

Extension of authorisations for minor uses

1. The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations or 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.

2. Member States shall extend the authorisation provided that:

(a) the intended use is minor in nature;

(b) the conditions referred to in points (b), (d) and (e) of Article 4(3) and Article 29(1)(i) are satisfied;

(c) the extension is in the public interest; and

(d) the documentation and information to support the extension of use has been submitted by the persons or bodies referred to in paragraph 1, especially data on the magnitude of residues and where necessary on the risk assessment to the operator, worker and bystander.

3. Member States may take measures to facilitate or encourage the submission of applications to extend the authorisation of already authorised plant protection products to minor uses.

4. The extension may take the form of an amendment to the existing authorisation or may be a separate authorisation, in accordance with the administrative procedures of the Member State concerned.

5. When Member States grant an extension of authorisation for a minor use, they shall inform if necessary 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.

The official publication or where applicable the label shall include a reference to the liability of the person using the plant protection product with respect to failures concerning the efficacy or to phytotoxicity of the product for which the minor use was granted. The minor use extension shall be separately identified in the label.

6. Extensions on the basis of this Article shall be separately identified and separate reference shall be made to liability restrictions.

7. The applicants referred to in paragraph 1 may also apply for authorisation of a plant protection product for minor uses in accordance with Article 40(1) provided that a plant protection product concerned is authorised in that Member State. Member States shall authorise such uses in accordance with the provisions of Article 41 provided that those uses are also considered minor in the Member States of application.

8. Member States shall establish and regularly update a list of minor uses.

9. By 14 December 2011, the Commission shall present a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal.

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

Article 52

Parallel trade

1. A plant protection product that is authorised in one Member State (Member State of origin) may, subject to granting a parallel trade permit, be introduced, placed on the market or used in another Member State (Member State of introduction), if this Member State determines that the plant protection product is identical in composition to a plant protection product already authorised in its territory (reference product). The application shall be submitted to the competent authority of the Member State of introduction.

2. From receiving a complete application, a parallel trade permit shall be granted in a simplified procedure within 45 working days if the plant protection product to be introduced is identical in terms of paragraph 3. Member States shall on request provide each other with the information necessary to assess whether the products are identical within 10 working days of receiving the request. The procedure for granting a parallel trade permit is interrupted from the day the request for information is sent to the competent authority of the Member State of origin until the complete information required is delivered to the competent authority of the Member State of introduction.

3. Plant protection products shall be considered as identical to the reference products if:

(a) they have been manufactured by the same company or by an associated undertaking or under licence in accordance with the same manufacturing process;

(b) they are identical in specification and content to the active substances, safeners and synergists, and in the type of formulation; and

(c) they are either the same or equivalent in the co-formulants present and the packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human or animal health or the environment.

4. The application for a parallel trade permit shall include the following information:

(a) the name and registration number of the plant protection product in the Member State of origin;

(b) the Member State of origin;

(c) the name and address of the authorisation holder in the Member State of origin;

(d) the original label and 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 of the Member State of introduction. This competent authority may require a translation of the relevant parts of the original instructions for use;

(e) the name and address of the applicant;

(f) the name to be given to the plant protection product to be distributed in the Member State of introduction;

(g) a draft label for the product intended to be placed on the market;

(h) a sample of the product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;

(i) the name and registration number of the reference product.

The information requirements may be amended or completed and further details and specific requirements shall be established in cases of application for a plant protection product for which a parallel trade permit has already been granted and in cases of an application for a plant protection product for a personal use in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

5. A plant protection product for which a parallel trade permit has been issued shall be placed on the market and used only in accordance with the provisions of the authorisation of the reference product. To facilitate monitoring and controls the Commission shall set out specific control requirements for the product to be introduced in a Regulation referred to in Article 68.

6. The parallel trade permit shall be 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 45(1) and the requirements of Article 29 are still fulfilled, the validity of the parallel trade permit shall expire by the date on which the authorisation of the reference product would normally have expired.

7. Without prejudice to specific provisions of this Article, Articles 44, 45, 46, and 55 and Article 56(4) and Chapters VI to X shall apply to parallel traded plant protection products correspondingly.

8. Without prejudice to Article 44, 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.

9. Where the product is not identical, in terms of paragraph 3, 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 29.

10. The provisions of this Article shall not apply to plant protection products which are authorised in the Member State of origin in accordance with Article 53 or 54.

11. Without prejudice to Article 63, Member State authorities shall make publicly available information about parallel trade permits.

Subsection 6

Derogations

Article 53

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 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 1 month of the date of the request.

3. If necessary, a decision shall be taken, in accordance with the regulatory procedure referred to in Article 79(3), as to when and under what conditions the Member State:

(a) may or may not extend the duration of the measure or repeat it; or

(b) shall withdraw or amend its measure.

4. Paragraphs 1 to 3 shall not apply to plant protection products containing or composed of genetically modified organisms unless such release has been accepted in accordance with Directive 2001/18/EC.

Article 54

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 or involving unauthorised use of a 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 a permit for trial purposes. The permit 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 a permit 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. A permit for trial purposes shall not be granted for experiments or tests involving the release into the environment of a genetically modified organism unless such release has been accepted under Directive 2001/18/EC.

4. Paragraph 2 shall not apply if the Member State has granted the person concerned the right to undertake certain experiments and tests and has determined the conditions under which the experiments and tests have to be undertaken.

5. Detailed rules for the implementation 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, may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

SECTION 2

Use and information

Article 55

Use of plant protection products

Plant protection products shall be used properly.

Proper use shall include the application of the principles of good plant protection practice and compliance with the conditions established in accordance with Article 31 and specified on the labelling. It shall also comply with the provisions of Directive 2009/128/EC and, in particular, with general principles of integrated pest management, as referred to in Article 14 of and Annex III to that Directive, which shall apply at the latest by 1 January 2014.

Article 56

Information on potentially harmful or unacceptable 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, the active substance, its metabolites, a safener, synergist or co-formulant contained in the plant protection product, which suggests that the plant protection product 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, its metabolites, a safener, synergist or co-formulant 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, in animals and the environment related to the use of the plant protection product.

The obligation to notify shall include relevant information on decisions or assessments by international organisations or 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 would result in the plant protection product or the active substance, its metabolites, a safener, or synergist or co-formulant no longer complying with the requirements set out in Article 29 and Article 4 or Article 27, respectively.

3. Without prejudice to the right of Member States to adopt interim protective measures, the Member State which first 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 44.

That Member State shall inform the other Member States 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 or whether in the case of a co-formulant it has been considered unacceptable 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 authorities of the Member States which authorised his plant protection product if he has any information available relating to the lack of expected efficacy, the development of resistance and to any unexpected effect on plants, plant products or the environment.

Article 57

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 and the authorisation number;

(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 classification, risk and safety phrases in accordance to Directive 1999/45/EC and to the Regulation referred to in Article 65;

(f) the use or uses for which it is authorised;

(g) the reasons for withdrawal of an authorisation if they are related to safety concerns;

(h) the list of minor uses referred to in Article 51(8).

2. The information referred to in paragraph 1 shall be readily accessible and updated at least once every 3 months.

3. In accordance with the regulatory procedure referred to in Article 79(3), an authorisation information system may be set up to facilitate the application of paragraphs 1 and 2 of this Article.

CHAPTER IV

ADJUVANTS

Article 58

Placing on the market and use of adjuvants

1. An adjuvant shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with the conditions established in the Regulation referred to in paragraph 2.

2. Detailed rules for the authorisation of adjuvants, including data requirements, notification, evaluation, assessment and decision making procedures shall be set out in a Regulation to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

3. Article 81(3) shall apply.

CHAPTER V

DATA PROTECTION AND DATA SHARING

Article 59

Data protection

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

The protection shall apply to test and study reports concerning the active substance, safener or synergist, adjuvants and the plant protection product as referred to in Article 8(2) when they are submitted to a Member State by an applicant for authorisation under this Regulation, (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 of good experimental practice.

Where a report is protected, it may not be used by the Member State which received it for the benefit of other applicants for authorisation of plant protection products, safeners or synergists and adjuvants, except as provided in paragraph 2 of this Article, in Article 62 or in Article 80.

The period of data protection is 10 years starting at the date of first authorisation in that Member State, except as provided in paragraph 2 of this Article or in Article 62. That period is extended to 13 years for plant protection products covered by Article 47.

Those periods shall be extended by 3 months for each extension of authorisation for minor uses as defined in Article 51(1), except where the extension of authorisation is based on extrapolation, if the applications for such authorisations are made by the authorisation holder at the latest 5 years after the date of the first authorisation in that Member State. The total period of data protection may in no case exceed 13 years. For plant protection products covered by Article 47 the total period of data protection may in no case exceed 15 years.

The same data protection rules as for the first authorisation shall also apply to test and study reports submitted by third parties for the purpose of extension of authorisation for minor uses as referred to in Article 51(1).

A study shall also be protected if it was necessary for the renewal or review of an authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply *mutatis mutandis*.

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 for test and study reports concerning the active substance, safener or synergist, adjuvant and the plant protection product at the time of submitting the dossier and has provided to the Member State concerned for each test or study report the information referred to in point (f) of Article 8(1) and in point (d) of Article 33(3) as well as confirmation that a period of data protection has never been granted for the test or study report or that any period granted has not expired.

Article 60

List of test and study reports

1. For each active substance, safener and synergist and adjuvant, rapporteur Member States shall prepare a list of the test and study reports necessary for first approval, amendment of approval conditions or renewal of the approval and make it available to the Member States and the Commission.

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 concerning the active substance, safener or synergist, adjuvant and the plant protection product 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 the applicant claimed data protection under Article 59 and any reasons 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 of good experimental practice.

Article 61

General rules on avoidance of duplicative testing

1. In order to avoid duplicative testing, any persons intending to seek an authorisation for a plant protection product shall, before carrying out tests or studies, consult the information referred to in Article 57 to ascertain if and to whom an authorisation has already been granted for a plant protection product containing the same active substance, safener or synergist or for an adjuvant. The competent authority shall on request from the prospective applicant provide him with the list of test and study reports prepared in accordance with Article 60 for that product.

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, or the renewal or review thereof, 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 59, in a fair, transparent and non-discriminatory way.

Article 62

Sharing of tests and studies involving vertebrate animals

1. Testing on vertebrate animals for the purposes of this Regulation shall be undertaken only where no other methods are available. Duplication of tests and studies on vertebrates undertaken for the purposes of this Regulation shall be avoided in accordance with paragraphs 2 to 6.

2. Member States shall not accept duplication of tests and studies on vertebrate animals or those initiated where conventional methods described in Annex II to Directive 1999/45/EC could reasonably have been used, in support of applications for authorisations. Any person intending to perform 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.

3. 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. 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.

4. 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, or of adjuvants cannot reach agreement on the sharing of test and study reports involving vertebrate animals, the prospective applicant shall inform the competent authority of the Member State referred to in Article 61(1).

The failure to reach agreement, as provided in paragraph 3, shall not prevent the competent authority of that Member State from using the test and study reports involving vertebrate animals for the purpose of the application of the prospective applicant.

5. By 14 December 2016, the Commission shall report on the effects of the provisions in this Regulation concerning data protection of tests and studies involving vertebrate animals. The Commission shall submit this report to the European Parliament and the Council accompanied, if necessary, by an appropriate legislative proposal.

6. The holder or holders of the relevant authorisation shall have a claim on the prospective applicant for a fair share of the costs incurred by him. The competent authority of the Member State may direct the parties involved to resolve the matter by formal and binding arbitration administered under national law. Otherwise the parties may resolve the matter through litigation in the courts of the Member States. Awards from arbitration or litigation shall have regard to the principles determined in paragraph 3 and shall be enforceable in the courts of the Member States.

CHAPTER VI

PUBLIC ACCESS TO INFORMATION

Article 63

Confidentiality

1. A person requesting that information submitted under this Regulation is to be treated as confidential shall provide verifiable evidence to show that the disclosure of the information might undermine his commercial interests, or the protection of privacy and the integrity of the individual.

2. Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or of privacy and the integrity of the individuals concerned:

(a) the method of manufacture;

(b) the specification of impurity of the active substance except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant;

(c) results of production batches of the active substance including impurities;

(d) methods of analysis for impurities in the active substance as manufactured except for methods for impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant;

(e) links between a producer or importer and the applicant or the authorisation holder;

(f) information on the complete composition of a plant protection product;

(g) names and addresses of persons involved in testing on vertebrate animals.

3. This Article is without prejudice to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information ([1]).

([1]) OJ L 41, 14.2.2003, p. 26.

CHAPTER VII

PACKAGING, LABELLING AND ADVERTISING OF PLANT PROTECTION PRODUCTS AND ADJUVANTS

Article 64

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 65

Labelling

1. The labelling of plant protection products shall include the classification, labelling and packaging requirements of Directive 1999/45/EC and shall comply with the requirements set out in a Regulation adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

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 text of Article 16 of and the text of the Annexes IV and V to 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 before the 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 considered for inclusion 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 66

Advertising

1. Plant protection products which are not authorised shall not be advertised. 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 easily legible and 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 in text or graphic form 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'.

Only in the case of low-risk plant protection products shall the term 'authorised as low-risk plant protection product in accordance with Regulation (EC) No 1107/2009' be allowed in the advertisement. It cannot be used as a claim on the label of the plant protection product.

3. Member States may prohibit or restrict the advertising of plant protection products in certain media, subject to Community law.

4. All statements used in advertising shall be technically justifiable.

5. Advertisements shall not contain any visual representation of potentially dangerous practices, such as mixing or application without sufficient protective clothing, nor any use near food or use by or in the vicinity of children.

6. Advertising or promotional material shall draw attention to the appropriate warning phrases and symbols as laid down in the labelling.

CHAPTER VIII

CONTROLS

Article 67

Record-keeping

1. Producers, suppliers, distributors, importers, and exporters of plant protection products shall keep records of the plant protection products they produce, import, export, store or place on the market for at least 5 years. Professional users of plant protection products shall, for at least 3 years, keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used.

They shall make the relevant information contained in these records available to the competent authority on request. Third parties such as the drinking water industry, retailers or residents, may request access to this information by addressing the competent authority.

The competent authorities shall provide access to such information in accordance with applicable national or Community law.

By 14 December 2012, the Commission shall present a report to the European Parliament and the Council on the costs and benefits of the traceability of information from users to retailers concerning the applications of plant protection products on agricultural products, accompanied, if necessary, by appropriate legislative proposals.

2. Producers of plant protection products shall undertake post-authorisation monitoring on the request of the competent authorities. They shall notify the competent authorities of the relevant results.

3. Authorisation holders shall provide the competent authorities of the Member States with all data relating to the volume of sales of plant protection products in accordance with Community legislation concerning statistics on plant protection products.

4. Implementing measures to ensure the uniform application of paragraphs 1, 2 and 3 may be adopted in accordance with the regulatory procedure referred to in Article 79(3).

Article 68

Monitoring and controls

Member States shall carry out official controls in order to enforce compliance with this Regulation. 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, adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4), shall set out provisions for the controls, in particular on the production, packaging, labelling, storage, transport, marketing, formulation, parallel trade and use of plant protection products. It shall also contain provisions concerning the collection of information and reporting on suspected poisonings.

CHAPTER IX

EMERGENCIES

Article 69

Emergency measures

Where it is clear that an approved active 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 regulatory procedure referred to in Article 79(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 70

Emergency measures in cases of extreme urgency

By way of derogation from Article 69, the Commission may in cases of extreme urgency provisionally adopt emergency measures 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 regulatory procedure referred to in Article 79(3).

Article 71

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 Article 69 or 70, 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 79(1) in accordance with the regulatory procedure referred to in Article 79(3) with a view to the extension, amendment or repeal 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 72

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 shall be effective, proportionate and dissuasive.

The Member States shall notify those rules and any subsequent amendment to the Commission without delay.

Article 73

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 74

Fees and charges

1. Member States may recover the costs associated with any work they carry out within the scope of this Regulation, by means of fees or charges.

2. Member States shall ensure that the fees or charges referred to in paragraph 1:

(a) are established in a transparent manner; and

(b) correspond to the actual total cost of the work involved except if it is in public interest to lower the fees or charges.

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

Article 75

Competent authority

1. Each Member State shall designate a competent authority or authorities to carry out the obligations of the Member States laid down 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. Member States shall ensure that competent authorities have a sufficient number of suitably qualified and experienced staff so that the obligations laid down in this Regulation shall be carried out efficiently and effectively.

4. 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.

5. The Commission shall publish and keep updated on its website a list of the authorities referred to in paragraphs 1 and 2.

Article 76

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 Commission and the Authority 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 Commission and the Authority;

(f) development of guidance to facilitate the day-to-day application 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 68;

(h) training of control staff;

(i) financing of other measures needed to ensure application of the Regulation adopted under Article 68.

2. The appropriations required under paragraph 1 shall be subject to authorisation by the budgetary authority each financial year.

Article 77

Guidance documents

The Commission may, in accordance with the advisory procedure referred to in Article 79(2), adopt or amend technical and other guidance documents such as explanatory notes or guidance documents on the content of the application concerning micro-organisms, pheromones and biological products, for the implementation of this Regulation. The Commission may ask the Authority to prepare or to contribute to such guidance documents.

Article 78

Amendments and implementing measures

1. The following measures designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4):

(a) amendments to the Annexes, taking into account current scientific and technical knowledge;

(b) amendments to the Regulations on data requirements for active substances and for plant protection products, as referred to in points (b) and (c) of Article 8(1), taking into account current 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 current scientific and technical knowledge;

(d) a Regulation postponing the expiry of the approval period referred to in the second subparagraph of Article 17;

(e) a Regulation on data requirements for safeners and synergists referred to in Article 25(3);

(f) a Regulation establishing a work programme for safeners and synergists referred to in Article 26;

(g) adoption of the harmonised methods referred to in Article 29(4);

(h) inclusion of co-formulants in Annex III, as referred to in Article 27(2);

(i) extension of the date of application of this Regulation to provisional authorisations, as referred to in Article 30(3);

(j) information requirements for parallel trade, as referred to in Article 52(4);

(k) rules for the application of Article 54, in particular the maximum quantities of plant protection products to be released;

(l) detailed rules for adjuvants, as referred to in Article 58(2);

(m) a Regulation containing the requirements of the labelling of plant protection products, as referred to in Article 65(1);

(n) a Regulation on controls, as referred to in the third subparagraph of Article 68.

2. Any further measures necessary for the implementation of this Regulation may be adopted in accordance with the regulatory procedure referred to in Article 79(3).

3. In accordance with the advisory procedure referred to in Article 79(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 79

Committee procedure

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.

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 3 months.

4. 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.

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

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

CHAPTER XI

TRANSITIONAL AND FINAL PROVISIONS

Article 80

Transitional measures

1. Directive 91/414/EEC shall continue to apply, with respect to the procedure and the conditions for approval:

(a) to active substances for which a decision has been adopted in accordance with Article 6(3) of Directive 91/414/EEC before 14 June 2011;

(b) to active substances listed in Annex I to Regulation (EC) No 737/2007 [1];

(c) to active substances for which completeness has been established in accordance with Article 16 of Regulation (EC) No 33/2008 [2];

(d) to active substances for which completeness has been established in accordance with Article 6 of Regulation (EC) No 33/2008 before 14 June 2011.

On the basis of the examination carried out under Directive 91/414/EEC, a Regulation on the approval of such a substance shall be adopted in accordance with Article 13(2) of this Regulation. For active substances referred to in point (b) of this paragraph that approval shall not be considered as the renewal of approval referred to in Article 14 of this Regulation.

2. Article 13(1) to (4) and Annexes II and III to Directive 91/414/EEC shall continue to apply with respect to active substances included in Annex I to that Directive and to active substances approved in accordance with paragraph 1 of this Article:

(a) for a period of five years from the date of their inclusion or approval, for active substances covered by Article 8(2) of Directive 91/414/EEC;

(b) for a period of 10 years from the date of their inclusion or approval, for active substances which were not on the market on 26 July 1993;

[1] OJ L 169, 29.6.2007, p. 10.
[2] OJ L 15, 18.1.2008, p. 5.

(c) 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 Directive 91/414/EEC expires by 24 November 2011. 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 by that date.

3. Where Article 13 of Directive 91/414/EEC applies by virtue of paragraph 1 or paragraph 2 of this Article, it shall be subject to any special rules concerning Directive 91/414/EEC 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 by 14 December 2012, 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:

(a) under Article 4 of Directive 91/414/EEC which are pending in the Member States; or

(b) which are due to be amended or withdrawn following an inclusion in Annex I to Directive 91/414/EEC or following an approval in accordance with paragraph 1 of this Article;

on 14 June 2011 shall be decided on the basis of national law in force before that date.

After that decision, this Regulation shall apply.

6. Products labelled in accordance with Article 16 of Directive 91/414/EEC may continue to be placed on the market until 14 June 2015.

7. By 14 December 2013, the Commission shall establish a list of substances included in Annex I to Directive 91/414/EEC which satisfy the criteria set out in point 4 of Annex II to this Regulation and to which the provisions of Article 50 of this Regulation shall apply.

Article 81

Derogation for safeners and synergists, co-formulants and adjuvants

1. By way of derogation from Article 28(1), a Member State may, for a period of 5 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.

2. By way of derogation from Article 27 and without prejudice to Community law, Member States may apply national provisions for co-formulants not included in Annex III until 14 June 2016.

Where, after 14 June 2016, a Member State has serious grounds for considering that a co-formulant not included in Annex III is likely to constitute a serious risk to human or animal health or the environment, it may temporarily prohibit or restrict the application of a co-formulant in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision. Article 71 shall apply.

3. By way of derogation from Article 58(1) Member States may apply national provisions for authorisation of adjuvants until the adoption of detailed rules referred to in Article 58(2).

Article 82

Review clause

By 14 December 2014, the Commission shall present a report to the European Parliament and the Council on the functioning of mutual recognition of authorisations and in particular on the application by the Member States of the provisions referred to in Article 36(3) and Article 50(2), the division of the Community into three zones and on the application of the criteria for the approval of active substances, safeners and synergists as set out in Annex II and the impact thereof on the diversification and competitiveness of agriculture as well as on human health and on the environment. The report may be accompanied, if necessary, by the appropriate legislative proposals to amend those provisions.

Article 83

Repeal

Without prejudice to Article 80, Directives 79/117/EEC and 91/414/EEC, as amended by the acts listed in Annex V, are repealed with effect from 14 June 2011, 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. In particular, references in other Community legislation, such as Regulation (EC) No 1782/2003, to Article 3 of Directive 91/414/EEC shall be construed as references to Article 55 of this Regulation.

Article 84

Entry into force and application

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

By 14 June 2011, the Commission shall adopt the following:

(a) a Regulation containing the list of the active substances already approved at the moment of adoption of that Regulation;

(b) a Regulation on data requirements for active substances, as referred to in Article 8(1)(b);

(c) a Regulation on data requirements for plant protection products, as referred to in Article 8(1)(c);

(d) a Regulation on uniform principles for risk assessment for plant protection products, as referred to in Article 36;

(e) a Regulation containing the requirements of the labelling of plant protection products, as referred to in Article 65(1).

This Regulation shall apply from 14 June 2011.

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

Done at Strasbourg, 21 October 2009.

For the European Parliament
The President
J. BUZEK

For the Council
The President
C. MALMSTRÖM

ANNEX I

Definition of zones for the authorisation of plant protection products as referred to in Article 3(17)

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, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom

Zone C — South

The following Member States belong to this zone:

Bulgaria, 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 further explanations or 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 4 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, safener or synergist shall only be approved where a complete dossier is submitted.

In exceptional cases an active substance, safener or synergist 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 confidence in the decision.

2.3. Restrictions on approval

Where necessary, the approval may be subject to conditions and restrictions as referred to in Article 6.

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, safener or synergist for which one or more 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 to be defined and to be determined by appropriate methods in general use 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 alone or associated with a safener or synergist shall only be approved where it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective. This requirement shall be evaluated in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6).

3.3. Relevance of metabolites

Where applicable the documentation submitted shall be sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.

3.4. Composition of the active substance, safener or synergist

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 Food and Agriculture Organisation specification as appropriate, 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, safener or synergist 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, safener or synergist as manufactured, shall have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.

3.5.2. The methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, 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 29(6).

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. When the critical effect is judged of particular significance, such as developmental neurotoxic or immunotoxic effects, an increased margin of safety shall be considered, and applied if necessary.

3.6.2. An active substance, safener or synergist 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, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as mutagen category 1A or 1B.

3.6.3. An active substance, safener or synergist 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, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.

3.6.4. An active substance, safener or synergist 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, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.

By 14 December 2013, the Commission shall present to the Standing Committee on the Food Chain and Animal Health a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Pending the adoption of these criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties.

In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.

3.7. Fate and behaviour in the environment

3.7.1. An active substance, safener or synergist shall only be approved where it is not considered to be a persistent organic pollutant (POP).

A substance that fulfils all three of the criteria of the points below is a POP.

3.7.1.1. Persistence

An active substance, safener or synergist fulfils the persistence criterion where there is evidence that the time it takes for a degradation of 50 % (DT50) in water is greater than 2 months, or that its DT50 in soil is greater than 6 months, or that its DT50 in sediment is greater than 6 months.

3.7.1.2. Bioaccumulation

An active substance, safener or synergist fulfils the bioaccumulation criterion where there is:

— evidence that its bio-concentration factor or bioaccumulation factor in aquatic species is greater than 5 000 or, in the absence of such data, that the partition coefficient n-octanol/water (log Ko/w) is greater than 5, or

— evidence that the active substance, safener or synergist present other reasons for concern, such as high bioaccumulation in other non-target species, high toxicity or ecotoxicity.

3.7.1.3. Potential for long-range environmental transport:

An active substance, safener or synergist fulfils the potential for long-range environmental transport criterion where:

— measured levels of the active substance, safener or synergist in locations distant from the sources of its release are of potential concern,

— monitoring data show that long-range environmental transport of the active substance, safener or synergist, with the potential for transfer to a receiving environment, may have occurred via air, water or migratory species, or

— environmental fate properties and/or model results demonstrate that the active substance, safener or synergist 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 safener or synergist that migrates significantly through the air, its DT50 in air is to be greater than 2 days.

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

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

3.7.2.1. Persistence

An active substance, safener or synergist fulfils the persistence criterion where:

— the half-life in marine water is higher than 60 days,

— the half-life in fresh or estuarine water is higher than 40 days,

— the half-life in marine sediment is higher than 180 days,

— 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, safener or synergist fulfils the bioaccumulation criterion where the bioconcentration factor is higher than 2 000.

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, safener or synergist fulfils the toxicity criterion where:

— the long-term no-observed effect concentration for marine or freshwater organisms is less than 0,01 mg/l,

— the substance is classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) pursuant to Regulation (EC) No 1272/2008, or

— there is other evidence of chronic toxicity, as identified by the classifications STOT RE 1 or STOT RE 2 pursuant to Regulation (EC) No 1272/2008.

3.7.3. An active substance, safener or synergist shall only be approved if it is not considered to be a very persistent and very bioaccumulative substance (vPvB).

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

3.7.3.1. Persistence

An active substance, safener or synergist fulfils the 'very persistent' criterion where:

— the half-life in marine, fresh- or estuarine water is higher than 60 days,

— 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, safener or synergist fulfils the 'very bioaccumulative' criterion where the bioconcentration factor is greater than 5 000.

3.8. Ecotoxicology

3.8.1. An active substance, safener or synergist shall only be approved 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 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. 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, safener or synergist is expected to affect adversely by the intended use.

3.8.2. An active substance, safener or synergist 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 cause adverse effects 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.

3.8.3. An active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:

— will result in a negligible exposure of honeybees, or

— has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.

3.9. Residue definition

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

3.10. Fate and behaviour concerning groundwater

An active substance shall only be approved where it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6).

4. 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 within groups of substances/use categories,

— it meets two of the criteria to be considered as a PBT substance,

— there are reasons for concern linked to the nature of the critical effects (such as developmental neurotoxic or immunotoxic effects) which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; 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,

— it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 1A or 1B, if the substance has not been excluded in accordance with the criteria laid down in point 3.6.3,

— it is or is to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B if the substance has not been excluded in accordance with the criteria laid down in point 3.6.4,

— if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, reviewed by the Authority, it is considered to have endocrine disrupting properties that may cause adverse effects in humans if the substance has not been excluded in accordance with the criteria laid down in point 3.6.5.

5. Low-risk active substances

An active substance shall not be considered of low risk where it is or has to be classified in accordance with Regulation (EC) No 1272/2008 as at least one of the following:

— carcinogenic,

— mutagenic,

— toxic to reproduction,

— sensitising chemicals,

— very toxic or toxic,

— explosive,

— corrosive.

It shall also not be considered as of low risk if:

— persistent (half-life in soil is more than 60 days),

— bioconcentration factor is higher than 100,

— it is deemed to be an endocrine disrupter, or

— it has neurotoxic or immunotoxic effects.

ANNEX III

List of co-formulants which are not accepted for inclusion in plant protection products as referred to in Article 27

ANNEX IV

Comparative assessment pursuant to Article 50

1. Conditions for comparative assessment

Where refusal or withdrawal of an authorisation of a plant protection product in favour of an alternative plant protection product or a non-chemical control or prevention method is considered, referred to as '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 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 as follows:

(a) substitution shall be applied only where other methods or the chemical diversity of the active substances is sufficient to minimise the occurrence of resistance in the target organism;

(b) substitution shall be applied only to plant protection products where their use presents a significantly higher level of risk to human health or the environment; and

(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 shall be identified on a case-by-case basis by the competent authorities. The properties of the active substance and plant protection product, 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, drinking 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 shall also be considered.

For the environment, if relevant, a factor of at least 10 for the toxicity/exposure ratio (TER) of different plant protection products 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 are available or economically feasible.

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

The comparative assessment shall take authorised minor uses into account.

ANNEX V

Repealed Directives and their successive amendments as referred to in Article 83

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	—

Acts amending Directive 91/414/EEC	Deadline for transposition
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
Directive 2006/41/EC	31 January 2007
Directive 2006/45/EC	18 September 2006
Directive 2006/64/EC	31 October 2007
Directive 2006/74/EC	30 November 2007
Directive 2006/75/EC	31 March 2007
Directive 2006/85/EC	31 January 2008
Directive 2006/104/EC	1 January 2007
Directive 2006/131/EC	30 June 2007
Directive 2006/132/EC	30 June 2007
Directive 2006/133/EC	30 June 2007
Directive 2006/134/EC	30 June 2007
Directive 2006/135/EC	30 June 2007
Directive 2006/136/EC	30 June 2007
Directive 2007/5/EC	31 March 2008
Directive 2007/6/EC	31 July 2007
Directive 2007/21/EC	12 December 2007
Directive 2007/25/EC	31 March 2008
Directive 2007/31/EC	1 September 2007

Acts amending Directive 91/414/EEC	Deadline for transposition
Directive 2007/50/EC	31 May 2008
Directive 2007/52/EC	31 March 2008
Directive 2007/76/EC	30 April 2009
Directive 2008/40/EC	30 April 2009
Directive 2008/41/EC	30 June 2009
Directive 2008/45/EC	8 August 2008
Directive 2008/66/EC	30 June 2009

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 91/188/EEC	31 March 1992
Regulation (EC) No 807/2003	—
Regulation (EC) No 850/2004	—

REGULATION (EC) No 1108/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 21 October 2009

amending Regulation (EC) No 216/2008 in the field of aerodromes, air traffic management and air navigation services and repealing Directive 2006/23/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 80(2) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Having regard to the opinion of the Committee of the Regions [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) In its communication of 15 November 2005 to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions entitled 'Extending the tasks of the European Aviation Safety Agency — an agenda for 2010', the Commission announced its intention to progressively extend the tasks of the European Aviation Safety Agency (the Agency), with a view towards a 'total system approach', to aerodrome/airport safety and interoperability, air navigation services (ANS) and air traffic management (ATM).

(2) The continuous growth of aviation in Europe leads to many challenges, in particular regarding the key safety factors of aerodromes and ATM/ANS. Therefore, necessary risk mitigation measures need to be established to ensure safety through a harmonised, holistic regulatory approach across the Member States.

(3) The achievements of the single European sky initiative need to be complemented by the harmonised safety element to be applied to aerodromes and ATM/ANS. To this end, the appropriate safety regulatory framework should also be developed with regard to the deployment of new technologies in this field.

(4) The Community should lay down, in line with the Standards and Recommended Practices set by the Convention on International Civil Aviation, signed in Chicago on 7 December 1944 (the Chicago Convention), essential requirements applicable to aeronautical products, parts and appliances, aerodromes and the provision of ATM/ANS; essential requirements applicable to persons and organisations involved in the operation of aerodromes and in the provision of ATM/ANS; and essential requirements applicable to persons and products involved in the training and medical assessment of air traffic controllers. The Commission should be empowered to develop the necessary related implementing rules.

(5) Taking into account that services consisting in the origination and processing of data and formatting and delivering data for the purpose of air navigation are different from ANS services as defined in Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation) [4], the Commission should develop specific requirements adapted to such services.

(6) It would not be appropriate to subject all aerodromes to common rules. In particular, aerodromes which are not open to public use and aerodromes mainly used for recreational flying or serving commercial air transport other than in accordance with instrument flight procedures and with paved runways of less than 800 metres, should remain under the regulatory control of the Member States, without any obligation under this Regulation on other Member States to recognise such national arrangements. However, proportionate measures should be taken by Member States to increase generally the level of safety of recreational aviation and of all commercial air transport. The Commission will re-examine in due time, extending the scope of application to aerodromes currently excluded in a modular manner, and taking full account of the impact this might have on such aerodromes.

[1] OJ C 182, 4.8.2009, p. 50.
[2] OJ C 120, 28.5.2009, p. 52.
[3] Opinion of the European Parliament of 25 March 2009 (not yet published in the Official Journal) and Council Decision of 7 September 2009.
[4] OJ L 96, 31.3.2004, p. 1.

(7) Taking into account the large variety of aerodromes and their highly individual infrastructures and environments, common aerodrome safety rules should provide for the necessary flexibility for customised compliance, through an adequate balance between implementing rules, certification specifications and acceptable means of compliance. These rules should be proportionate to the size, traffic, category and complexity of the aerodrome and nature and volume of operations thereon, thereby avoiding unnecessary bureaucratic and economic burdens in particular for smaller aerodromes which only involve very limited passenger traffic.

(8) Aerodrome infrastructure and operations should be certified by means of a single certificate. However, Member States may certify aerodrome infrastructure and operations separately. In that case, certificates should be delivered by the same authority. Operators of multiple aerodromes, having established appropriate central functions, may request a single certificate, covering operations and management at all aerodromes under their responsibility.

(9) Aeronautical products, parts and appliances, aerodromes and their equipment, operators involved in commercial air transport and in the operation of aerodromes, ATM/ANS systems and providers, as well as pilots and air traffic controllers, and persons, products and organisations involved in their training and medical assessment, should be certified or licensed once they have been found to comply with essential requirements to be laid down by the Community in line with Standards and Recommended Practices set by the Chicago Convention. The Commission should be empowered to develop the necessary implementing rules for establishing the conditions for the issue of the certificate or the conditions for its replacement by a declaration of capability, taking into account the risks associated with the different types of operations or services.

(10) Implementing rules relating to the certification of the design, manufacture and maintenance of ATM/ANS systems and constituents as well as to organisations engaged in the design, manufacture and maintenance should only be laid down when related to safety-critical issues identified following a detailed impact assessment study.

(11) The Commission intends to begin work, in due time, on an examination of the feasibility and the necessity of introducing accredited bodies for the certification of ATM/ANS systems and an evaluation of all possible options and impacts. The Commission could, if appropriate, make a proposal for further revision of this Regulation based on a full impact assessment.

(12) Under the Community institutional system, implementation of Community law is primarily the responsibility of the Member States. Certification tasks required by this Regulation and its implementing rules are therefore to be executed at national level. In certain clearly defined cases, however, the Agency should also be empowered to conduct certification tasks as specified in this Regulation. The Agency should, for the same reason, be allowed to take the necessary measures related to the fields covered by this Regulation when this is the best means to ensure uniformity and facilitate the functioning of the internal market.

(13) The implementing rules to be developed by the Agency in the domain of ATM/ANS should be prepared in accordance with the results of the consultation process of the Agency on a basis that should be adapted to new stakeholders, and build on the provisions of Regulation (EC) No 549/2004, Regulation (EC) No 550/2004 of the European Parliament and of the Council of 10 March 2004 on the provision of air navigation services in the single European sky (the service provision Regulation) ([1]), Regulation (EC) No 551/2004 of the European Parliament and of the Council of 10 March 2004 on the organisation and use of the airspace in the single European sky (the airspace Regulation) ([2]), Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation) ([3]), and in particular the transposed Eurocontrol Safety Regulatory Requirements. Such implementing rules should be adopted by the Commission in accordance with the regulatory procedure set out in Article 5 of Regulation (EC) No 549/2004. Transitional mechanisms should be designed in order to provide for the continuity of approvals already granted under the rules of those Regulations.

(14) Regulations (EC) No 549/2004, (EC) No 550/2004, (EC) No 551/2004 and (EC) No 552/2004 include provisions on several regulatory functions of ATM, such as, but not limited to interoperability and the management of air traffic flows and of the airspace. All these areas involve safety aspects, which need to be properly addressed. Therefore, when regulating on these subjects, Member States and the Commission should ensure proper coverage of such safety aspects by means of appropriate coordination with the Agency.

(15) It is a general objective that the transfer of functions and tasks from the Member States, including those resulting from their cooperation through the Safety Regulation Commission of Eurocontrol, to the Agency should be done efficiently, without any reduction in the current high levels of safety, and without any negative impact on certification schedules. Appropriate measures should be adopted to provide for the necessary transition. The Agency should have sufficient resources for its new tasks, and the timing of the allocation of these resources should be based on a defined need and schedule for the adoption and the respective applicability of the related implementing rules.

([1]) OJ L 96, 31.3.2004, p. 10.
([2]) OJ L 96, 31.3.2004, p. 20.
([3]) OJ L 96, 31.3.2004, p. 26.

(16) Regulation (EC) No 216/2008 of the European Parliament and of the Council [1] establishes an appropriate and comprehensive framework for the definition and implementation of common technical requirements and administrative procedures in the field of civil aviation. Directive 2006/23/EC of the European Parliament and of the Council of 5 April 2006 on a Community air traffic controller licence [2] should therefore be repealed, without prejudice to the certification or licensing of products, persons and organisations already carried out in accordance with that Directive.

(17) With regard to the regulation of professions which are not covered by this Regulation, the competence of Member States should be retained to establish or maintain at their own discretion, inter alia, certification or licensing requirements of the personnel.

(18) The implementing rules to be developed by the Agency in the domain of ATM/ANS should be developed in the context of a comprehensive review of the safety requirements in the single European sky legislation, namely, Regulations (EC) No 549/2004, (EC) No 550/2004, (EC) No 551/2004 and (EC) No 552/2004. In order to avoid duplication of safety requirements applicable to ATM/ANS services on the one hand, and to avoid a legal void without applicable safety requirements on the other hand, the date of entry into force of the amendments to the single European sky legislation should be in line with those of the new safety measures made under this Regulation.

(19) 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 Commission [3].

(20) In particular the Commission should be empowered to adopt implementing rules for air traffic controller licensing and associated approvals, aerodromes and aerodrome operations, air traffic management and air navigation services, and associated certificates, oversight and enforcement, as well as to adopt a regulation on the fees and charges of the Agency. Since those measures are of general scope and are designed to amend non-essential elements of Regulation (EC) No 216/2008, inter alia, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(21) Without prejudice to the competences of the Member States, the Commission, if necessary, could make recommendations to the Council to establish a framework of coordination between the Community and the International Civil Aviation Organization (ICAO) on safety audits, with the aim of avoiding duplication and in the interests of the efficient use of resources.

(22) When drafting safety rules, the Agency should ensure the involvement of all interested parties. Rule-making opinions should be based on a full scale consultation of all stakeholders, including the smaller industry operators, as well as on a proper assessment of their potential impact in the applicable fields. As provided for in Regulation (EC) No 216/2008, the advisory body of interested parties should be consulted by the Agency prior to making decisions,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 216/2008 is hereby amended as follows:

1. Article 1 is replaced by the following:

'*Article 1*

Scope

1. This Regulation shall apply to:

(a) the design, production, maintenance and operation of aeronautical products, parts and appliances, as well as personnel and organisations involved in the design, production and maintenance of such products, parts and appliances;

(b) personnel and organisations involved in the operation of aircraft;

(c) the design, maintenance and operation of aerodromes, as well as personnel and organisations involved therein and, without prejudice to Community and national legislation on environment and land-use planning, the safeguarding of surroundings of aerodromes;

(d) the design, production and maintenance of aerodrome equipment, as well as personnel and organisations involved therein;

(e) the design, production and maintenance of systems and constituents for air traffic management and air navigation services (ATM/ANS), as well as personnel and organisations involved therein;

(f) ATM/ANS, as well as personnel and organisations involved therein.

[1] OJ L 79, 19.3.2008, p. 1.
[2] OJ L 114, 27.4.2006, p. 22.
[3] OJ L 184, 17.7.1999, p. 23.

2. This Regulation shall not apply to:

(a) products, parts, appliances, personnel and organisations referred to in paragraph 1(a) and (b) while carrying out military, customs, police, search and rescue, firefighting, coastguard or similar activities or services. The Member States shall undertake to ensure that such activities or services have due regard as far as practicable to the objectives of this Regulation;

(b) aerodromes or part thereof, as well as equipment, personnel and organisations, referred to in paragraph 1(c) and (d), that are controlled and operated by the military;

(c) ATM/ANS, including systems and constituents, personnel and organisations, referred to in paragraph 1(e) and (f), that are provided or made available by the military. The Member States shall undertake to ensure that aircraft referred to in point (a) of this paragraph are separated, where appropriate, from other aircraft.

3. Member States shall, as far as practicable, ensure that any military facilities open to public use referred to in paragraph 2(b) or services provided by military personnel to the public referred to in paragraph 2(c), offer a level of safety that is at least as effective as that required by the essential requirements as defined in Annexes Va and Vb.';

2. Article 3 is amended as follows:

(a) point (d) is replaced by the following:

'(d) "parts and appliances" shall mean any instrument, equipment, mechanism, part, apparatus, appurtenance, software or accessory, including communications equipment, that is used or intended to be used in operating or controlling an aircraft in flight; it shall include parts of an airframe, engine or propeller, or equipment used to manoeuvre the aircraft from the ground;';

(b) the following point is inserted:

'(da) "ATM/ANS constituents" shall mean any constituent as defined in Article 2(19) of Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation) (*);

(*) OJ L 96, 31.3.2004, p. 1.';

(c) point (h) is replaced by the following:

'(h) "operator" shall mean any legal or natural person, operating or proposing to operate one or more aircraft or one or more aerodromes;';

(d) the following points are added:

'(m) "aerodrome" shall mean a defined area (including any buildings, installations and equipment) on land or water or on a fixed, fixed offshore or floating structure intended to be used either wholly or in part for the arrival, departure and surface movement of aircraft;

(n) "aerodrome equipment" shall mean any equipment, apparatus, appurtenance, software or accessory, that is used or intended to be used to contribute to the operation of aircraft at an aerodrome;

(o) "apron" shall mean a defined area intended to accommodate aircraft for purposes of loading or unloading passengers, mail or cargo, fuelling, parking or maintenance;

(p) "apron management service" shall mean a service provided to manage the activities and the movement of aircraft and vehicles on an apron;

(q) "ATM/ANS" shall mean the air traffic management functions as defined in Article 2(10) of Regulation (EC) No 549/2004, air navigation services defined in Article 2(4) of that Regulation, and services consisting in the origination and processing of data and formatting and delivering data to general air traffic for the purpose of safety-critical air navigation;

(r) "ATM/ANS system" shall mean any combination of safety-related equipment and systems as defined in Article 2(39) of Regulation (EC) No 549/2004;

(s) "flight information service" shall mean a service provided for the purpose of giving advice and information useful for the safe and efficient conduct of flights.';

3. in Article 4, the following paragraphs are inserted:

'3a. Aerodromes, including equipment, located in the territory subject to the provisions of the Treaty, open to public use and which serve commercial air transport and where operations using instrument approach or departure procedures are provided, and:

(a) have a paved runway of 800 metres or above; or

(b) exclusively serve helicopters;

shall comply with this Regulation. Personnel and organisations involved in the operation of these aerodromes shall comply with this Regulation.

3b. By way of derogation from paragraph 3a, Member States may decide to exempt from the provisions of this Regulation an aerodrome which:

— handles no more than 10 000 passengers per year, and

— handles no more than 850 movements related to cargo operations per year.

If such exemption by a Member State does not comply with the general safety objectives of this Regulation or any other rule of Community law, the Commission shall take a decision in accordance with the safeguard procedure referred to in Article 65(7) not to permit the exemption in question. In such a case, the Member State concerned shall revoke the exemption.

3c. ATM/ANS provided in the airspace of the territory to which the Treaty applies, as well as in any other airspace where Member States apply Regulation (EC) No 551/2004 of the European Parliament and of the Council of 10 March 2004 on the organisation and use of the airspace in the single European sky (the airspace Regulation) (*) in accordance with Article 1(3) of that Regulation, shall comply with this Regulation. Systems and constituents, personnel and organisations involved in the provision of these ATM/ANS shall comply with this Regulation.

(*) OJ L 96, 31.3.2004, p. 20.';

4. in Article 5, paragraph 2, points (b) and (c) are replaced by the following:

'(b) the measures referred to in paragraph 5 may lay down a requirement for certification in respect of parts and appliances. The certificates for parts and appliances shall be issued when the applicant has shown that the parts and appliances comply with the detailed airworthiness specifications established to ensure compliance with the essential requirements referred to in paragraph 1;

(c) no aircraft shall be operated, unless it has a valid certificate of airworthiness. The certificate shall be issued when the applicant has shown that the aircraft conforms to the type design approved in its type-certificate and that relevant documentation, inspections and tests demonstrate that the aircraft is in condition for safe operation. This certificate of airworthiness shall remain valid as long as it is not suspended, revoked or terminated and as long as the aircraft is maintained in accordance with the essential requirements related to continuing airworthiness set out in point 1.d of Annex I and the measures adopted pursuant to paragraph 5;';

5. in Article 7, paragraph 4 is replaced by the following:

'4. A certificate shall be required in respect of each flight simulation training device used for the training of pilots. The certificate shall be issued when the applicant has shown that the device complies with the rules established to ensure compliance with the relevant essential requirements as set out in Annex III.';

6. Article 8 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The operation of aircraft referred to in Article 4(1)(b) and (c) shall comply with the essential requirements set out in Annex IV and, if applicable, Annex Vb.';

(b) paragraph 5 is amended as follows:

(i) point (a) is replaced by the following:

'(a) conditions to operate an aircraft in compliance with the essential requirements set out in Annex IV and, if applicable, Annex Vb;';

(ii) point (g) is replaced by the following:

'(g) how operations of aircraft referred to in point (a)(ii) and points (d) and (h) of Annex II, when used for commercial air transportation, comply with the relevant essential requirements set out in Annex IV and, if applicable, Annex Vb.';

(c) in paragraph 6, the following indent is added:

'— take into account the safety aspects related to ATM/ANS,';

7. the following Articles are inserted:

'Article 8a

Aerodromes

1. Aerodromes and aerodrome equipment as well as the operation of aerodromes shall comply with the essential requirements set out in Annex Va and, if applicable, Annex Vb.

2. The compliance of aerodromes, aerodrome equipment and operation of aerodromes with the essential requirements shall be established in accordance with the following:

(a) a certificate shall be required in respect of each aerodrome. The certificate and certification of changes to that certificate shall be issued when the applicant has shown that the aerodrome complies with the aerodrome certification basis set out in point (b), and that the aerodrome has no feature or characteristic making it unsafe for operation. The certificate shall cover the aerodrome, its operation and its safety-related equipment;

(b) the certification basis for an aerodrome shall consist of the following:

(i) the applicable certification specifications related to the type of aerodromes;

(ii) the provisions for which an equivalent level of safety has been accepted; and

(iii) the special detailed technical specifications necessary when the design features of a particular aerodrome or the experience in operation render any of the specifications referred to in point (i) inadequate or inappropriate to ensure conformity with the essential requirements set out in Annex Va;

(c) the measures referred to in paragraph 5 may lay down a requirement of certification in respect of safety-critical aerodrome equipment. The certificate for such equipment shall be issued when the applicant has shown that the equipment complies with the detailed specifications established to ensure compliance with the essential requirements referred to in paragraph 1;

(d) organisations responsible for the operation of aerodromes shall demonstrate their capability and means to discharge the responsibilities associated with their privileges. These capabilities and means shall be recognised through the issuance of the certificate referred to in point (a). They may also be recognised through the issuance of a separate certificate if the Member State where the aerodrome is located so decides. The privileges granted to the certified organisation and the scope of the certificate, including a list of aerodromes to be operated, shall be specified in the certificate;

(e) by way of derogation from point (d), Member States may decide that providers of apron management services shall be allowed to declare their capability and means of discharging the responsibilities associated with the services provided.

3. Member States shall ensure that provisions are in place to safeguard aerodromes against activities and developments in their surroundings which may cause unacceptable risks to aircraft using the aerodrome.

4. Aerodrome operators shall monitor activities and developments which may cause unacceptable safety risks to aviation in the aerodrome surroundings and take, within their competence, mitigating measures as appropriate.

5. The measures designed to amend non-essential elements of the requirements referred to in this Article, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 65(4).

Those measures shall specify in particular:

(a) the conditions for establishing and notifying to an applicant the certification basis applicable to an aerodrome;

(b) the conditions for establishing and notifying to an applicant the detailed specifications applicable to aerodrome equipment;

(c) the conditions for issuing, maintaining, amending, suspending or revoking certificates for aerodromes and certificates for aerodrome equipment, including operating limitations related to the specific design of the aerodrome;

(d) the conditions for operating an aerodrome in compliance with the essential requirements set out in Annex Va and, if applicable, Annex Vb;

(e) the conditions for issuing, maintaining, amending, suspending or revoking the certificates referred to in paragraph 2(d);

(f) the responsibilities of the holders of certificates;

(g) the conditions for the acceptance and for the conversion of aerodrome certificates issued by Member States, including measures which are already authorised by the Member State concerned on the basis of notified deviations from Annex 14 of the Chicago Convention before the entry into force of this Regulation;

(h) the conditions for the decision not to permit exemptions referred to in Article 4(3b), including criteria for cargo aerodromes, the notification of exempted aerodromes and for the review of granted exemptions;

(i) the conditions under which operations shall be prohibited, limited or subject to certain conditions in the interest of safety;

(j) the conditions and procedures for the declaration by and for the oversight of service providers referred to in paragraph 2(e).

6. The measures referred to in paragraph 5 shall:

(a) reflect the state of the art and the best practices in the field of aerodromes and take into account the applicable ICAO Standards and Recommended Practices;

(b) be proportionate to the size, traffic, category and complexity of the aerodrome and nature and volume of operations thereon;

(c) take into account worldwide aerodrome operation experience, and scientific and technical progress;

(d) allow for immediate reaction to established causes of accidents and serious incidents;

(e) provide for the necessary flexibility for customised compliance.

Article 8b

ATM/ANS

1. Provision of ATM/ANS shall comply with the essential requirements set out in Annex Vb and, as far as practicable, Annex Va.

2. ATM/ANS providers shall be required to hold a certificate. The certificate shall be issued when the provider has demonstrated its capability and means of discharging the responsibilities associated with the provider's privileges. The privileges granted and the scope of the services provided shall be specified in the certificate.

3. By way of derogation from paragraph 2, Member States may decide that providers of flight information services shall be allowed to declare their capability and means of discharging the responsibilities associated with the services provided.

4. The measures referred to in paragraph 6 may lay down a requirement for certification in respect of organisations engaged in the design, manufacture and maintenance of safety-critical ATM/ANS systems and constituents. The certificate for those organisations shall be issued when they have demonstrated their capability and means of discharging the responsibilities associated with their privileges. The privileges granted shall be specified in the certificate.

5. The measures referred to in paragraph 6 may lay down a requirement for certification, or alternatively, validation by the ATM/ANS provider, in respect of safety-critical ATM/ANS systems and constituents. The certificate for those systems and constituents shall be issued, or validation shall be given, when the applicant has shown that the systems and constituents comply with the detailed specifications established to ensure compliance with the essential requirements referred to in paragraph 1.

6. The measures necessary for the implementation of this Article shall be adopted in accordance with the regulatory procedure referred to in Article 5(3) of Regulation (EC) No 549/2004.

Those measures shall specify in particular:

(a) the conditions for the provision of ATM/ANS in compliance with the essential requirements set out in Annex Vb and, if applicable, in Annex Va;

(b) the conditions for establishing and notifying to an applicant the detailed specifications applicable to ATM/ANS systems and constituents;

(c) the conditions for issuing, maintaining, amending, suspending or revoking the certificates referred to in paragraphs 2 and 4;

(d) the responsibilities of the holders of certificates;

(e) the conditions and procedures for the declaration by, and for the oversight of service providers referred to in paragraph 3;

(f) the conditions under which operations shall be prohibited, limited or subject to certain conditions in the interest of safety.

7. The measures referred to in paragraph 6 shall:

(a) reflect the state of the art and the best practices in the field of ATM/ANS;

(b) be proportionate to the type and complexity of the services provided;

(c) take into account worldwide ATM/ANS experience, and scientific and technical progress;

(d) be developed using as far as practicable the relevant provisions of Regulation (EC) No 549/2004 and of Regulation (EC) No 550/2004 of the European Parliament and of the Council of 10 March 2004 on the provision of air navigation services in the single European sky (the service provision Regulation) (*), Regulation (EC) No 551/2004 and Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation) (**) and provide for transitional mechanisms to ensure the continuity of certificates already granted under those Regulations; initially they shall include the safety provisions of those Regulations and, where appropriate, in case of future amendments, take into account latest scientific and technical progress;

(e) allow for immediate reaction to established causes of accidents and serious incidents.

Article 8c

Air traffic controllers

1. Air traffic controllers as well as persons and organisations involved in the training, testing, checking or medical assessment of air traffic controllers, shall comply with the relevant essential requirements set out in Annex Vb.

2. Air traffic controllers shall be required to hold a licence and a medical certificate appropriate to the service provided.

3. The licence referred to in paragraph 2 shall only be issued when the applicant for the licence demonstrates that he or she complies with the rules established to ensure compliance with the essential requirements regarding theoretical knowledge, practical skill, language proficiency and experience as set out in Annex Vb.

4. The medical certificate referred to in paragraph 2 shall only be issued when the air traffic controller complies with the rules established to ensure compliance with the essential requirements on medical fitness as set out in Annex Vb. The medical certificate may be issued by aero medical examiners or by aero medical centres.

5. The privileges granted to the air traffic controller and the scope of the licence and the medical certificate shall be specified in such licence and certificate.

6. The capability of air traffic controller training organisations, aero medical examiners and aero medical centres to discharge the responsibilities associated with their privileges in relation to the issuance of licences and medical certificates shall be recognised by the issuance of a certificate.

7. A certificate shall be issued to training organisations, aero medical examiners and aero medical centres for air traffic controllers that have demonstrated that they comply with the rules established to ensure compliance with the relevant essential requirements as set out in Annex Vb. The privileges granted by the certificate shall be specified therein.

8. Persons responsible for providing practical training or for assessing air traffic controllers' skill shall hold a certificate. The certificate shall be issued when the person concerned has demonstrated that he or she complies with the rules established to ensure compliance with the relevant essential requirements as set out in Annex Vb. The privileges granted by the certificate shall be specified therein.

9. Synthetic training devices shall comply with the relevant essential requirements set out in Annex Vb.

10. The measures designed to amend non-essential elements of this Article by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 65(4).

Those measures shall specify in particular:

(a) the different ratings and endorsements for air traffic controllers' licences;

(b) the conditions for issuing, maintaining, amending, limiting, suspending or revoking licences, ratings and endorsements for licences, medical certificates, approvals and certificates, and the conditions under which such certificates and approvals need not be requested, while providing for transitional mechanisms to ensure the continuity of approvals and certificates already granted;

(c) the privileges and responsibilities of the holders of licences, ratings and endorsements for licences, medical certificates, approvals and certificates;

(d) the conditions for the acceptance and for the conversion of air traffic controllers' licences as well as the conditions for the acceptance and for the conversion of national medical certificates into commonly recognised medical certificates.

11. The measures referred to in paragraph 10 shall reflect the state of the art, including best practices and scientific and technical progress, in the field of air traffic controller training. They shall initially be developed on the basis of the provisions of Directive 2006/23/EC of the European Parliament and of the Council of 5 April 2006 on a Community air traffic controller licence (***).

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(*) OJ L 96, 31.3.2004, p. 10.
(**) OJ L 96, 31.3.2004, p. 26.
(***) OJ L 114, 27.4.2006, p. 22.';

8. Article 9 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Aircraft referred to in Article 4(1)(d), as well as their crew and their operations, shall comply with applicable ICAO standards. To the extent that there are no such standards, these aircraft and their operations shall comply with the requirements set out in Annexes I, III, IV and, if applicable, Annex Vb, provided these requirements are not in conflict with the rights of third countries under international conventions.';

(b) in paragraph 5, the following point is added:

'(e) safety aspects related to ATM/ANS are taken into account.';

9. in Article 10, paragraph 1 is replaced by the following:

'1. The Member States, the Commission and the Agency shall cooperate with a view to ensuring compliance with this Regulation and its implementing rules.';

10. Article 11 is amended as follows:

(a) paragraphs 4 and 5 are replaced by the following:

'4. Pending the entry into effect of the measures referred to in Articles 5(5), 7(6) and 9(4) and the expiry of any transition periods provided for by those measures, and without prejudice to Article 69(4), certificates which cannot be issued in accordance with this Regulation may be issued on the basis of the applicable national regulations.

5. Pending the entry into effect of the measures referred to in Article 8(5) and the expiry of any transition periods provided for by those measures, and without prejudice to Article 69(4), certificates which cannot be issued in accordance with this Regulation may be issued on the basis of the applicable national regulations.';

(b) the following paragraphs are inserted:

'5a. Pending the entry into effect of the measures referred to in Articles 8a(5) and 8c(10) and the expiry of any transition periods provided for by those measures, and without prejudice to Article 69(4), certificates which cannot be issued in accordance with this Regulation may be issued on the basis of the applicable national regulations.

5b. Pending the entry into effect of the measures referred to in Article 8b(6) and the expiry of any transition periods provided for by those measures, and without prejudice to Article 69(4), certificates which cannot be issued in accordance with this Regulation may be issued on the basis of the applicable national regulations or, where applicable, on the basis of the relevant requirements of Commission Regulation (EC) No 2096/2005 of 20 December 2005 laying down common requirements for the provision of air navigation services (*).

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(*) OJ L 335, 21.12.2005, p. 13.';

11. in Article 13, the following paragraph is added:

'Qualified entities shall not issue certificates.';

12. in Article 18, points (c) and (d) are replaced by the following:

'(c) issue certification specifications and acceptable means of compliance, as well as any guidance material for the application of this Regulation and its implementing rules;

(d) take the appropriate decisions for the application of Articles 20, 21, 22, 22a, 22b, 23, 54 and 55 including the granting of exemptions to holders of certificates it has issued, from the substantive requirements laid down in this Regulation and its implementing rules in the event of unforeseen urgent operational circumstances or operational needs of a limited duration, provided that the level of safety is not affected, that they are granted for a period not exceeding two months, that they are notified to the Commission and that they are not renewed;';

13. in Article 19(2), point (a) is replaced by the following:

'(a) certification specifications and acceptable means of compliance; and';

14. the following Articles are inserted:

'*Article 22a*

ATM/ANS

With regard to ATM/ANS referred to in Article 4(3c) the Agency shall:

(a) conduct, itself or through national aviation authorities or qualified entities, inspections, and audits of the organisations it certifies;

(b) issue and renew certificates of organisations located outside the territory subject to the provisions of the Treaty, responsible for providing services in the airspace of the territory to which the Treaty applies;

(c) issue and renew certificates of organisations providing pan-European services;

(d) amend, suspend or revoke the relevant certificate, when the conditions according to which it was issued are no longer fulfilled or if the holder of the certificate fails to fulfil the obligations imposed on it by this Regulation or by its implementing rules.

Article 22b

Air traffic controller certification

With regard to the persons and organisations referred to in Article 8c(1), the Agency shall:

(a) conduct, itself or through national aviation authorities or qualified entities, investigations and audits of the organisations it certifies and, where relevant, their personnel;

(b) issue and renew the certificates of air traffic controller training organisations located outside the territory of the Member States and, where relevant, their personnel;

(c) amend, suspend or revoke the relevant certificate when the conditions according to which it was issued by it are no longer fulfilled, or if the legal or natural person holding the certificate fails to fulfil the obligations imposed on it by this Regulation or its implementing rules.';

15. in Article 33(2)(c), the date '30 September' is replaced by '30 November';

16. in Article 44, paragraph 1 is replaced by the following:

'1. An appeal may be brought against decisions of the Agency taken pursuant to Articles 20, 21, 22, 22a, 22b, 23, 55 or 64.';

17. in Article 50, paragraph 2 is replaced by the following:

'2. Actions for the annulment of decisions of the Agency taken pursuant to Articles 20, 21, 22, 22a, 22b, 23, 55 or 64 may be brought before the Court of Justice of the European Communities only after all appeal procedures within the Agency have been exhausted.';

18. Article 52 is amended as follows:

(a) in paragraph 1, the first subparagraph is replaced by the following:

'As soon as possible after the entry into force of this Regulation, the Management Board shall establish transparent procedures for issuing opinions, certification specifications, acceptable means of compliance and guidance material referred to in Article 18(a) and(c).';

(b) paragraph 2 is replaced by the following:

'2. When the Agency, pursuant to Article 19, develops opinions, certification specifications, acceptable means of compliance and guidance material to be applied by Member States, it shall establish a procedure for consulting the Member States. To this effect, it may create a working group in which each Member State is entitled to designate an expert.';

19. in Article 55, paragraph 1, the first sentence is replaced by the following:

'The Agency may itself conduct or assign to national aviation authorities or qualified entities all necessary investigations of undertakings in accordance with Articles 7, 20 21, 22, 22a, 22b 23 and 24(2).';

20. the following Article is inserted:

'*Article 65a*

Amendments

In accordance with the provisions of the Treaty, the Commission shall propose to amend Regulations (EC) No 549/2004, (EC) No 550/2004, (EC) No 551/2004 and (EC) No 552/2004 in order to take into account the requirements of this Regulation.';

21. the title of Annex V is replaced by the following:

'Criteria for qualified entities referred to in Article 13 ("qualified entity" or "entity")';

22. Annexes Va and Vb as set out in the Annex to this Regulation are inserted.

Article 2

Directive 2006/23/EC is hereby repealed.

The provisions of Directive 2006/23/EC shall continue to apply, on a transitional basis, until the date of application of the measures referred to in Article 8c(10) of Regulation (EC) No 216/2008 as amended by this Regulation.

Article 3

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

The Commission shall adopt the measures referred to in Article 8a(5) of Regulation (EC) No 216/2008 as amended by this Regulation before 31 December 2013. Article 8a shall apply as from the dates specified in those measures.

The Commission shall adopt the measures referred to in Article 8b(6) and Article 8c(10) of Regulation (EC) No 216/2008 as amended by this Regulation before 31 December 2012. Articles 8b and 8c shall apply as from the dates specified in those measures.

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

Done at Strasbourg, 21 October 2009.

For the European Parliament
The President
J. BUZEK

For the Council
The President
C. MALMSTRÖM

ANNEX

'ANNEX Va

ESSENTIAL REQUIREMENTS FOR AERODROMES

A — **Physical characteristics, infrastructure and equipment**

1. *Movement area*

(a) Aerodromes shall have a designated area for the landing and take-off of aircraft, which satisfies the following conditions:

(i) the landing and take-off area shall have dimensions and characteristics suitable for the aircraft intended to use the facility;

(ii) the landing and take-off area, where applicable, shall have a bearing strength sufficient to support repetitive operations of the intended aircraft. Those areas not intended for repetitive operations only need to be capable of supporting the aircraft;

(iii) the landing and take-off area shall be designed to drain water and to prevent standing water becoming an unacceptable risk to aircraft operations;

(iv) the slope and slope changes of the landing and take-off area shall not create an unacceptable risk to aircraft operations;

(v) the surface characteristics of the landing and take-off area shall be adequate for use by the intended aircraft; and

(vi) the landing and take-off area shall be free from objects which might create an unacceptable risk to aircraft operations.

(b) Where there are several designated landing and take-off areas, they shall be such that they do not create an unacceptable risk to aircraft operations.

(c) The designated landing and take-off area shall be surrounded by defined areas. These areas are intended to protect aircraft flying over them during take-off or landing operations or to mitigate the consequences of undershooting, running off the side or overrunning the take-off and landing area, and shall satisfy the following conditions:

(i) these areas shall have dimensions appropriate to the aircraft operations anticipated;

(ii) the slope and slope changes of these areas shall not create an unacceptable risk to aircraft operations;

(iii) these areas shall be free from objects which might create an unacceptable risk to aircraft operations. This should not preclude frangible equipment to be located in those areas, if required to assist aircraft operations; and

(iv) each of these areas shall have a bearing strength sufficient to serve its purpose.

(d) Those areas of an aerodrome, with their associated immediate surroundings, that are to be used for taxiing or parking aircraft, shall be designed to permit safe operation of the aircraft expected to use the particular facility under all the conditions planned for, and shall satisfy the following conditions:

(i) these areas shall have a bearing strength sufficient to support repetitive operations of the intended aircraft, except for areas which are expected for only occasional use which only need to be capable of supporting the aircraft;

(ii) these areas shall be designed to drain water and to prevent standing water becoming an unacceptable risk to aircraft operations;

(iii) the slope and slope changes of these areas shall not create an unacceptable risk to aircraft operations;

(iv) the surface characteristics of these areas shall be adequate for use by the intended aircraft; and

(v) these areas shall be free from objects which might create an unacceptable risk to aircraft. This should not preclude parking equipment required for that area in specifically identified positions or zones.

(e) Other infrastructure intended for use by aircraft shall be so designed that use of that infrastructure does not create an unacceptable risk to aircraft using it.

(f) Constructions, buildings, equipment or storage areas shall be located and designed so as not to create an unacceptable risk for aircraft operations.

(g) Suitable means shall be provided to prevent unauthorised persons, unauthorised vehicles or animals large enough to create an unacceptable risk to aircraft operations from entering the movement area, without prejudice to national and international animal protection provisions.

2. *Obstacle clearances*

(a) To protect aircraft proceeding to an aerodrome for landing, or for their departure from an aerodrome, arrival and departure routes or areas shall be established. Such routes or areas shall provide aircraft with the required clearance from obstacles located in the area surrounding the aerodrome taking due account of the local physical characteristics.

(b) Such obstacle clearance shall be appropriate to the phase of flight and type of operation being conducted. It shall also take into account the equipment being used for determining the position of the aircraft.

3. *Visual and non-visual aids and aerodrome equipment*

(a) AIDS shall be fit for purpose, recognisable and provide unambiguous information to users under all intended operational conditions.

(b) Aerodrome equipment shall function as intended under the foreseen operating conditions. Under operating conditions or in case of failure, aerodrome equipment shall not cause an unacceptable risk to aviation safety.

(c) The aids and their electrical power supply system shall be so designed that failures do not result in inappropriate, misleading or insufficient information being given to users or in interruption of an essential service.

(d) Suitable means of protection shall be provided to avoid damage or disturbance to such aids.

(e) Sources of radiation or the presence of moving or fixed objects shall not interfere with or adversely affect the performance of aeronautical communications, navigation and surveillance systems.

(f) Information on operation and use of aerodrome equipment shall be made available to relevant staff, including clear indications of the conditions which may create unacceptable risks to aviation safety.

4. *Aerodrome data*

(a) Data relevant to the aerodrome and the available services shall be established and kept up to date.

(b) The data shall be accurate, readable, complete and unambiguous. Appropriate integrity levels shall be maintained.

(c) The data shall be made available to the users and the relevant ANS providers in a timely manner, using a sufficiently secure and expeditious method of communication.

B — **Operations and management**

1. *The aerodrome operator is responsible for operation of the aerodrome. The responsibilities of the aerodrome operator are as follows:*

(a) the aerodrome operator shall have, directly or under contracts, all the means necessary to ensure safe operation of aircraft at the aerodrome. These means shall include, but are not limited to, facilities, personnel, equipment and material, documentation of tasks, responsibilities and procedures, access to relevant data and record-keeping;

(b) the aerodrome operator shall verify that the requirements of Section A are complied with at all times or take appropriate measures to mitigate the risks associated with non-compliance. Procedures shall be established and applied to make all users aware of such measures in a timely manner;

(c) the aerodrome operator shall establish and implement an appropriate aerodrome wildlife risk management programme;

(d) the aerodrome operator shall ensure that movements of vehicles and persons in the movement area and other operational areas are coordinated with movements of aircraft in order to avoid collisions and damage to aircraft;

(e) the aerodrome operator shall ensure that procedures to mitigate risks related to aerodrome operations in winter operation, adverse weather conditions, reduced visibility or at night, if applicable, are established and implemented;

(f) the aerodrome operator shall establish arrangements with other relevant organisations to ensure continuing compliance with these essential requirements for aerodromes. These organisations include, but are not limited to, aircraft operators, air navigation service providers, ground handling service providers and other organisations whose activities or products may have an effect on aircraft safety;

(g) the aerodrome operator, either by itself or by means of contracts with third parties, shall ensure that procedures exist to provide aircraft with fuel which is uncontaminated and of the correct specification;

(h) manuals for maintenance of aerodrome equipment shall be available, applied in practice and cover maintenance and repair instructions, servicing information, troubleshooting and inspection procedures;

(i) the aerodrome operator shall establish and implement an aerodrome emergency plan, covering emergency scenarios that may occur at the aerodrome or in its surroundings. This plan shall be coordinated, as appropriate, with the local community emergency plan;

(j) the aerodrome operator shall ensure that adequate aerodrome rescue and firefighting services are provided. Such services shall respond to an incident or accident with due urgency and shall include at least equipment, extinguishing agents and a sufficient number of personnel;

(k) the aerodrome operator shall use only trained and qualified personnel for aerodrome operations and maintenance and shall implement and maintain training and check programmes to ensure the continuing competence of all relevant personnel;

(l) the aerodrome operator shall ensure that any person permitted unescorted access to the movement area or other operational areas is adequately trained and qualified for such access;

(m) the rescue and firefighting personnel shall be properly trained and qualified to operate in the aerodrome environment. The aerodrome operator shall implement and maintain training and check programmes to ensure the continuing competence of this personnel; and

(n) all rescue and firefighting personnel potentially required to act in aviation emergencies shall periodically demonstrate their medical fitness to execute their functions satisfactorily, taking into account the type of activity. In this context, medical fitness, comprising both physical and mental fitness, means not suffering from any disease or disability which could make this personnel unable:

(i) to execute the tasks necessary to operate in aviation emergencies;

(ii) to perform their assigned duties at any time; or

(iii) to perceive their environment correctly.

2. *Management systems*

(a) The aerodrome operator shall implement and maintain a management system to ensure compliance with these essential requirements for aerodromes and to aim for continuous and proactive improvement of safety. The management system shall include organisational structures, accountability, responsibilities, policies and procedures.

(b) The management system shall include an accident and incident prevention programme, including an occurrence-reporting and analysis scheme. The analysis shall involve the parties listed in point 1(f) above, as appropriate.

(c) The aerodrome operator shall develop an aerodrome manual and operate in accordance with that manual. Such manuals shall contain all necessary instructions, information and procedures for the aerodrome, the management system and for operations personnel to perform their duties.

C — **Aerodrome surroundings**

1. The airspace around aerodrome movement areas shall be safeguarded from obstacles so as to permit the intended aircraft operations at the aerodromes without creating an unacceptable risk caused by the development of obstacles around the aerodrome. Obstacle monitoring surfaces shall therefore be developed, implemented and continuously monitored to identify any infringing penetration.

(a) Any infringement of these surfaces will require an assessment to identify whether or not the object creates an unacceptable risk. Any object posing an unacceptable risk shall be removed or appropriate mitigating action shall be taken to protect aircraft using the aerodrome.

(b) Any remaining such obstacles shall be published and, depending on the need, shall be marked and, where necessary, made visible by means of lights.

2. Hazards related to human activities and land use, such as, but not limited to, items on the following list, shall be monitored. The risk caused by them shall be assessed and mitigated as appropriate:

(a) any development or change in land use in the aerodrome area;

(b) the possibility of obstacle-induced turbulence;

(c) the use of hazardous, confusing and misleading lights;

(d) the dazzling caused by large and highly reflective surfaces;

(e) the creation of areas that might encourage wildlife activity in the surroundings of the aerodrome movement area;

(f) sources of non-visible radiation or the presence of moving or fixed objects which may interfere with, or adversely affect, the performance of aeronautical communications, navigation and surveillance systems.

3. A local community emergency plan shall be established for aviation emergency situations occurring in the aerodrome local area.

D — **Others**

Except for aircraft emergency situations, when diverting to an alternate aerodrome, or under other conditions specified in each case, an aerodrome or parts thereof shall not be used by aircraft for which the aerodrome design and operating procedures are not normally intended.

ANNEX Vb

ESSENTIAL REQUIREMENTS FOR ATM/ANS AND AIR TRAFFIC CONTROLLERS

1. **Use of the airspace**

(a) All aircraft, excluding those engaged in the activities referred to in Article 1(2)(a), in all phases of flight or on the movement area of an aerodrome, shall be operated in accordance with common general operating rules and any applicable procedure specified for use of that airspace.

(b) All aircraft, excluding those engaged in the activities referred to in Article 1(2)(a), shall be equipped with the required constituents and operated accordingly. Constituents used in the ATM/ANS system shall also comply with the requirements in point 3.

2. **Services**

(a) Aeronautical information and data for airspace users for the purpose of air navigation

(i) The data used as a source for aeronautical information shall be of sufficient quality, complete, current and provided in a timely manner.

(ii) Aeronautical information shall be accurate, complete, current, unambiguous and be of adequate integrity in a suitable format for users.

(iii) The dissemination of such aeronautical information to airspace users shall be timely and use sufficiently reliable and expeditious means of communication protected from interference and corruption.

(b) Meteorological information

(i) The data used as a source for aeronautical meteorological information shall be of sufficient quality, complete and current.

(ii) To the extent possible, aeronautical meteorological information shall be precise, complete, current, be of adequate integrity and unambiguous in order to meet the needs of airspace users.

(iii) The dissemination of such aeronautical meteorological information to airspace users shall be timely and use sufficiently reliable and expeditious means of communication protected from interference and corruption.

(c) Air traffic services

(i) The data used as a source for the provision of air traffic services shall be correct, complete and current.

(ii) Air traffic services shall be sufficiently precise, complete, current, and unambiguous to meet the safety needs of users.

(iii) Automated tools providing information or advice to users shall be properly designed, manufactured and maintained to ensure that they are fit for their intended purpose.

(iv) Air traffic control services and related processes shall provide for adequate separation between aircraft and, where appropriate, assist in protection from obstacles and other airborne hazards and shall ensure prompt and timely coordination with all relevant users and adjacent volumes of airspace.

(v) Communication between air traffic services and aircraft and between relevant air traffic services units shall be timely, clear, correct and unambiguous, protected from interference and commonly understood and, if applicable, acknowledged by all actors involved.

(vi) Means shall be in place to detect possible emergencies and, when appropriate, to initiate effective search and rescue action. Such means shall, as a minimum, comprise appropriate alerting mechanisms, coordination measures and procedures, means and personnel to cover the area of responsibility efficiently.

(d) Communication services

Communication services shall achieve and maintain sufficient performance with regard to their availability, integrity, continuity and timeliness. They shall be expeditious and protected from corruption.

(e) Navigation service

Navigation services shall achieve and maintain a sufficient level of performance with regard to guidance, positioning and, when provided, timing information. The performance criteria include accuracy, integrity, availability and continuity of the service.

(f) Surveillance service

Surveillance services shall determine the respective position of aircraft in the air and of other aircraft and ground vehicles on the aerodrome surface, with sufficient performance with regard to their accuracy, integrity, continuity and probability of detection.

(g) Air traffic flow management

The tactical management of air traffic flows at Community level shall use and provide sufficiently precise and current information of the volume and nature of the planned air traffic affecting service provision and shall coordinate and negotiate re-routing or delaying traffic flows in order to reduce the risk of overloading situations occurring in the air or at the aerodromes.

(h) Airspace management

The designation of specific volumes of airspace for a certain use shall be monitored, coordinated and promulgated in a timely manner in order to reduce the risk of loss of separation between aircraft in all circumstances.

(i) Airspace design

Airspace structures and flight procedures shall be properly designed, surveyed and validated before they can be deployed and used by aircraft.

3. **Systems and constituents**

(a) General

ATM/ANS systems and constituents providing related information to and from the aircraft and on the ground shall be properly designed, manufactured, installed, maintained and operated to ensure that they are fit for their intended purpose.

(b) System and constituent integrity, performance and reliability

The integrity and safety-related performance of systems and constituents whether on aircraft, on the ground or in space, shall be fit for their intended purpose. They shall meet the required level of operational performance for all their foreseeable operating conditions and for their whole operational life.

(c) Design of systems and constituents

(i) Systems and constituents shall be designed to meet applicable safety requirements.

(ii) Systems and constituents, considered collectively, separately and in relation to each other, shall be designed in such a way that an inverse relationship exists between the probability that any failure can result in a total system failure and the severity of its effect on the safety of services.

(iii) Systems and constituents, considered individually and in combination with each other, shall be designed taking into account limitations related to human capabilities and performance.

(iv) Systems and constituents shall be designed in a manner that protects them from unintended harmful interactions with external elements.

(v) Information needed for manufacturing installation, operation and maintenance of the systems and constituents as well as information concerning unsafe conditions shall be provided to personnel in a clear, consistent and unambiguous manner.

(d) Continuing level of service

Safety levels of systems and constituents shall be maintained during service and any modifications to service.

4. **Qualification of air traffic controllers**

(a) General

A person undertaking training as an air traffic controller or as a student air traffic controller, shall be sufficiently mature educationally, physically and mentally to acquire, retain and demonstrate the relevant theoretical knowledge and practical skill.

(b) Theoretical knowledge

(i) An air traffic controller shall acquire and maintain a level of knowledge appropriate to the functions exercised and proportionate to the risks associated with the type of service.

(ii) Acquisition and retention of theoretical knowledge shall be demonstrated by continuous assessment during training, or by appropriate examinations.

(iii) An appropriate level of theoretical knowledge shall be maintained. Compliance shall be demonstrated by regular assessments or examinations. The frequency of examinations shall be proportionate to the level of risk associated with the type of service.

(c) Practical skill

(i) An air traffic controller shall acquire and maintain the practical skills appropriate to exercise his/her functions. Such skills shall be proportionate to the risks associated with the type of service and shall cover at least, if appropriate to the functions exercised, the following items:

i. operational procedures;

ii. task specific aspects;

iii. abnormal and emergency situations; and

iv. human factors.

(ii) An air traffic controller shall demonstrate the ability to perform the associated procedures and tasks with a level of competence appropriate to the functions exercised.

(iii) A satisfactory level of competence in practical skill shall be maintained. Compliance shall be verified by regular assessments. The frequency of these assessments shall be proportionate to the complexity and the level of risk associated with the type of service and the tasks performed.

(d) Language proficiency

(i) An air traffic controller shall demonstrate proficiency to speak and understand English to the extent he/she is able to communicate effectively in voice-only (telephone/radiotelephone) and in face-to-face situations on concrete and work-related topics, including in emergency situations.

(ii) Whenever necessary in a defined volume of airspace for ATS service provision purposes, an air traffic controller shall also have proficiency to speak and understand the national language(s) to the extent described above.

(e) Synthetic training devices (STD)

When an STD is used for practical training on situational awareness and human factors or to demonstrate that skills are acquired or maintained, it shall have a level of performance that allows adequate simulation of the working environment and operational situations appropriate to the training provided.

(f) Training course

(i) Training shall be given by a training course, which may comprise theoretical and practical instruction, including training on an STD, if applicable.

(ii) A course shall be defined and approved for each type of training.

(g) Instructors

(i) Theoretical instruction shall be given by appropriately qualified instructors. They shall:

i. have appropriate knowledge in the field where instruction is to be given; and

ii. have demonstrated the ability to use appropriate instructional techniques.

(ii) Instruction on practical skills shall be given by appropriately qualified instructors, who have the following qualifications:

i. meet the theoretical knowledge and the experience requirements appropriate to the instruction being given;

ii. have demonstrated the ability to instruct and to use appropriate instructional techniques;

iii. have practised instructional techniques in those procedures in which it is intended to provide instruction; and

iv. receive regular refresher training to ensure that the instructional competences are maintained.

(iii) Instructors on practical skills shall also be or have been entitled to act as an air traffic controller.

(h) Assessors

(i) Persons responsible for assessing the skill of air traffic controllers shall:

i. have demonstrated the ability to assess the performance of, and conduct tests and checks on air traffic controllers; and

ii. receive regular refresher training to ensure that the assessment standards are maintained up to date.

(ii) Assessors on practical skills shall also be or have been entitled to act as an air traffic controller in those areas in which assessment is to be made.

(i) Medical fitness of an air traffic controller

(i) Medical criteria

i. All air traffic controllers shall periodically demonstrate medical fitness to satisfactorily execute their functions. Compliance shall be shown by appropriate assessment taking into account the possible mental and physical degradation due to age;

ii. Demonstration of medical fitness, comprising physical and mental fitness, shall include the demonstrated absence of any disease or disability, which makes the person providing an air traffic control (ATC) service unable:

— to execute properly the tasks necessary to provide an ATC service,

— to perform assigned duties at any time, or

— to perceive correctly his/her environment.

(ii) Where medical fitness cannot be fully demonstrated, mitigation measures that provide equivalent safety may be implemented.

5. **Service providers and training organisations**

(a) Service provision shall not be undertaken unless the following conditions are met:

(i) the service provider shall have directly or indirectly through contracts the means necessary for the scale and scope of the service. These means shall comprise but are not limited to the following: systems, facilities, including power supply, management structure, personnel, equipment and its maintenance, documentation of tasks, responsibilities and procedures, access to relevant data and record-keeping;

(ii) the service provider shall develop and keep up-to-date management and operations manuals relating to the provision of its services and operate in accordance with those manuals. Such manuals shall contain all necessary instructions, information and procedures for the operations, the management system and for operations personnel to perform their duties;

(iii) the service provider shall implement and maintain a risk-based management system to ensure compliance with the essential requirements in this Annex and aim for continuous proactive improvement of this system;

(iv) the service provider shall use only suitably qualified and trained personnel and implement and maintain training and checking programmes for the personnel;

(v) the service provider shall establish formal interfaces with all the other contributors to the service provision to ensure compliance with these essential requirements;

(vi) the service provider shall establish and implement a contingency plan covering emergency and abnormal situations that may occur in relation to its services;

(vii) the service provider shall establish and maintain an accident and incident prevention and safety programme including an occurrence reporting and analysis programme, which shall be used by the management system in order to contribute to the aim of continuous improvement of safety; and

(viii) the service provider shall make arrangements to verify that the safety performance requirements of any system and constituent they operate are met at any time.

(b) ATC service provision shall not be undertaken unless the following conditions are met:

(i) the prevention of fatigue of personnel providing an ATC service shall be managed through a rostering system. Such a rostering system needs to address duty periods, duty time and adapted rest periods. Limitations established within the rostering system shall take into account relevant factors contributing to fatigue such as, in particular, sleep deprivation, disruption of circadian cycles, night hours, cumulative duty time for given periods of time and also the sharing of allocated tasks between personnel;

(ii) the prevention of stress of personnel providing an ATC service shall be managed through education and prevention programmes;

(iii) the ATC service provider shall have in place procedures to verify that the cognitive judgement of personnel providing ATC services is not impaired or their medical fitness insufficient;

(iv) the ATC service provider shall take into account operational and technical constraints as well as human factor principles in its planning and operations.

(c) Communication, navigation and/or surveillance service provision shall not be undertaken unless the following condition is met:

The service provider shall keep relevant airspace users and ATS units informed on a timely basis of the operational status (and changes thereof) of their services provided for ATS purposes.

(d) Training organisations

A training organisation providing training for personnel providing an ATC service shall meet the following requirements:

(i) have all the means necessary for the scope of responsibilities associated with their activity. These means comprise, but are not limited to, the following: facilities, personnel, equipment, methodology, documentation of tasks, responsibilities and procedures, access to relevant data and record-keeping;

(ii) implement and maintain a management system relating to safety and the standard of training, and aim for continuous improvement of this system; and

(iii) establish arrangements with other relevant organisations, as necessary, to ensure continuing compliance with these essential requirements.'

DIRECTIVES

DIRECTIVE 2009/128/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 21 October 2009

establishing a framework for Community action to achieve the sustainable use of pesticides

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Having regard to the opinion of the Committee of the Regions [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) In line with Articles 2 and 7 of Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme [4], a common legal framework for achieving a sustainable use of pesticides should be established, taking account of precautionary and preventive approaches.

(2) At present, this Directive should apply to pesticides which are plant protection products. However, it is anticipated that the scope of this Directive will be extended to cover biocidal products.

(3) The measures provided for in this Directive should be complementary to, and not affect, measures laid down in other related Community legislation, in particular Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds [5], Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora [6], 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 policy [7], Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin [8] and Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 on the placing of plant protection products on the market [9]. These measures should also not prejudice voluntary measures in the context of Regulations for Structural Funds or of Council Regulation (EC) No 1698/2005 of 20 September 2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) [10].

(4) Economic instruments can play a crucial role in the achievement of objectives relating to the sustainable use of pesticides. The use of such instruments at the appropriate level should therefore be encouraged while stressing that individual Member States can decide on their use without prejudice to the applicability of the State aid rules.

(5) National Action Plans aimed at setting quantitative objectives, targets, measures, timetables and indicators to reduce risks and impacts of pesticide use on human health and the environment and at encouraging the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides should be used by Member States in order to facilitate the implementation of this Directive. Member States should monitor the use of plant protection products containing active substances of particular concern and

[1] OJ C 161, 13.7.2007, p. 48.
[2] OJ C 146, 30.6.2007, p. 48.
[3] Opinion of the European Parliament of 23 October 2007 (OJ C 263 E, 16.10.2008, p. 158), Council Common Position of 19 May 2008 (OJ C 254 E, 7.10.2008, p. 1) and Position of the European Parliament of 13 January 2009 (not yet published in the Official Journal). Council Decision of 24 September 2009.
[4] OJ L 242, 10.9.2002, p. 1.
[5] OJ L 103, 25.4.1979, p. 1.
[6] OJ L 206, 22.7.1992, p. 7.
[7] OJ L 327, 22.12.2000, p. 1.
[8] OJ L 70, 16.3.2005, p. 1.
[9] See page 1 of this Official Journal.
[10] OJ L 277, 21.10.2005, p. 1.

establish timetables and targets for the reduction of their use, in particular when it is an appropriate means to achieve risk reduction targets. National Action Plans should be coordinated with implementation plans under other relevant Community legislation and could be used for grouping together objectives to be achieved under other Community legislation related to pesticides.

(6) The exchange of information on the objectives and actions Member States lay down in their National Action Plans is a very important element for achieving the objectives of this Directive. Therefore, it is appropriate to request Member States to report regularly to the Commission and to the other Member States, in particular on the implementation and results of their National Action Plans and on their experiences. On the basis of information transmitted by the Member States, the Commission should submit relevant reports to the European Parliament and to the Council, accompanied, if necessary, by appropriate legislative proposals.

(7) For the preparation and modification of National Action Plans, it is appropriate to provide for the application of Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment ([1]).

(8) It is essential that Member States set up systems of both initial and additional training for distributors, advisors and professional users of pesticides and certification systems to record such training so that those who use or will use pesticides are fully aware of the potential risks to human health and the environment and of the appropriate measures to reduce those risks as much as possible. Training activities for professional users may be coordinated with those organised in the framework of Regulation (EC) No 1698/2005.

(9) Sales of pesticides, including Internet sales, are an important element in the distribution chain, where specific advice on safety instructions for human health and the environment should be given to the end user at the time of sale, in particular to professional users. For non-professional users who in general do not have the same level of education and training, recommendations should be given, in particular on safe handling and storage of pesticides as well as on disposal of the packaging.

(10) Considering the possible risks from the use of pesticides, the general public should be better informed of the overall impacts of the use of pesticides through awareness-raising campaigns, information passed on through retailers and other appropriate measures.

([1]) OJ L 156, 25.6.2003, p. 17.

(11) Research programmes aimed at determining the impacts of pesticide use on human health and the environment, including studies on high-risk groups, should be promoted at European and national level.

(12) To the extent that the handling and application of pesticides require the setting of minimum health and safety requirements at the workplace, covering the risks arising from exposure of workers to such products, as well as general and specific preventive measures to reduce those risks, those measures are covered by Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work ([2]) and Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to their exposure to carcinogens or mutagens at work ([3]).

(13) Since Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery ([4]) will provide for rules on the placing on the market of pesticide application equipment ensuring that environmental requirements are met, it is appropriate, in order to minimise the adverse impacts of pesticides on human health and the environment caused by such equipment, to provide for systems for regular technical inspection of pesticide application equipment already in use. Member States should describe in their National Action Plans how they will ensure the implementation of those requirements.

(14) Aerial spraying of pesticides has the potential to cause significant adverse impacts on human health and the environment, in particular from spray drift. Therefore, aerial spraying should generally be prohibited with derogations possible where it represents clear advantages in terms of reduced impacts on human health and the environment in comparison with other spraying methods, or where there are no viable alternatives, provided that the best available technology to reduce drift is used.

(15) The aquatic environment is especially sensitive to pesticides. It is therefore necessary for particular attention to be paid to avoiding pollution of surface water and groundwater by taking appropriate measures, such as the establishment of buffer and safeguard zones or planting hedges along surface waters to reduce exposure of water bodies to spray drift, drain flow and run-off. The dimensions of buffer zones should depend in particular on soil characteristics and pesticide properties, as well as agricultural characteristics of the areas concerned. Use of pesticides in areas for the abstraction of drinking water, on or along transport

([2]) OJ L 131, 5.5.1998, p. 11.
([3]) OJ L 158, 30.4.2004, p. 50.
([4]) OJ L 157, 9.6.2006, p. 24.

routes, such as railway lines, or on sealed or very permeable surfaces can lead to higher risks of pollution of the aquatic environment. In such areas the pesticide use should, therefore, be reduced as far as possible, or eliminated, if appropriate.

(16) Use of pesticides can be particularly dangerous in very sensitive areas, such as Natura 2000 sites protected in accordance with Directives 79/409/EEC and 92/43/EEC. In other places such as public parks and gardens, sports and recreation grounds, school grounds and children's playgrounds, and in the close vicinity of healthcare facilities, the risks from exposure to pesticides are high. In these areas, the use of pesticides should be minimised or prohibited. When pesticides are used, appropriate risk management measures should be established and low-risk pesticides as well as biological control measures should be considered in the first place.

(17) Handling of pesticides, including storage, diluting and mixing the pesticides and cleaning of pesticide application equipment after use, and recovery and disposal of tank mixtures, empty packaging and remnants of pesticides are particularly prone to unwanted exposure of humans and the environment. Therefore, it is appropriate to provide for specific measures addressing those activities as a complement to the measures provided for under Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste [1], and Council Directive 91/689/EEC of 12 December 1991 on hazardous waste [2]. Measures should also encompass non-professional users, since inappropriate handling is very likely to occur in this group of users due to their lack of knowledge.

(18) The application of general principles and crop and sector-specific guidelines with respect to integrated pest management by all farmers would result in a better targeted use of all available pest control measures, including pesticides. Therefore, it would contribute to a further reduction of the risks to human health and the environment and the dependency on the use of pesticides. Member States should promote low pesticide-input pest management, in particular integrated pest management, and establish the necessary conditions and measures for its implementation.

(19) On the basis of Regulation (EC) No 1107/2009 and of this Directive, implementation of the principles of integrated pest management is obligatory and the subsidiarity principle applies to the way the principles for integrated pest management are implemented. Member States should describe in their National Action Plan how they ensure the implementation of the principles of integrated pest management, with priority given wherever possible to non-chemical methods of plant protection and pest and crop management.

(20) It is necessary to measure the progress achieved in the reduction of risks and adverse impacts from pesticide use for human health and the environment. Appropriate means are harmonised risk indicators that will be established at Community level. Member States should use those indicators for risk management at national level and for reporting purposes, while the Commission should calculate indicators to evaluate progress at Community level. Statistical data collected in accordance with the Community legislation concerning statistics on plant protection products should be used. Member States should be entitled to use, in addition to harmonised common indicators, their national indicators.

(21) Member States should determine penalties applicable to infringements of national provisions adopted pursuant to this Directive and ensure that they are implemented. The penalties should be effective, proportionate and dissuasive.

(22) Since the objective of this Directive, namely to protect human health and the environment from possible risks associated with the use of pesticides, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(23) This Directive respects the fundamental rights and observes the principles recognised notably by the Charter of Fundamental Rights of the European Union. In particular, this Directive seeks to promote the integration into Community policies of a high level of environmental protection in accordance with the principle of sustainable development as laid down in Article 37 of that Charter.

(24) The measures necessary for the implementation of this Directive 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 Commission [3].

(25) In particular, the Commission should be empowered to establish and update the Annexes to this Directive. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, inter alia, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

[1] OJ L 114, 27.4.2006, p. 9.
[2] OJ L 377, 31.12.1991, p. 20.
[3] OJ L 184, 17.7.1999, p. 23.

(26) In accordance with point 34 of the Interinstitutional agreement on better law-making [1], Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Directive establishes a framework to achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of integrated pest management and of alternative approaches or techniques such as non-chemical alternatives to pesticides.

Article 2

Scope

1. This Directive shall apply to pesticides that are plant protection products as defined in point 10(a) of Article 3.

2. This Directive shall apply without prejudice to any other relevant Community legislation.

3. The provisions of this Directive shall not prevent Member States from applying the precautionary principle in restricting or prohibiting the use of pesticides in specific circumstances or areas.

Article 3

Definitions

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

1. 'professional user' means any person who uses pesticides in the course of their professional activities, including operators, technicians, employers and self-employed people, both in the farming and other sectors;

2. 'distributor' means any natural or legal person who makes a pesticide available on the market, including wholesalers, retailers, vendors and suppliers;

3. 'advisor' means any person who has acquired adequate knowledge and advises on pest management and the safe use of pesticides, in the context of a professional capacity or commercial service, including private self-employed and public advisory services, commercial agents, food producers and retailers where applicable;

4. 'pesticide application equipment' means any apparatus specifically intended for the application of pesticides, including accessories that are essential for the effective operation of such equipment, such as nozzles, manometers, filters, strainers and cleaning devices for tanks;

5. 'aerial spraying' means application of pesticides from an aircraft (plane or helicopter);

6. 'integrated pest management' means careful consideration of all available plant protection methods and subsequent integration of appropriate measures that discourage the development of populations of harmful organisms and keep the use of plant protection products and other forms of intervention to levels that are economically and ecologically 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;

7. 'risk indicator' means the result of a method of calculation that is used to evaluate risks of pesticides on human health and/or the environment;

8. 'non-chemical methods' means alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques such as those referred to in point 1 of Annex III, or physical, mechanical or biological pest control methods;

9. the terms 'surface water' and 'groundwater' have the same meaning as in Directive 2000/60/EC;

10. 'pesticide' means:

(a) a plant protection product as defined in Regulation (EC) No 1107/2009;

(b) a biocidal product as defined in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing on the market of biocidal products [2].

[1] OJ C 321, 31.12.2003, p. 1.

[2] OJ L 123, 24.4.1998, p. 1.

Article 4

National Action Plans

1. Member States shall adopt National Action Plans to set up their quantitative objectives, targets, measures and timetables to reduce risks and impacts of pesticide use on human health and the environment and to encourage the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides. These targets may cover different areas of concern, for example worker protection, protection of the environment, residues, use of specific techniques or use in specific crops.

The National Action Plans shall also include indicators to monitor the use of plant protection products containing active substances of particular concern, especially if alternatives are available. Member States shall give particular attention to the plant protection products containing active substances approved in accordance with Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant products on the market [1] which, when subject to renewal of approval under Regulation (EC) No 1107/2009 will not fulfil the criteria relevant for approval laid down in Annex II, points 3.6 to 3.8 of that Regulation.

On the basis of such indicators and taking into account where applicable the risk or use reduction targets achieved already prior to the application of this Directive, timetables and targets for the reduction of use shall also be established, in particular if the reduction of use constitutes an appropriate means to achieve risk reduction with regard to priority items identified under Article 15(2)(c). These targets may be intermediate or final. Member States shall use all necessary means designed to achieve these targets.

When drawing up and revising their National Action Plans, Member States shall take account of the health, social, economic and environmental impacts of the measures envisaged, of specific national, regional and local conditions and all relevant stakeholder groups. Member States shall describe in their National Action Plans how they will implement measures pursuant to Articles 5 to 15 in order to achieve the objectives referred to in the first subparagraph of this paragraph.

The National Action Plans shall take into account plans under other Community legislation on the use of pesticides, such as planned measures under Directive 2000/60/EC.

2. By 14 December 2012, Member States shall communicate their National Action Plans to the Commission and to other Member States.

National Action Plans shall be reviewed at least every five years and any substantial changes to National Action Plans shall be reported to the Commission without undue delay.

3. By 14 December 2014, the Commission shall submit to the European Parliament and to the Council a report on the information communicated by the Member States in relation to the National Action Plans. The report shall contain methods used and the implications concerning the establishment of different types of targets to reduce the risks and use of pesticides.

By 14 December 2018, the Commission shall submit to the European Parliament and to the Council a report on the experience gained by Member States on the implementation of national targets established in accordance with paragraph 1 in order to achieve the objectives of this Directive. It may be accompanied, if necessary, by appropriate legislative proposals.

4. The Commission shall make information communicated in accordance with paragraph 2 available to the public on a website.

5. The provisions on public participation laid down in Article 2 of Directive 2003/35/EC shall apply to the preparation and the modification of the National Action Plans.

CHAPTER II

TRAINING, SALES OF PESTICIDES, INFORMATION AND AWARENESS-RAISING

Article 5

Training

1. Member States shall ensure that all professional users, distributors and advisors have access to appropriate training by bodies designated by the competent authorities. This shall consist of both initial and additional training to acquire and update knowledge as appropriate.

The training shall be designed to ensure that such users, distributors and advisors acquire sufficient knowledge regarding the subjects listed in Annex I, taking account of their different roles and responsibilities.

2. By 14 December 2013, Member States shall establish certification systems and designate the competent authorities responsible for their implementation. These certificates shall, as a minimum, provide evidence of sufficient knowledge of the subjects listed in Annex I acquired by professional users, distributors and advisors either by undergoing training or by other means.

[1] OJ L 230, 19.8.1991, p. 1.

Certification systems shall include requirements and procedures for the granting, renewal and withdrawal of certificates.

3. Measures designed to amend non-essential elements of this Directive relating to amending Annex I in order to take account of scientific and technical progress shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(2).

Article 6

Requirements for sales of pesticides

1. Member States shall ensure that distributors have sufficient staff in their employment holding a certificate referred to in Article 5(2). Such persons shall be available at the time of sale to provide adequate information to customers as regards pesticide use, health and environmental risks and safety instructions to manage those risks for the products in question. Micro distributors selling only products for non-professional use may be exempted if they do not offer for sale pesticide formulations classified as toxic, very toxic, carcinogenic, mutagenic or toxic for reproduction pursuant to 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 preparations ([1]).

2. Member States shall take necessary measures to restrict sales of pesticides authorised for professional use to persons holding a certificate referred to in Article 5(2).

3. Member States shall require distributors selling pesticides to non-professional users to provide general information regarding the risks for human health and the environment of pesticide use, in particular on hazards, exposure, proper storage, handling, application and safe disposal in accordance with Community legislation on waste, as well as regarding low-risk alternatives. Member States may require pesticide producers to provide such information.

4. The measures provided for in paragraphs 1 and 2 shall be established by 14 December 2015.

Article 7

Information and awareness-raising

1. Member States shall take measures to inform the general public and to promote and facilitate information and awareness-raising programmes and the availability of accurate and balanced information relating to pesticides for the general public, in particular regarding the risks and the potential acute and chronic effects for human health, non-target organisms and the environment arising from their use, and the use of non-chemical alternatives.

2. Member States shall put in place systems for gathering information on pesticide acute poisoning incidents, as well as chronic poisoning developments where available, among groups that may be exposed regularly to pesticides such as operators, agricultural workers or persons living close to pesticide application areas.

3. To enhance the comparability of information, the Commission, in cooperation with the Member States, shall develop by 14 December 2012 a strategic guidance document on monitoring and surveying of impacts of pesticide use on human health and the environment.

CHAPTER III

PESTICIDE APPLICATION EQUIPMENT

Article 8

Inspection of equipment in use

1. Member States shall ensure that pesticide application equipment in professional use shall be subject to inspections at regular intervals. The interval between inspections shall not exceed five years until 2020 and shall not exceed three years thereafter.

2. By 14 December 2016, Member States shall ensure that pesticide application equipment has been inspected at least once. After this date only pesticide application equipment having successfully passed inspection shall be in professional use.

New equipment shall be inspected at least once within a period of five years after purchase.

3. By way of derogation from paragraphs 1 and 2 and, following a risk assessment for human health and the environment including an assessment of the scale of the use of the equipment, Member States may:

(a) apply different timetables and inspection intervals to pesticide application equipment not used for spraying pesticides, to handheld pesticide application equipment or knapsack sprayers and to additional pesticide application equipment that represent a very low scale of use, which shall be listed in the National Action Plans provided for in Article 4.

The following additional pesticide application equipment shall never be considered as constituting a very low scale of use:

(i) spraying equipment mounted on trains or aircraft;

([1]) OJ L 200, 30.7.1999, p. 1.

(ii) boom sprayers larger than 3 m, including boom sprayers that are mounted on sowing equipment;

(b) exempt from inspection handheld pesticide application equipment or knapsack sprayers. In this case the Member States shall ensure that operators have been informed of the need to change regularly the accessories, of the specific risks linked to that equipment, and that operators are trained for the proper use of that application equipment in accordance with Article 5.

4. The inspections shall verify that pesticide application equipment satisfies the relevant requirements listed in Annex II, in order to achieve a high level of protection for human health and the environment.

Pesticide application equipment complying with harmonised standards developed in accordance with Article 20(1) shall be presumed to comply with the essential health and safety and environmental requirements.

5. Professional users shall conduct regular calibrations and technical checks of the pesticide application equipment in accordance with the appropriate training received as provided for in Article 5.

6. Member States shall designate bodies responsible for implementing the inspection systems and inform the Commission thereof.

Each Member State shall establish certificate systems designed to allow the verification of inspections and recognise the certificates granted in other Member States following the requirements referred to in paragraph 4 and where the time period since the last inspection carried out in another Member State is equal to or shorter than the time period of the inspection interval applicable in its own territory.

Member States shall endeavour to recognise the certificates issued in other Member States provided that the inspection intervals referred to in paragraph 1 are complied with.

7. Measures designed to amend non-essential elements of this Directive relating to amending Annex II in order to take account of scientific and technical progress shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(2).

CHAPTER IV

SPECIFIC PRACTICES AND USES

Article 9

Aerial spraying

1. Member States shall ensure that aerial spraying is prohibited.

2. By way of derogation from paragraph 1 aerial spraying may only be allowed in special cases provided the following conditions are met:

(a) there must be no viable alternatives, or there must be clear advantages in terms of reduced impacts on human health and the environment as compared with land-based application of pesticides;

(b) the pesticides used must be explicitly approved for aerial spraying by the Member State following a specific assessment addressing risks from aerial spraying;

(c) the operator carrying out the aerial spraying must hold a certificate as referred to in Article 5(2). During the transitional period where certification systems are not yet in place, Member States may accept other evidence of sufficient knowledge;

(d) the enterprise responsible for providing aerial spray applications shall be certified by a competent authority for authorising equipment and aircraft for aerial application of pesticides;

(e) if the area to be sprayed is in close proximity to areas open to the public, specific risk management measures to ensure that there are no adverse effects on the health of bystanders shall be included in the approval. The area to be sprayed shall not be in close proximity to residential areas;

(f) as from 2013, the aircraft shall be equipped with accessories that constitute the best available technology to reduce spray drift.

3. Member States shall designate the authorities competent for establishing the specific conditions by which aerial spraying may be carried out, for examining requests pursuant to paragraph 4 and for making public information on crops, areas, circumstances and particular requirements for application including weather conditions where aerial spraying may be allowed.

In the approval the competent authorities shall specify the measures necessary for warning residents and bystanders in due time and to protect the environment in the vicinity of the area sprayed.

4. A professional user wishing to apply pesticides by aerial spraying shall submit a request for approval of an application plan to the competent authority accompanied by evidence to show that the conditions referred to in paragraphs 2 and 3 are fulfilled. The request for application of aerial spraying in accordance with the approved application plan shall be submitted in due time to the competent authority. It shall contain information about the provisional time of spraying and the amounts and the type of pesticides applied.

Member States may provide that requests for applications of aerial spraying in accordance with an approved application plan, for which no answer was received on the decision taken within the time period laid down by the competent authorities, shall be deemed to be approved.

In particular circumstances such as emergency or specific difficult situations, single requests for application of aerial spraying may also be submitted for approval. Where justified, competent authorities shall have a possibility to apply an accelerated procedure in order to verify that the conditions referred to in paragraphs 2 and 3 are fulfilled before the application of aerial spraying.

5. Member States shall ensure that the conditions referred to in paragraphs 2 and 3 are met by conducting appropriate monitoring.

6. The competent authorities shall keep records of the requests and approvals as referred to in paragraph 4 and shall make available to the public the relevant information contained therein such as the area to be sprayed, the provisional day and time of the spraying and the type of pesticide, in accordance with the applicable national or Community law.

Article 10

Information to the public

Member States may include in their National Action Plans provisions on informing persons who could be exposed to the spray drift.

Article 11

Specific measures to protect the aquatic environment and drinking water

1. Member States shall ensure that appropriate measures to protect the aquatic environment and drinking water supplies from the impact of pesticides are adopted. Those measures shall support and be compatible with relevant provisions of Directive 2000/60/EC and Regulation (EC) No 1107/2009.

2. The measures provided in paragraph 1 shall include:

(a) giving preference to pesticides that are not classified as dangerous for the aquatic environment pursuant to Directive 1999/45/EC nor containing priority hazardous substances as set out in Article 16(3) of Directive 2000/60/EC;

(b) giving preference to the most efficient application techniques such as the use of low-drift pesticide application equipment especially in vertical crops such as hops and those found in orchards and vineyards;

(c) use of mitigation measures which minimise the risk of off-site pollution caused by spray drift, drain-flow and run-off. These shall include the establishment of appropriately-sized buffer zones for the protection of non-target aquatic organisms and safeguard zones for surface and groundwater used for the abstraction of drinking water, where pesticides must not be used or stored;

(d) reducing as far as possible or eliminating applications on or along roads, railway lines, very permeable surfaces or other infrastructure close to surface water or groundwater or on sealed surfaces with a high risk of run-off into surface water or sewage systems.

Article 12

Reduction of pesticide use or risks in specific areas

Member States shall, having due regard for the necessary hygiene and public health requirements and biodiversity, or the results of relevant risk assessments, ensure that the use of pesticides is minimised or prohibited in certain specific areas. Appropriate risk management measures shall be taken and the use of low-risk plant protection products as defined in Regulation (EC) No 1107/2009 and biological control measures shall be considered in the first place. The specific areas in question are:

(a) areas used by the general public or by vulnerable groups as defined in Article 3 of Regulation (EC) No 1107/2009, such as public parks and gardens, sports and recreation grounds, school grounds and children's playgrounds and in the close vicinity of healthcare facilities;

(b) protected areas as defined in Directive 2000/60/EC or other areas identified for the purposes of establishing the necessary conservation measures in accordance with the provisions of Directives 79/409/EEC and 92/43/EEC;

(c) recently treated areas used by or accessible to agricultural workers.

Article 13

Handling and storage of pesticides and treatment of their packaging and remnants

1. Member States shall adopt the necessary measures to ensure that the following operations by professional users and where applicable by distributors do not endanger human health or the environment:

(a) storage, handling, dilution and mixing of pesticides before application;

(b) handling of packaging and remnants of pesticides;

(c) disposal of tank mixtures remaining after application;

(d) cleaning of the equipment used after application;

(e) recovery or disposal of pesticide remnants and their packaging in accordance with Community legislation on waste.

2. Member States shall take all necessary measures regarding pesticides authorised for non-professional users to avoid dangerous handling operations. These measures may include use of pesticides of low toxicity, ready to use formulations and limits on sizes of containers or packaging.

3. Member States shall ensure that storage areas for pesticides for professional use are constructed in such a way as to prevent unwanted releases. Particular attention shall be paid to location, size and construction materials.

Article 14

Integrated pest management

1. Member States shall take all necessary measures to promote low pesticide-input pest management, giving wherever possible priority to non-chemical methods, so that professional users of pesticides switch to practices and products with the lowest risk to human health and the environment among those available for the same pest problem. Low pesticide-input pest management includes integrated pest management as well as organic farming according to Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products ([1]).

([1]) OJ L 189, 20.7.2007, p. 1.

2. Member States shall establish or support the establishment of necessary conditions for the implementation of integrated pest management. In particular, they shall ensure that professional users have at their disposal information and tools for pest monitoring and decision making, as well as advisory services on integrated pest management.

3. By 30 June 2013, Member States shall report to the Commission on the implementation of paragraphs 1 and 2 and, in particular, whether the necessary conditions for implementation of integrated pest management are in place.

4. Member States shall describe in their National Action Plans how they ensure that the general principles of integrated pest management as set out in Annex III are implemented by all professional users by 1 January 2014.

Measures designed to amend non-essential elements of this Directive relating to amending Annex III in order to take account of scientific and technical progress shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(2).

5. Member States shall establish appropriate incentives to encourage professional users to implement crop or sector-specific guidelines for integrated pest management on a voluntary basis. Public authorities and/or organisations representing particular professional users may draw up such guidelines. Member States shall refer to those guidelines that they consider relevant and appropriate in their National Action Plans.

CHAPTER V

INDICATORS, REPORTING AND INFORMATION EXCHANGE

Article 15

Indicators

1. Harmonised risk indicators as referred to in Annex IV shall be established. However, Member States may continue to use existing national indicators or adopt other appropriate indicators in addition to the harmonised ones.

Measures designed to amend non-essential elements of this Directive relating to amending Annex IV in order to take account of scientific and technical progress shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 21(2).

2. Member States shall:

(a) calculate harmonised risk indicators as referred to in paragraph 1 by using statistical data collected in accordance with the Community legislation concerning statistics on plant protection products together with other relevant data;

(b) identify trends in the use of certain active substances;

(c) identify priority items, such as active substances, crops, regions or practices, that require particular attention or good practices that can be used as examples in order to achieve the objectives of this Directive to reduce the risks and impacts of pesticide use on human health and the environment and to encourage the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides.

3. Member States shall communicate the results of the evaluations carried out pursuant to paragraph 2 to the Commission and to other Member States and shall make this information available to the public.

4. The Commission shall calculate risk indicators at Community level by using statistical data collected in accordance with the Community legislation concerning statistics on plant protection products and other relevant data, in order to estimate trends in risks from pesticide use.

The Commission shall also use these data and this information to assess progress in achieving the objectives of other Community policies aimed at reducing the impact of pesticides on human health and on the environment.

The results shall be made available to the public on the website referred to in Article 4(4).

Article 16

Reporting

The Commission shall regularly submit to the European Parliament and to the Council a report on progress in the implementation of this Directive, accompanied where appropriate by proposals for amendments.

CHAPTER VI

FINAL PROVISIONS

Article 17

Penalties

Member States shall determine penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.

Member States shall notify those provisions to the Commission by 14 December 2012 and shall notify it without delay of any subsequent amendment.

Article 18

Exchange of information and best practice

The Commission shall put forward as a priority for discussion in the expert group on the thematic strategy on the sustainable use of pesticides the exchange of information and best practice in the field of sustainable use of pesticides and integrated pest management.

Article 19

Fees and charges

1. Member States may recover the costs associated with any work pursuant to obligations under this Directive by means of a fee or charge.

2. Member States shall ensure that the fee or charge referred to in paragraph 1 is established in a transparent manner and corresponds to the actual cost of the work involved.

Article 20

Standardisation

1. The standards referred to in Article 8(4) of this Directive shall be established in accordance with the procedure provided for in Article 6(3) of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services [1].

The request for developing these standards may be established in consultation with the Committee referred to in Article 21(1).

2. The Commission shall publish the references of the standards in the *Official Journal of the European Union*.

[1] OJ L 204, 21.7.1998, p. 37.

3. When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in Annex II, the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall, having consulted the relevant European standardisation bodies, deliver its opinion without delay.

In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the *Official Journal of the European Union*.

The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

Article 21

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1].

2. 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.

Article 22

Expenditure

In order to support the establishment of a harmonised policy and systems in the field of sustainable use of pesticides, the Commission may finance:

(a) the development of a harmonised system including an appropriate database to gather and store all information relating to pesticide risk indicators, and to make such information available to the competent authorities, other interested parties and the general public;

(b) the performance of studies necessary for the preparation and development of legislation, including the adaptation of the Annexes to this Directive to technical progress;

(c) the development of guidance and best practices to facilitate the implementation of this Directive.

Article 23

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 14 December 2011.

When Member States adopt these measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The method of making such reference shall be laid down by Member States.

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

Article 24

Entry into force

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

Article 25

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 21 October 2009.

For the European Parliament	*For the Council*
The President	*The President*
J. BUZEK	C. MALMSTRÖM

[1] OJ L 31, 1.2.2002, p. 1.

ANNEX I

Training subjects referred to in Article 5

1. All relevant legislation regarding pesticides and their use.

2. The existence and risks of illegal (counterfeit) plant protection products, and the methods to identify such products.

3. The hazards and risks associated with pesticides, and how to identify and control them, in particular:

   (a) risks to humans (operators, residents, bystanders, people entering treated areas and those handling or eating treated items) and how factors such as smoking exacerbate these risks;

   (b) symptoms of pesticide poisoning and first aid measures;

   (c) risks to non-target plants, beneficial insects, wildlife, biodiversity and the environment in general.

4. Notions on integrated pest management strategies and techniques, integrated crop management strategies and techniques, organic farming principles, biological pest control methods, information on the general principles and crop or sector-specific guidelines for integrated pest management.

5. Initiation to comparative assessment at user level to help professional users make the most appropriate choices on pesticides with the least side effects on human health, non-target organisms and the environment among all authorised products for a given pest problem, in a given situation.

6. Measures to minimise risks to humans, non-target organisms and the environment: safe working practices for storing, handling and mixing pesticides, and disposing of empty packaging, other contaminated materials and surplus pesticides (including tank mixes), whether in concentrate or dilute form; recommended way to control operator exposure (personal protection equipment).

7. Risk-based approaches which take into account the local water extraction variables such as climate, soil and crop types, and relieves.

8. Procedures for preparing pesticide application equipment for work, including its calibration, and for its operation with minimum risks to the user, other humans, non-target animal and plant species, biodiversity and the environment, including water resources.

9. Use of pesticide application equipment and its maintenance, and specific spraying techniques (e.g. low-volume spraying and low-drift nozzles), as well as the objectives of the technical check of sprayers in use and ways to improve spray quality. Specific risks linked to use of handheld pesticide application equipment or knapsack sprayers and the relevant risk management measures.

10. Emergency action to protect human health, the environment including water resources in case of accidental spillage and contamination and extreme weather events that would result in pesticide leaching risks.

11. Special care in protection areas established under Articles 6 and 7 of Directive 2000/60/EC.

12. Health monitoring and access facilities to report on any incidents or suspected incidents.

13. Record keeping of any use of pesticides, in accordance with the relevant legislation.

ANNEX II

Health and safety and environmental requirements relating to the inspection of pesticide application equipment

The inspection of pesticide application equipment shall cover all aspects important to achieve a high level of safety and protection of human health and the environment. Full effectiveness of the application operation should be ensured by proper performance of devices and functions of the equipment to guarantee the following objectives are met.

The pesticide application equipment must function reliably and be used properly for its intended purpose ensuring that pesticides can be accurately dosed and distributed. The equipment must be in such a condition as to be filled and emptied safely, easily and completely and prevent leakage of pesticides. It must permit easy and thorough cleaning. It must also ensure safe operations, and be controlled and capable of being immediately stopped from the operator's seat. Where necessary, adjustments must be simple, accurate and capable of being reproduced.

Particular attention should be paid to:

1. Power transmission parts

   The power take-off driveshaft guard and the guard of the power input connection shall be fitted and in good condition and the protective devices and any moving or rotating power transmission parts shall not be affected in their function so as to ensure protection of the operator.

2. Pump

   The pump capacity shall be suited to the needs of the equipment and the pump must function properly in order to ensure a stable and reliable application rate. There shall be no leakages from the pump.

3. Agitation

   Agitation devices must ensure a proper recirculation in order to achieve an even concentration of the whole volume of the liquid spray mixture in the tank.

4. Spray liquid tank

   Spray tanks including indicator of tank content, filling devices, strainers and filters, emptying and rinsing systems, and mixing devices shall operate in such a way as to minimise accidental spillage, uneven concentration distribution, operator exposure and residual content.

5. Measuring systems, control and regulation systems

   All devices for measuring, switching on and off and adjusting pressure and/or flow rate shall be properly calibrated and work correctly and there shall be no leakages. Control of pressure and operation of pressure adjustment devices shall be easily possible during application. Pressure adjustment devices shall maintain a constant working pressure at constant revolutions of the pump, in order to ensure that a stable volume application rate is applied.

6. Pipes and hoses

   Pipes and hoses shall be in proper condition to avoid disturbance of liquid flow or accidental spillage in case of failure. There shall be no leakages from pipes or hoses when run with the maximum obtainable pressure for the system.

7. Filtering

   In order to avoid turbulence and heterogeneity in spray patterns, filters shall be in good condition and the mesh size of the filters shall correspond to the size of nozzles fitted on the sprayer. Where applicable the filter blockage indication system shall operate correctly.

8. Spray boom (for equipment spraying pesticides by means of a horizontally positioned boom, located close to the crop or the material to be treated).

   The spray boom must be in good condition and stable in all directions. The fixation and adjustment systems and the devices for damping unintended movements and slope compensation must work correctly.

9. Nozzles

   Nozzles must work properly to control dripping when spraying stops. To ensure homogeneity of the spray pattern, the flow rate of each individual nozzle shall not deviate significantly from the data of the flow rate tables provided by the manufacturer.

10. Distribution

The transverse and vertical (in case of applications in vertical crops) distribution of the spray mixture in the target area must be even, where relevant.

11. Blower (for equipment distributing pesticides by air assistance)

The blower must be in good condition and must ensure a stable and reliable air stream.

ANNEX III

General principles of integrated pest management

1. The prevention and/or suppression of harmful organisms should be achieved or supported among other options especially by:

   — crop rotation,

   — use of adequate cultivation techniques (e.g. stale seedbed technique, sowing dates and densities, under-sowing, conservation tillage, pruning and direct sowing),

   — use, where appropriate, of resistant/tolerant cultivars and standard/certified seed and planting material,

   — use of balanced fertilisation, liming and irrigation/drainage practices,

   — preventing the spreading of harmful organisms by hygiene measures (e.g. by regular cleansing of machinery and equipment),

   — protection and enhancement of important beneficial organisms, e.g. by adequate plant protection measures or the utilisation of ecological infrastructures inside and outside production sites.

2. Harmful organisms must be monitored by adequate methods and tools, where available. Such adequate tools should include observations in the field as well as scientifically sound warning, forecasting and early diagnosis systems, where feasible, as well as the use of advice from professionally qualified advisors.

3. Based on the results of the monitoring the professional user has to decide whether and when to apply plant protection measures. Robust and scientifically sound threshold values are essential components for decision making. For harmful organisms threshold levels defined for the region, specific areas, crops and particular climatic conditions must be taken into account before treatments, where feasible.

4. Sustainable biological, physical and other non-chemical methods must be preferred to chemical methods if they provide satisfactory pest control.

5. The pesticides applied shall be as specific as possible for the target and shall have the least side effects on human health, non-target organisms and the environment.

6. The professional user should keep the use of pesticides and other forms of intervention to levels that are necessary, e.g. by reduced doses, reduced application frequency or partial applications, considering that the level of risk in vegetation is acceptable and they do not increase the risk for development of resistance in populations of harmful organisms.

7. Where the risk of resistance against a plant protection measure is known and where the level of harmful organisms requires repeated application of pesticides to the crops, available anti-resistance strategies should be applied to maintain the effectiveness of the products. This may include the use of multiple pesticides with different modes of action.

8. Based on the records on the use of pesticides and on the monitoring of harmful organisms the professional user should check the success of the applied plant protection measures.

ANNEX IV

Harmonised risk indicators

CORRIGENDA

Corrigendum to Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I)

(Official Journal of the European Union L 177 of 4 July 2008)

On page 16, Article 28, 'Application in time':

for: 'This Regulation shall apply to contracts concluded after 17 December 2009.',

read: 'This Regulation shall apply to contracts concluded as from 17 December 2009.'.

Corrigendum to Regulation (EC) No 715/2009 of the European Parliament and of the Council of 13 July 2009 on conditions for access to the natural gas transmission networks and repealing Regulation (EC) No 1775/2005

(Official Journal of the European Union L 211 of 14 August 2009)

On page 49, Article 27(1), last sentence:

for: 'They shall notify the Commission of those rules not corresponding to the provisions laid down in Regulation (EC) No 1775/2005 by 3 September 2009 and shall notify the Commission without delay of any subsequent amendment affecting them.',

read: 'They shall notify the Commission of those rules not corresponding to the provisions laid down in Regulation (EC) No 1775/2005 by 3 March 2011 and shall notify the Commission without delay of any subsequent amendment affecting them.'.

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