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***II
RECOMMENDATION FOR SECOND READING

on the Council common position for adopting a regulation of the European Parliament and of the Council on the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (11119/8/2008 – C6-0326/2008 – 2006/0136(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Hiltrud Breyer

PR_COD_2am

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics*.** In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council common position for adopting a regulation of the European Parliament and of the Council on the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
(11119/8/2008 – C6-0326/2008 – 2006/0136(COD))

(Codecision procedure: second reading)

The European Parliament,

– having regard to the Council common position (11119/8/2008 – C6-0326/2008),

– having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(2006)0388),

– having regard to the amended Commission proposal (COM(2008)0093),

– having regard to Article 251(2) of the EC Treaty,

– having regard to Rule 62 of its Rules of Procedure,

– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A6-0444/2008),

1. Approves the common position as amended;

2. Instructs its President to forward its position to the Council and Commission.

Amendment 1

Council common position
Citation 1

Council common position	*Amendment*
Having regard to the Treaty establishing the European Community, and in particular ***Articles 37(2) and 95*** thereof,	Having regard to the Treaty establishing the European Community, and in particular ***Articles 152(4)(b) and 175(1)*** thereof,

Justification

According to Recital 8 of the Commission proposal, the purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment. The

[1] Texts adopted, 23.10.2007, P6_TA(2007)0445.

choice of the legal basis should reflect the aim and the purpose of the regulation. A dual legal basis shall be used only if several objectives are pursued, which are inseparably linked, which is the case in the present proposal.
Article 37 was used in 1991, when the Treaty did not yet provide for a specific legal basis for protection of human health and the environment. It is not anymore appropriate to be used here.

Reinstating first reading Amendment 1.

Amendment 2

Council common position
Recital 10 a (new)

Council common position	*Amendment*
	(10a) To apply the 'polluter pays' principle, the Commission should examine how manufacturers of plant protection products or of the active substances they contain should be appropriately involved in dealing with or rectifying harm to human health or to the environment which may result from the use of plant protection products.

Justification

Reinstating first reading Amendment 8.

Amendment 3

Council common position
Recital 10 b (new)

Council common position	*Amendment*
	(10b) In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation should be undertaken only as a last resort. This Regulation, and the legislation establishing data requirements for active substances, plant protection products, safeners and synergists, should ensure that testing on vertebrate animals is

minimised and that double testing is avoided, and promote the use of non-animal test methods and intelligent testing strategies. Existing results from tests on vertebrate animals should be shared in the process of developing new plant protection products. 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[1], tests on vertebrate animals must also be replaced, restricted or refined. Implementation of this Regulation should where possible be based on the use of appropriate alternative testing methods. Not later than ...*, the Commission should review the rules on the data protection of results from tests on vertebrate animals and where necessary change those rules.

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

**** Seven years after the entry into force of this Regulation.***

Justification

In line with the requirement in the Protocol on the Protection and Welfare of Animals that the Community and the Member States pay full regard to the welfare requirements of animals in formulating and implementing policies, it should be included that animal testing is kept to an absolute minimum and carried out only as a last resort, and that the use of alternatives is promoted. This is also in line with the requirements under REACH.

Reinstating first reading Amendment 6.

Amendment 4

Council common position
Recital 10 c (new)

Council common position	*Amendment*
	(10c) The development of non-animal in vitro (test tube) test methods should be

	promoted in order to produce safety data more relevant to humans than results of animal studies currently in use.

Justification

The vast majority of animal test methods have never been validated to modern standards, and in many cases their relevance and reliability are in doubt. The promotion of non animal test methods is important for the protection of human health, as well as to prevent animal suffering.

Reinstating first reading Amendment 9.

Amendment 5

Council common position
Recital 14

Council common position	*Amendment*
(14) In the interest of safety, the approval period for active substances should be limited in time. The approval period should be proportional to the possible risks inherent in the use of such substances. Experience gained from the actual use of plant protection products containing the substances concerned and any developments in science and technology should be taken into account when any decision regarding the renewal of an approval is taken.	(14) In the interest of safety, the approval period for active substances should be limited in time. The approval period should be proportional to the possible risks inherent in the use of such substances. Experience gained from the actual use of plant protection products containing the substances concerned and any developments in science and technology should be taken into account when any decision regarding the renewal of an approval is taken. ***After the first renewal, a regular review of substances should take place.***

Justification

Reinstating first reading Amendment 10 with the first 4 words being the Commission's original text.

Amendment 6

Council common position
Recital 15

Council common position	*Amendment*
(15) The possibility of amending or withdrawing the approval of an active substance in cases where the criteria for approval are no longer satisfied should be provided for.	(15) 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[1] and its daughter directives may be compromised,*** should be provided for. ***[1] OJ L 327, 22.12.2000, p. 1.***

Justification

Directive 2000/60/EC sets quality standards for chemicals in groundwater and surface water, among them plant protection products. If these quality standards are not met, there must be a direct feedback-mechanism to amend or withdraw the approval of an active substance, in line with the existing feedback-mechanism to Directive 2000/60/EC in the authorisation of chemicals (REACH).

Reinstating first reading Amendment 11.

Amendment 7

Council common position
Recital 18

Council common position	*Amendment*
(18) Some active substances ***may only be acceptable when extensive risk mitigation measures are taken. Such substances*** should be identified at Community level as candidates for substitution. Member States should ***regularly re-examine whether*** plant protection products containing such ***active*** substances ***can be replaced*** by plant protection products containing active substances which require less risk	(18) 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 substances with ***the aim of replacing them*** by plant protection products containing active substances which require ***significantly*** less ***or no*** risk mitigation ***or by alternative non-***

mitigation.	***chemical agricultural practices and methods of crop protection**. **After a positive check, such active substances should be replaced swiftly..***

Justification

Reinstating first reading Amendment 14.

Amendment 8

Council common position
Recital 19 a (new)

Council common position	*Amendment*
	(19a) To encourage the development of plant protection products, incentives should be established for placing on the market products with a low risk profile or a risk profile that is lower than that of products already on the market. Clear and objective criteria must be laid down to define which products may claim such a profile.

Justification

The proposal does include incentives for the use of products with a low risk profile. But the definition does not say which substances should be eligible. Article 22 comes up with a very broad definition that is likely to be interpreted in a number of different ways. But businesses need clarity and legal certainty, especially in view of the costly investment in research that is involved in developing new substances.

Reinstating first reading Amendment 12.

Amendment 9

Council common position
Recital 20

Council common position	*Amendment*
(20) In addition to active substances, plant protection products may contain safeners or synergists for which similar ***rules*** should	(20) In addition to active substances, plant protection products may contain safeners or synergists for which similar ***legislation***

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 provisions have been established.	should be provided. The ***provisions*** necessary for the review of such substances should be established ***on the basis of a legislative proposal from the Commission***. Substances currently on the market should only be reviewed after those provisions have been established.

Justification

Consistent with the change proposed by the rapporteur in Article 26 to adopt this review in co-decision.

Reinstatement of first reading Amendment 16.

Amendment 10

Council common position
Recital 26 b (new)

Council common position	*Amendment*
	(26b) Good administrative cooperation between Member States should be increased during all steps of the authorisation procedure and should be facilitated by a European helpdesk.

Justification

Instead of compulsory mutual recognition in a zonal approach, emphasis should be put on sharing of data between Member States, avoiding duplicate testing and generally improved cooperation between the competent authorities. The Commission could facilitate such co-operation by establishing a Help-Desk unit.

Reinstating first reading Amendment 295.

Amendment 11

Council common position
Recital 27

Council common position	*Amendment*
(27) The principle of mutual recognition is one of the means of ensuring the free movement of goods within the	(27) 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 a Member State might require that, on application, Member States*** recognise an authorisation issued by another Member State, amend it or refrain from authorising the plant protection product in their territory, if justified because of specific agricultural circumstances or if the high level of protection of ***both*** human ***and*** animal health ***and*** the environment set out in this Regulation *can not* be achieved.

Community. To avoid ***unnecessary*** duplication of work, to reduce the administrative burden for industry and for Member States and to ***facilitate*** more harmonised availability of plant protection products, authorisations granted by one Member State should be ***notified to*** other Member States ***in which the applicant wishes to put the product on the market***. ***Those Member States should be entitled to*** recognise an authorisation issued by another Member State, amend it or refrain from authorising the plant protection product in their territory, if justified because of specific agricultural ***or environmental*** circumstances ***that may be, but do not need to be, limited to that Member State,*** or if the high level of protection of human ***or*** animal health ***or*** the environment set out in this Regulation *cannot* be achieved, ***or to maintain a higher protection level in their territory in line with their national action plan to reduce the risks associated with, and dependence on, the use of pesticides, adopted in accordance with Directive 2008/.../EC of the European Parliament and of the Council of ... [establishing a framework for Community action to achieve a sustainable use of pesticides][1].***

[1] OJ

Justification

The division into authorization zones is not appropriate as conditions in the proposed zones are often not comparable. While harmonization of the procedures is desirable, it must not come at the expense political sovereignty of Member States. Member States should be entitled to decide within a clear time period whether they confirm, amend or reject an authorization pursuant to their national situation. The discretion given to Member States in the Common Position is so restrictive that it is virtually non-existent, and hence needs to be broadened.

Reinstating first reading Amendment 19. Replaces amendment 16 by the rapporteur.

Amendment 12

Council common position
Recital 30

Council common position	*Amendment*
(30) 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 which cannot be ***combatted*** by any other means. Such authorisations should be reviewed at Community level.	(30) In exceptional cases, ***it*** should be permitted to authorise plant protection products not complying with the conditions provided for in this Regulation, where it is necessary to do so because of a danger or threat to plant production ***and ecosystems*** which cannot be ***contained*** by any other means. Such ***temporary*** authorisations should be reviewed at Community level.

Justification

.Reinstatement of first reading Amendment 20.

Amendment 13

Council common position
Recital 33

Council common position	*Amendment*
(33) In order to ensure a high level of protection of human health and the environment, plant protection products should be used properly having regard to the principles of integrated pest management. The Council should include in the statutory management requirement referred to in 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 the principles of integrated pest management, including good plant protection practice.	(33) In order to ensure a high level of protection of human 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 of*** 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 the principles of integrated pest management, including good plant protection practice ***and non-chemical***

methods of plant protection and pest and crop management. A transitional period should therefore be provided for to allow Member States to put in place the necessary structures to enable users of plant protection products to apply the principles of integrated pest management and non-chemical alternatives to plant protection and pest and crop management.

Justification

The priority should always be given to non-chemical methods of pest management as the only truly preventative and sustainable solution which is more in line with the objectives for sustainable crop protection, than the reliance on complex chemicals designed to kill plants, insects or other forms of life, which cannot be classified as sustainable. Member States need to promote and encourage the widespread adoption of non-chemical alternatives to plant protection and pest and crop management.

Reinstatement of first reading Amendment 21.

Amendment 14

Council common position
Recital 37

Council common position	*Amendment*
(37) Studies represent a major investment. This investment should be protected in order to stimulate research. For this reason, studies lodged by one applicant with a Member State should be protected against use by another applicant. This protection should, however, be limited in time in order to allow competition. It should also be limited to studies which are genuinely necessary for regulatory purposes, to avoid applicants artificially extending the period of protection by submitting new studies which are not necessary.	(37) Studies represent a major investment. This investment should be protected in order to stimulate research. For this reason, studies***, other than those involving tests on vertebrate animals and other studies that may prevent animal testing,*** 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.

Justification

It should be clarified that data protection should be limited also in order to avoid animal testing.

Reinstatement of first reading Amendment 23.

Amendment 15

Council common position
Recital 38

Council common position	*Amendment*
(38) Rules should be laid down to avoid duplication of tests and studies. In particular, repetition of studies involving vertebrates should be prohibited. In this context, there should be an obligation to allow access to studies on vertebrates ***on reasonable terms.*** In order to allow operators to know what studies have been carried out by others, Member States should ***keep a list of*** such studies even where they are not covered by the above system of compulsory access.	(38) Rules should be laid down to avoid duplication of tests and studies. In particular, repetition of studies involving vertebrates should be prohibited. In this context, there should be an obligation to allow access to studies on vertebrates ***and other studies that may prevent animal testing.*** In order to allow operators to know what studies have been carried out by others, Member States should ***forward to the Authority all*** such studies even where they are not covered by the above system of compulsory access***. The Authority should establish a central database for such studies***.

Justification

As other studies than those on vertebrates may also prevent animal testing they should be included here as well.
In order to facilitate data sharing it is necessary to establish one central database with all the information on tests and studies carried out previously for the purposes of this Regulation, managed by the EFSA. Applicants would then have to consult only one database before carrying out any tests or studies.
This would also increase transparency of the procedure.

Reinstatement of first reading Amendment 24.

Amendment 16

Council common position
Recital 41

Council common position	*Amendment*
(41) To ensure that advertisements do not mislead users of plant protection products, it is appropriate to lay down rules on the advertising of those products.	(41) 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.

Justification

Advertisements regarding pesticides and pesticide products must not mislead users or the public.

Reinstating first reading Amendment 26.

Amendment 17

Council common position
Recital 43 a (new)

Council common position	*Amendment*
	(43a) Operators must have the same opportunities in respect of market access, in particular so that small and medium-sized enterprises can operate, in order to ensure that sufficient safe and effective plant protection products are available to farmers.

Justification

There should be a level playing field as regards access to the market for different operators. This would foster innovation and the development of new products, as well as resulting in improvements to existing ones. It will also be good for competition within the market and lead to more products being available to farmers.

Reinstatement of first reading Amendment 29.

Amendment 18

Council common position
Recital 44 a (new)

Council common position	*Amendment*
	(44a) The bureaucratic burden on farmers should be as limited as possible.

Justification

Reinstatement of first reading Amendment 31.

Amendment 19

Council common position
Recital 45

Council common position	*Amendment*
(45) ***Close coordination should be ensured with other*** Community legislation, in particular Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, and ***with*** Community legislation on the protection of workers and anyone concerned with the contained use and deliberate release of genetically modified organisms.	(45) ***The measures provided for in this Regulation should apply without prejudice to existing*** Community legislation, in particular ***Directive 2008/.../EC [establishing a framework for Community action to achieve a sustainable use of pesticides], Directive 2000/60/EC,*** Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residues levels of pesticides in or on food and feed of plant and animal origin [2]and Community legislation on the protection of workers and anyone concerned with the contained use and deliberate release of genetically modified organisms. **[+] *OJ: please insert number*** [2] OJ L 70, 16.3.2005, p. 1.

Justification

To ensure coherence between all related legislation.

Reinstatement of first reading Amendment 32.

Amendment 20

Council common position
Recital 53

Council common position	*Amendment*
(53) In particular, the Commission should be empowered 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.	(53) In particular, the Commission should be empowered ***to approve active substances, to renew or review their approval, 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, to adopt detailed rules for allowing derogations from authorisation of plant protection products for research and development and the list of approved substances, and*** to adopt Regulations concerning labelling requirements, rules for adjuvants, 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.

Justification

This amendment is necessary to bring the text in line with the provisions of the new decision on comitology. Linked to several specific amendments calling applying the new procedure.

Partial reinstatement of amendment 33 of first reading.

Amendment 21

Council common position
Recital 56

Council common position	*Amendment*
(56) 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***.	(56) It is also appropriate to use the advisory procedure to adopt some purely technical measures.

Justification

Guidelines are of important nature and should therefore be adopted by the regulatory procedure.

Amendment of a new recital introduced by Council.

Amendment 22

Council common position
Article 1

Council common position	*Amendment*
Subject matter	Subject matter ***and purpose***
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.	***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.
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.	***2.*** This Regulation lays down both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants.
	3. The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment.
	4. This Regulation is based on the precautionary principle in order to ensure that substances or products placed on the market do not adversely affect human or

animal health or the environment.

5. The purpose of this Regulation is furthermore to harmonise the rules on the placing on the market of plant protection products in order to harmonise the availability of plant protection products between farmers in different Member States.

6. Member States may not be prevented from applying the precautionary principle in restricting or prohibiting pesticides.

7. Member States may establish any pesticide-free zones they deem necessary in order to safeguard drinking water resources. Such pesticide-free zones may cover the entire Member State.

Justification

The purpose, objective and basic principles of the Regulation should be laid down in Article 1, not only in the recitals of the Regulation.

Paragraph 6 is to make the provisions of this Regulation minimum rules, thereby enabling individual Member States to make further progress with the development of pesticides.

Paragraphs 7 and 8 are important to ensure that the achievements secured in the groundwater directive are carried over into this Regulation in order to safeguard drinking water.

Reinstatement of first reading Amendment 34.

Amendment 23

Council common position
Article 2 – paragraph 2

Council common position	*Amendment*
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, hereinafter referred to as "active substances".	2. This Regulation shall apply to substances, including micro-organisms ***and viruses,*** having general or specific action against harmful organisms or on plants, parts of plants or plant products, hereinafter 'active substances'. ***It shall, however, cease to apply to micro-***

organisms, viruses, pheromones and biological products once a specific regulation on biological control products has been adopted.

Justification

It should be emphasized that the provisions foreseen in the present regulation are designed to reduce harmful effects of synthetic plant protection products and are not in all cases suited for assessing risks and the potential impact of biological control substances. In order to take account of the specific properties of such products, a regulation on biological control products should be foreseen.

Reinstatement of first reading Amendment 35.

Amendment 24

Council common position
Article 3 – point 2 a (new)

Council common position	*Amendment*
	(2a) "active substances"
	Substances, including their metabolites present in the use phase, micro-organisms and viruses, having general or specific action against target organisms or on plants, parts of plants or plant products;

Justification

This definition is needed in order to make sure that when evaluating an active substance, all metabolites present in a given product will be included. This definition is similar to the definition given in Directive 91/414/EEC.

Reinstating first reading Amendment 37.

Amendment 25

Council common position
Article 3 – point 3

Council common position	*Amendment*
3) "preparations"	(3) "preparations"
Mixtures composed of two or more	Mixtures ***or solutions*** composed of two or

substances intended for use as a plant protection product or as an adjuvant;	more substances***, at least one of which is an active substance,*** intended for use as a plant protection product or as an adjuvant;

Justification

The definition of the term 'preparations' should cover not just mixtures (composite substances which can easily be separated into their component parts by simple physical means (using filter paper, mechanical separation, centrifugation) but also solutions (homogeneous substances), which have different properties.

Reinstating first reading Amendment 38.

Amendment 26

Council common position
Article 3 – point 4

Council common position	*Amendment*
4) "substance of concern"	(4) "substance of concern"
Any substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment ***and is present or is produced in a plant protection product in sufficient concentration to present risks of such an effect***.	Any substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment.
Such substances include, but are not limited to, substances ***meeting the criteria to be*** classified as dangerous in accordance with Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, and ***present in the plant protection product at a concentration leading the product to be*** regarded as dangerous within the meaning of Article 3 of Directive 1999/45/EC;	Such substances include, but are not limited to, substances classified as dangerous in accordance with Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, and regarded as dangerous within the meaning of Article 3 of Directive 1999/45/EC.
	Any substance that has or potentially has either carcinogenic, mutagenic, endocrine disrupting, neurotoxic, immunotoxic, reprotoxic or genotoxic capabilities should be regarded as a substance of concern;

Justification

Substances of concern must include any substance that has the potential to cause any adverse effect on human or animal health or the environment. This includes any substances with carcinogenic, mutagenic, endocrine disrupting, neurotoxic, immunotoxic, reprotoxic or genotoxic capabilities.

Reinstating first reading Amendment 39.

Amendment 27

Council common position
Article 3 – point 4 a (new)

Council common position	*Amendment*
	(4a) "article"
	An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

Justification

This regulation should not only deal with active substances and plant protection products as such, but also include provisions on "articles" that might contain such substances (e.g. textiles). The definition proposed here is identical to the definition adopted under REACH.

Reinstating first reading Amendment 40.

Amendment 28

Council common position
Article 3 – point 5

Council common position	*Amendment*
5) "plants"	(5) "plants"
Live plants and live parts of plants, ***including*** fresh fruit, vegetables and ***seeds***;	Live plants and live parts of plants, ***together with seeds for sowing, in particular:*** fresh fruit, vegetables***, flowers, leaves, shoots, living pollen, seedlings, bulbs*** and ***roots***;

Justification

Clarification.

Reinstating first reading Amendment 42.

Amendment 29

Council common position
Article 3 – point 8

Council common position	*Amendment*
8) "placing on the market"	8) "placing on the market"
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;	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***, as well as imports,*** shall constitute placing on the market for the purposes of this Regulation;

Justification

Imported products must comply with all criteria set in this regulation.

Partial reinstatement of first reading Amendment 44.

Amendment 30

Council common position
Article 3 – point 8 a (new)

Council common position	*Amendment*
	(8a) "parallel trade"
	The import of a plant protection product from a Member State where the product has been authorised under the conditions of Directive 91/414/EEC or this Regulation with the intention of placing it on the market in the importing Member State where the plant protection product

or an identical reference product has been authorised under the conditions of Directive 91/414/EEC or this Regulation;

Justification

There is a need for a clear definition and a minimum set of community harmonized rules regulating the placing of PPPs on the market through parallel trade.

Reinstating first reading Amendment 45.

Amendment 31

Council common position
Article 3 – point 8 b (new)

Council common position	*Amendment*
	(8b) "importer"
	A person importing plant protection products for commercial purposes;

Justification

Reinstatement of first reading Amendment 47.

Amendment 32

Council common position
Article 3 – point 10 a (new)

Council common position	*Amendment*
	(10a) "low risk"
	Of a nature considered inherently unlikely to cause an adverse effect on humans, animals or the environment;

Justification

A definition is needed for clarity of provisions relating to low risk active substances and plant protection products.

Reinstating first reading Amendment 43.

Amendment 33

Council common position
Article 3 – point 12 a (new)

Council common position	*Amendment*
	(12a) "health"
	A state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity;

Justification

The definition of health given by the WHO should be included as it relates to the objective and other relevant provisions of this Regulation.

Reinstating first reading Amendment 48.

Amendment 34

Council common position
Article 3 – point 12 b (new)

Council common position	*Amendment*
	(12b) "vulnerable groups"
	Persons needing specific consideration when assessing the acute and chronic health effects of plant protection products. These include pregnant and nursing women, embryos and foetuses, infants and children, the elderly, people who are ill and those taking medication, and workers and residents subject to high pesticide exposure over the long term;

Justification

Vulnerable groups must receive particular attention in the authorisation procedure and should therefore be defined in Article 3 of this Regulation.

Reinstatement of first reading Amendment 49.

Amendment 35

Council common position
Article 3 – point 15

Council common position	*Amendment*
15) "zone"	***deleted***
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;	

Justification

The proposed definition is misleading because it refers to zones in Annex I which do not have relatively similar agriculture, plant health and environmental conditions. The proposed zoning system undermines the national authorisation and it is not in line with the EC principle of proportionality and subsidiarity because it is going beyond what is necessary to speeding up the decision making process These objectives can be reached by amending the mutual recognition system without the concept of zoning.
In addition, water management conditions can differ within the three proposed zones. Reinstating first reading Amendment 52.

Amendment 36

Council common position
Article 3 – point 15 a (new)

Council common position	*Amendment*
	(15a) "integrated pest management"
	Careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep plant protection products and other forms of intervention to levels that are economically 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 by giving priority to preventive crop-growing measures and the use of adapted varieties and of non-chemical methods of plant protection and pest and crop management;

Justification

The definition of integrated pest management (IPM) should not only include aspects of plant protection, but also management aspects linked to the choice of adapted varieties, crop rotation and nutrient strategy, which can considerably reduce the need to use plant protection products.

Reinstating first reading Amendment 50.

Amendment 37

Council common position
Article 3 – point 15 b (new)

Council common position	*Amendment*
	(15b) "non-chemical methods of plant protection and pest and crop management"
	The use of pest control and management techniques that do not have chemical properties. Non-chemical methods of plant protection and pest and crop management include rotation, physical and mechanical control and natural predator management;

Justification

The priority should always be given to non-chemical methods of pest management as the only truly preventative and sustainable solution which is more in line with the objectives for sustainable crop protection, than the reliance on complex chemicals designed to kill plants, insects or other forms of life, which cannot be classified as sustainable. Member States need to promote and encourage the widespread adoption of non-chemical alternatives to plant protection and pest and crop management.

Reinstatement of first reading Amendment 51.

Amendment 38

Council common position
Article 3 –point 18

Council common position	*Amendment*
18) 'good experimental practice'	18) 'good experimental practice'
Practice in accordance with ***the provisions of European and Mediterranean Plant Protection Organisation (EPPO) Guidelines 181 and 152;***	Practice in accordance ***with Directive 2004/10/EC;***

Justification

Reintroduction of amendment adopted in 1st reading.

Amendment 39

Council common position
Article 3 – point 19

Council common position	*Amendment*
19) "data protection"	(19) "data protection"
The temporary right of the owner of a test or study report to prevent it being used for the benefit of another ***applicant;***	A test or study report***, other than those involving tests on vertebrate animals and other tests or studies that may prevent animal testing, is covered by data protection where its owner has the right*** to prevent it being used for the benefit of another ***person;***

Justification

It should be included here that the owner of a test or study cannot prevent it being used by another person where this would avoid animal testing.

Reinstatement of first reading Amendment 55.

Amendment 40

Council common position
Article 3 – point 19 a (new)

Council common position	*Amendment*
	(19a) "rapporteur Member State"

The Member State which agrees to assume the responsibility for assessing the active substances, or safeners, or synergists. It is required to carry out this task in a professional manner and to publish an impact assessment report within a specified period;

Justification

There should be a definition of rapporteur Member State.

Reinstatement of first reading Amendment 56.

Amendment 41

Council common position
Article 3 – point 19 b (new)

Council common position	*Amendment*
	(19b) "tests and studies"
	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;

Justification

Test and study reports terminology is used repeatedly throughout this regulation. There is a need to insert a definition that includes not only study reports but also other information relevant to a risk assessment.

Reinstating first reading Amendment 57.

Amendment 42

Council common position
Article 4 - paragraph 2 – point (a)

Council common position	*Amendment*
(a) they shall not have any harmful effects on human health***, including*** vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the methods to assess such effects are ***agreed***, or on groundwater;	(a) they shall not have any harmful effects on human health, ***in particular that of users who are in direct contact with the products, residents, bystanders and*** vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the methods to assess such effects are ***available,*** or on groundwater;

Justification
All groups at special risks need to be considered. If methods are available to assess cumulative and synergistic effects, they should be used, rather than waiting for agreement on such methods, which might lead to endless delays.
Reinstatement of Amendment 296 from first reading and of text from the Commission proposal.

Amendment 43

Council common position
Article 4 – paragraph 2 – point (b)

Council common position	*Amendment*
(b) they shall not have any unacceptable effect on the environment.	(b) they shall not have any unacceptable effect on the environment***, taking into account cumulative and synergistic effects and all relevant exposure routes to organisms in the environment; methods to assess such effects will be presented by the Authority***.

Justification
The assessment needs to reflect the real-life scenario, including possible cumulative and synergistic effects.

Reinstating amendment 255 of first reading.

Amendment 44

Council common position
Article 4 – paragraph 3 – point (b)

Council common position	*Amendment*
(b) it shall have no immediate or delayed harmful effect on human 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 methods to assess such effects are ***agreed;*** or on groundwater;	(b) it shall have no immediate or delayed harmful effect on human ***health, in particular that of residents and bystanders and vulnerable groups*****,** or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, ***including in locations distant from its use following long-range transportation,*** or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects**,** where the methods to assess such effects are ***available;*** or on ***surface water or*** groundwater;

Justification

All the various subgroups at risk of exposure to pesticides must be protected, including residents, who can be regularly exposed to pesticides from various sources.

It often takes very long to agree on methods. If methods are available to assess cumulative and synergistic effects, they should be used.

Reinstatement of am 297 of first reading and of text from the Commission proposal.

Amendment 45

Council common position
Article 4 – paragraph 3 – point (e)

Council common position	*Amendment*
(e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations:	(e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations:
(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil;	(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, ***drinking water,***

		groundwater, air and soil, ***taking into account locations distant from its use following long-range environmental transportation***;
(ii)	its impact on non-target species;	(ii) its impact on non-target species***, including on the behaviour of those species***;
(iii)	its impact on biodiversity.	(iii) its impact on biodiversity ***and the ecosystem;***
		(iiia) its destructive impact on species threatened with extinction.

Justification

Many pesticides have indirect effects on the ecosystem, i.e. through food chain effects (reduced bird population in agro-ecosystems due to massive reduction of prey insects). These effects should be taken into account as far as possible.
Special attention should also be given to the environmental effects due to long-range environmental transportation of plant protection products, e.g. in the Arctic region.

Too often mortality alone is studied and not effects on behaviour. This must therefore be specified.

Habitats of species threatened with extinction which appear on the Red List are to be found in many parts of Europe.

Pesticides and other plant protection products are a threat to birds in particular, given that they migrate and feed in many different areas where spraying and other treatments involving pesticides, among other substances, may take place. Feeding by rare species of animal in contaminated areas could bring about the extinction of those species.

Reinstating first reading Amendment 64.

Amendment 46

Council common position
Article 4 –paragraph 7

Council common position	*Amendment*
7. By way of derogation from paragraph 1, where on the basis of documented evidence an active substance is necessary to control a serious danger to plant health which	7. By way of derogation from paragraph 1, where:

cannot be contained by other available means, such active substance may be approved for a time limited period 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.

a) it is proven by the applicant on the basis of documented evidence ***that*** an active substance is necessary to control a serious danger to plant health ***in a Member State*** which cannot be contained by other available means, ***including non-chemical means; and***

b) there is a public interest in controlling that danger,

such active substance may be approved for a time-limited period ***necessary to control that serious danger but*** not exceeding ***four*** years ***in that Member State*** 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***, and that a substitution plan on how to control the serious danger in two years' time by other means, including non-chemical methods, is presented by the applicant***.

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 Directive 67/548/EEC, as carcinogenic category 1 or

This derogation shall not apply to active substances which are or have to be classified in accordance with Directive 67/548/EEC, as carcinogenic category 1,

toxic for reproduction category 1.	***carcinogenic category 2 without a threshold,*** or toxic for reproduction category 1. ***If an applicant applies for a derogation under this paragraph, the timelines set out in Articles 12 and 13 shall be halved.***

Justification

Amendment 47

Council common position
Article 4 a (new)

Council common position	*Amendment*
	Article 4a ***Animal testing*** ***In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. The use of non-animal tests and intelligent testing strategies shall be promoted, and duplicate vertebrate animal testing shall be prohibited.***

Justification

The promotion of intelligent testing strategies and compulsory data sharing can significantly reduce the number of animals used.

Reinstating first reading Amendment 66.

Amendment 48

Council common position
Article 6 – point (ia) (new)

Council common position	*Amendment*
	(ia) restrictions or prohibitions for uses not compatible with integrated pest management schemes, or even detrimental to these schemes such as chemical soil treatment;

Justification

Specific uses, which are incompatible with good practices like IPM, should be restricted.

Reinstating first reading Amendment 68.

Amendment 49

Council common position
Article 7 – paragraph 1

Council common position	*Amendment*
	1. ***The Authority shall be responsible for coordinating the approval procedure.***
	In doing so, the Authority shall rely on the competent authorities of Member States.
1. An application for the approval of an active substance or for an amendment to the conditions of an approval shall be submitted by the producer of the active substance to ***a Member State, hereinafter referred to as "rapporteur Member State",*** together with a 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.	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 ***the Authority*** together with ***a complete and*** a summary dossier, as provided for in Article 8(1) and (2), ***or a letter of access to such dossiers*** or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in Article 4. ***The Authority shall inform the competent authorities of the Member States of the applications it has received.***
A joint application may be submitted by an association of producers designated by the producers for the purpose of compliance with this Regulation.	***A Member State may choose an active substance for which an application for approval has been received by the Authority, with the aim of becoming the rapporteur Member State.***
The application shall be examined by the Member State proposed by the applicant, unless another Member State agrees to examine it.	***In cases where two or more Member States have expressed an interest in becoming the rapporteur Member State and they cannot agree who should be the competent authority, the rapporteur Member State shall be determined in accordance with the regulatory procedure***

referred to in Article 79(3).

The decision shall be based on objective criteria such as geographic, agricultural and climatic conditions, especially with regard to the target organisms, the performance and impartiality of the competent authority and the reference laboratory, and the absence of interests linked to the producing companies.

Justification

Industry should not be entitled to choose a rapporteur Member State. Applications should be sent to the Authority and Member States should decide amongst themselves who to become the rapporteur Member State. Disagreement should be solved in comitology, on the basis of objective criteria.

Reinstating first reading Amendment 69.

Amendment 50

Council common position
Article 7 – paragraph 1 a (new)

Council common position	*Amendment*
	1a. A natural or legal person established outside the Community who submits an application shall appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on producers under this Regulation.

Justification

Article 70 of this Regulation requires compliance of measures in conformity with this Regulation to be without prejudice to general civil and criminal liability in the Member States of the producer. The amendment seeks to establish a level playing field for all producers, including the ones established in a jurisdiction outside the Community.

Reinstating first reading AM 70.

Amendment 51

Council common position
Article 7 – paragraph 1 b (new)

Council common position	*Amendment*
	1b. Assessment of an application may be performed by a number of Member States together under the co-rapporteur system.

Justification

The same provision applies to assessments under Directive 91/414/EEC and has a considerable influence on the speed and quality of the assessment reports on active substances.

Reinstating frist reading Amendment 71

Amendment 52

Council common position
Article 8 – paragraph 1 – point c a (new)

Council common position	*Amendment*
	(ca) for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplicative testing on vertebrate animals;

Justification

In order to facilitate that animal testing for the purposes of this Regulation is kept to an absolute minimum, applications should also be required to provide a justification of the steps taken to avoid animal testing in general.

Reinstatement of first reading Amendment 75.

Amendment 53

Council common position
Article 8 – paragraph 4 a (new)

Council common position	*Amendment*
	4a. All scientific peer-reviewed open literature on the active substance and its metabolites regarding negative side-effects on health, the environment and non-target species shall be added by the applicant to the dossier.

Justification

The applicant must have the obligation to collect and summarise all scientific literature on the substance. This will benefit unexpected effects in bees that are not detected in the risk assessment but are widely documented in the scientific literature.

Reinstating first reading Amendment 78.

Amendment 54

Council common position
Article 11 - paragraph 1

Council common position	*Amendment*
1. Within twelve months of the date of the notification provided for in the first subparagraph of Article 9(3), the rapporteur Member State shall prepare and submit to the Commission, with a copy to the Authority a report***,*** hereinafter referred to as "draft assessment report", assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4.	1. ***The rapporteur Member State may start the evaluation of test and study reports as soon as they are submitted by the applicant, including before the date of the notification provided for in the first subparagraph of Article 9(3).*** Within twelve months of the date of the notification provided for in the first subparagraph of Article 9(3), the rapporteur Member State shall prepare and submit to the Commission, with a copy to the Authority, a report ***(***hereinafter referred to as "draft assessment report"***)*** assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4.

Justification

Starting the evaluation of available information before the dossier is complete will speed up access of new, innovative products to the market.

Partially reinstating first reading Amendment 80.

Amendment 55

Council common position
Article 11 – paragraph 2 - subparagraph 1

Council common position	*Amendment*
2. The draft assessment report shall also include where relevant, a proposal to set maximum residue levels. ***In such a case the rapporteur Member State shall forward the application, the evaluation report and the supporting dossier referred to in Article 9 of Regulation (EC) No 396/2005 to the Commission no later than six months after the date of the notification provided for in the first subparagraph of Article 9(3) of this Regulation.***	2. The draft assessment report shall also include, where relevant, a proposal to set maximum residue levels.

Justification

Necessary clarification on the setting of the MRL if the conclusions of the Authority are not adopted within the prescribed time limit.

Amendment 56

Council common position
Article 12 – paragraph 2 - subparagraph 2

Council common position	*Amendment*
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	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.	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. ***Where a consultation as provided for in the first subparagraph is organised, the 120-day period shall be extended by 60 days.***

Justification

The Authority needs to be given enough time to prepare its conclusion. Current requirements grant six months to EFSA. Experience so far has shown that a period of six months is critical to conduct an effective and scientifically robust peer review. A 120-day period would for example not allow organising an expert meeting. As such, when a consultation of experts is required, the period should be extended by 60 days.

Compromise suggestion based on first reading Amendment 83.

Amendment 57

Council common position
Article 12 – paragraph 6 a (new)

Council common position	*Amendment*
	6a. Where the conclusion of the Authority is adopted within the time limit set out in paragraph 2 of this Article, extended by any additional time period set in 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.

Justification

Necessary clarification, the setting of the MRL can not take place before the conclusions of the Authority

Amendment 58

Council common position
Article 12 – paragraph 6 b (new)

Council common position	*Amendment*
	6b. 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 time period set in paragraph 3, the provisions of Articles 11 and 14 of Regulation (EC) No 396/2005 shall apply without delay.

Justification

Necessary clarification on the setting of the MRL if the conclusions of the Authority are not adopted within the prescribed time limit.

Amendment 59

Council common position
Article 13 – paragraph 1 – subparagraph 1

Council common position	*Amendment*
1. Within ***six months*** of receiving the conclusion from the Authority, the Commission shall present a report, hereinafter 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.	1. Within ***three months*** of receiving the conclusion from the Authority, the Commission shall present a report, ***(***hereinafter 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.

Justification
The Commission does not need half a year to draft a report on a fully examined dossier. The procedure needs to be accelerated.

Reinstating first reading Amendment 86.

Amendment 60

Council common position
Article 13 – paragraph 2 – introduction and point (a)

Council common position	*Amendment*
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:	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 ***with due justification*** shall be adopted in accordance with the regulatory procedure ***with scrutiny*** referred to in ***Article 79(4)***, providing that:
(a) an active substance is approved, subject to conditions and restrictions, as referred to in Article 6, where appropriate;	(a) an active substance is approved, subject to conditions and restrictions, as referred to in Article 6, where appropriate, ***and included in Annex IIa;***

Justification

This amendment is necessary to bring the text into line with the provisions of the new decision on comitology. The transparency of the procedure should be increased. Therefore the inclusion of approved substances in an Annex of the Regulation should be maintained.

Reinstating of first reading Amendment 88.

Amendment 61

Council common position
Article 13 – paragraph 4

Council common position	*Amendment*
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.***	4. The Commission shall maintain ***an updated*** list of approved active substances ***in Annex IIa and publish this list on the Internet***.

Justification

The transparency of the procedure should be increased. Therefore the inclusion of approved substances in an Annex of the Regulation should be maintained.

Reinstating first reading Amendment 89.

Amendment 62

Council common position
Article 14 – paragraph 2

Council common position	*Amendment*
2. ***The renewal of*** the approval ***shall be*** for a period not exceeding ***fifteen years. The renewal of approval of active substances covered by Article 4(7) shall be for a period not exceeding five years.***	2. The approval ***may be renewed once or repeatedly*** for a period not exceeding ***10 years***. ***The renewal of approval of active substances covered by Article 4(7) shall be for a period not exceeding four years.***

Justification

In the proposed text the renewal of the authorisation by the Member State follows the renewal of the active substance (Article 43(5)). This implies that also the authorisation would in principle be unlimited in time, after the first renewal. This is contrary to the precautionary principle and to the principle that decisions are made in the light of current scientific and technical knowledge, as is laid down in Article 4(1) of the proposed text, and the principle that a high standard of protection must be ensured (recital 9).

Reinstating first reading Amendment 90.

Amendment 63

Council common position
Article 15 – paragraph 1

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

Justification

Reinstating first reading Amendment 91.

Amendment 64

Council common position
Article 18 – point (b)

Council common position	*Amendment*
(b) the necessary data to be submitted;	(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***;

Justification

In order to ensure that animal testing for the purposes of this Regulation is kept to an absolute minimum, measures to facilitate this should also be included in the programme.

Reinstating first reading Amendment 92.

Amendment 65

Council common position
Article 20 – paragraph 1 – introductory part

Council common position	*Amendment*
1. A Regulation shall be adopted in accordance with the regulatory procedure referred to in ***Article 79(3),*** providing that:	1. A Regulation ***with due justification*** shall be adopted in accordance with the regulatory procedure ***with scrutiny*** referred to in ***Article 79(4)***, providing that:

Justification

Reinstating first reading Amendment 94.

Amendment 66

Council common position
Article 20 – paragraph 2

Council common position	*Amendment*
2. Where the reasons for not renewing the approval ***permit it***, the Regulation referred to in paragraph 1 shall provide for a grace period not exceeding one year for ***the placing on the market and in addition a maximum of one year for the disposal, storage, and use of existing*** stocks of the plant protection products concerned.	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 one year for ***using up*** stocks of the plant protection products concerned***. Past this period, producers shall ensure the removal and safe disposal of the remaining stocks***.
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.	In the case of a withdrawal of the approval or if the approval is not renewed because of concerns for human health or animal health or the environment, the plant protection products concerned shall be withdrawn from the market immediately.

Justification

A grace period of one year should only be granted if the reasons for not renewing the approval do not concern the protection of health or the environment. Beyond this period, producers should ensure the safe removal and disposal of their product. An immediate withdrawal shall occur whenever the plant protection product was not renewed because of the concerns for human health or animal health or the environment.

Reinstating first reading Amendment 95.

Amendment 67

Council common position
Article 21 – paragraph 1 – subparagraph 1

Council common position	*Amendment*
1. The Commission may review the approval of an active substance at any time. ***It may take into account the request of a Member State to review the approval of an active substance.***	1. The Commission may review the approval of an active substance at any time ***and shall give due consideration to requests for review from a Member State, the European Parliament or other stakeholders, based on current scientific***

and technical knowledge and monitoring data.

Justification

To ensure transparency in the process and align the proposal to the precautionary principle. The amendment also seeks to ensure that decisions take into account current scientific and technical knowledge, as it is laid down in Article 4(1) of the proposed text and the principle that a high standard of protection must be ensured, as stipulated in recital 9.

Reinstating first reading Amendment 97.

Amendment 68

Council common position
Article 21 – paragraph 1 – subparagraph 2 a (new)

Council common position	*Amendment*
	The Commission shall review the approval of an active substance where there are indications that the achievement of the objectives established in accordance with Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC may be compromised.

Justification

While the Commission can launch a review for a given substance at any time, it should be made clear that requests for review can also be initiated by other institutions or stakeholders. It is essential that, in cases of non-compliance with the objectives of Directive 2000/60/EC, it is possible to reconsider the approval of the substance. Moreover, this direct feedback mechanism between Directive 2000/60/EC and this Regulation will also provide an extra incentive for producers to seriously consider their responsibilities in terms of product stewardship.

Reinstating first reading Amendment 98.

Amendment 69

Council common position
Article 21 – paragraph 3 – subparagraph 1

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

Justification

This amendment is necessary to bring the text into line with the provisions of the new decision on comitology.

Reinstating first reading Amendment 99.

Amendment 70

Council common position
Article 21 – paragraph 3 a (new)

Council common position	*Amendment*
	3a. Where the Commission concludes that the objectives of reducing pollution from priority substances established in accordance with Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC cannot be met, a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4) of this Regulation.

Justification

It is essential that in case of non-compliance with the objectives of Directive 2000/60/EC for a substance, it is possible to reconsider the approval of the substance. The procedure should be in line with the provisions of the new decision on comitology.

Reinstatement of first reading Amendment 100.

Amendment 71

Council common position
Article 22 – paragraph 1 – subparagraph 1 a (new)

Council common position	*Amendment*
	This derogation shall not apply to any active substance classified in accordance with Directive 67/548/EEC as:
	– carcinogenic,
	– mutagenic,
	– toxic to reproduction,
	– sensitising chemicals,
	or to substances that are qualified as:
	– persistent with a half-life of more than 60 days,
	– endocrine disrupters appearing on the EU list of suspected endocrine disrupters,
	– toxic,
	– bioaccumulative and non-readily degradable.
	No later than ...*, the Commission shall review and if necessary specify the criteria for treating an active substance as a low risk substance and, if appropriate, submit proposals.
	**** One year after the entry into force of this Regulation.***

Justification

There is a need to lay down clear and objective criteria to define which substances can claim to have a low risk profile. There is no definition for this in the proposal. To encourage research for less harmful substances and products, it is important to provide businesses with clarity and legal certainty on what exactly is meant by a low risk profile. The criteria listed here are partly taken from the biocides directive, 98/8/EC. With these criteria 25% to 30% of active substances would be considered as low risk.

Reinstating first reading Amendment 102.

Amendment 72

Council common position
Article 22 – paragraph 1 a (new)

Council common position	*Amendment*
	1a. Notwithstanding Article 5, active substances based on biological control agents which comply with the criteria set out in Article 4 shall be given approval for a period not exceeding 15 years where plant protection products containing such biological control agents are expected to present only a low risk to human and animal health and the environment as defined in Article 47(1).

Justification

The use of plant protection substances based on biological control agents offers excellent prospects for the protection of human and animal health and of the environment and should be fully supported. In view of their low-risk nature, such biological control agents have great potential benefits. Since plant protection based on biological control agents often has a relatively small area of application, a 15-year approval period is necessary in order to promote sufficient research and development for such plant protection products.

Reinstating first reading Amendment 103.

Amendment 73

Council common position
Article 22 –paragraph 2

Council common position	*Amendment*
2. Articles 4 and 6 to 21 and Section 5 of Annex II shall apply. Low-risk active substances shall be listed separately in ***the Regulation referred to in Article 13(4).***	2. Articles 4 and 6 to 21 and Section 5 of Annex II shall apply. Low-risk active substances shall be listed separately in ***Annex IIa.***

Justification

Amendment in line with the amendment to Article 13(2) that establishes RPS for the approval of active substances.

Amendment of a new sentence introduced by Council.

Amendment 74

Council common position
Article 23 – paragraph 1 – subparagraph 2 a (new)

Council common position	*Amendment*
	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.

Justification

Substances which are foodstuffs according to Article 2 of Regulation (EC) No 178/2002 are per definition as foodstuffs not toxic. Such substances, e.g. sun flower oils, are currently used in organic farming.

Reinstating first reading Amendment 274.

Amendment 75

Council common position
Article 23 – paragraph 2

Council common position	*Amendment*
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.	2. A basic substance shall be approved ***in accordance with Article 4 and*** 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, ***provided that each point of the data requirements for active substances contained in plant protection products is given and the same decision-***

making procedures apply.

Justification

The risk assessment procedure shall be mandatory also for basic substances.

Reinstating first reading Amendment 105.

Amendment 76

Council common position
Article 23 –paragraph 5

Council common position	*Amendment*
5. Articles 6 and 13 shall apply. Basic substances shall be listed separately in ***the Regulation referred to in Article 13(4).***	5. Articles 6 and 13 shall apply. Basic substances shall be listed separately in ***Annex IIa.***

Justification

Amendment in line with the amendment to Article 13(2) that establishes RPS for the approval of active substances.

Amendment of a new sentence introduced by Council.

Amendment 77

Council common position
Article 24 – paragraph 1

Council common position	*Amendment*
1. An active substance complying with the criteria provided for in Article 4 shall be approved 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 a period not exceeding ***ten years***.	1. An active substance complying with the criteria provided for in Article 4 shall be approved 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 a period not exceeding ***five years***.

Justification

The approval time of candidates for substitution should not be the same as the general approval period. To ensure regular comparative assessment of products containing such substances, the approval period should be limited to 5 years (renewable).

This amendment should also clarify that Parliament never adopted a position that would have meant an automatic phase out of candidates for substitution. Such phase out is only required when a series of conditions is fulfilled (see Art. 50).

Partially reinstating first reading Amendment 106. Replaces amendment 92 by the rapporteur.

Amendment 78

Council common position
Article 24 –paragraph 2

Council common position	*Amendment*
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).***	2. Without prejudice to paragraph 1, Articles 4 to 21 shall apply. Candidates for substitution shall be listed separately in ***Annex IIa.***

Justification

Amendment in line with the amendment to Article 13(2) that establishes RPS for the approval of active substances.

Amendment of a new sentence introduced by Council.

Amendment 79

Council common position
Article 25 – paragraph 1 a (new)

Council common position	*Amendment*
	1a. For approval of a safener or synergist, paragraph 1 shall be deemed to be satisfied where compliance with Article 4 has been established with respect to one or more representative uses of at least one plant protection product for every

	different active substance the safener or synergist is combined with.

Justification

Safeners and synergists shall be assessed in relation to different active substances with which they are combined.

Reinstating first reading Amendment 107.

Amendment 80

Council common position
Article 26

Council common position	*Amendment*
By …*, 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 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 time period.	By ...*, a Regulation shall be adopted in accordance with the procedure referred to in ***Article 251 of the Treaty*** 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 time period.
* Note to OJ: ***60 months*** from the date of entry into force of this Regulation.	* Note to OJ: ***24 months*** from the date of entry into force of this Regulation.

Justification

The provisions for reviewing existing synergists and safeners shall not be left to a comitology decision, but shall be established in a legislative procedure based on the Treaty.

Reinstating first reading Amendment 108.

Amendment 81

Council common position
Article 27 - title and paragraphs 1 and 2

Council common position	*Amendment*
Co-formulants	***Approval of*** co-formulants
1. A co-formulant shall ***not be accepted for inclusion in a plant protection product*** where it has been established that:	1. A co-formulant shall ***be approved*** 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***	(a) ***the co-formulant or*** its residues, consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use, ***do not*** have a harmful effect on human or animal health or on groundwater or an unacceptable effect on the environment; ***and***
(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.	(b) its use, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, ***does not have*** a harmful effect on human or animal health or an unacceptable effect on plants, plant products or the environment.
2. Co-formulants ***which shall not be 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).	2. Co-formulants ***approved*** pursuant to paragraph 1 shall be included in Annex III in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Justification

Co-formulants can have an impact on human health and the environment. They should therefore be approved and included on a positive list, like safeners and synergists (see Article 25), in line with provisions of the new decision on comitology.

Good practice should be assumed, but can not be taken for granted. Instead, realistic conditions of use should be foreseen in line with the current provisions included in the test guidelines in Directive 91/414, where consideration must be given to "practical conditions of use" and "realistic conditions of use".

Reinstating first reading Amendment 109.

Amendment 82

Council common position
Article 27 – paragraph 2 a (new)

Council common position	*Amendment*
	2a. Where a co-formulant is used in a plant protection product authorised under this Regulation, its specific use in plant protection products shall be considered as being registered in accordance with Article 15 (1) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[1].

[1] OJ L 396, 30.12.2006, p. 1. Corrected in OJ L 136, 29.5.2007, p. 3.

Justification

Co-formulants used in plant protection products should not be subject to double regulation under REACH.

Reinstating first reading Amendment 110.

Amendment 83

Council common position
Article 28 – paragraph 2 – point (b)

Council common position	*Amendment*
(b) ***placing on the market and*** use of plant protection products for research or development purposes in accordance with Article 54;	(b) use of plant protection products for research or development purposes in accordance with Article 54;

Justification

The Regulation aims at having high standards for authorisation. Plant protection products authorised specifically for research and development purposes should not be placed on the market.

Reinstating first reading Amendment 111.

Amendment 84

Council common position
Article 29 – paragraph 1 – point (c)

Council common position	*Amendment*
(c) its co-formulants ***are not included in Annex III;***	(c) its co-formulants ***have been approved under Article 27;***

Justification

See justification on Amendment to Article 27 above.

Reinstating first reading Amendment 113..

Amendment 85

Council common position
Article 29 – paragraph 1 – point (c a) (new)

Council common position	*Amendment*
	(ca) its (technical) formulation is such that user exposure or other risks are limited as much as possible without compromising the functioning of the product;

Justification

Different formulations vary considerably in risk - e.g. powder compared to granule formulation and formulation containing organic solvent compared to water soluble emulsions. If it can be avoided, the formulation in itself should not increase the risk involved with the use of a specific plant protection product. The proposed text would help ensure that the formulation with the lowest possible risk is used when a product is placed on the market.

Reinstating first reading Amendment 114.

Amendment 86

Council common position
Article 29 – paragraph 1 – point (e a) (new)

Council common position	*Amendment*
	(ea) all metabolites of the active substance(s) present in the use-phase have been determined and comply with the criteria of the uniform principles referred to in paragraph 6;

Justification

The Uniform principles are a key element in the authorisation process.

Reinstating first reading Amendment 115.

Amendment 87

Council common position
Article 29 – paragraph 1 – point (f)

Council common position	*Amendment*
(f) its residues, resulting from authorised uses, ***and which are of toxicological, ecotoxicological or environmental relevance,*** can be determined by ***appropriate*** methods in general use;	(f) its residues, resulting from authorised uses, can be determined by ***standardised*** methods in general use ***in all Member States***, ***which are sufficiently sensitive with respect to any technically detectable levels that could be present in any environmental and biological media***. ***The residues shall be detectable with the common multi-residue methods as applied by Community reference laboratories;***

Justification

This is in line with the earlier amendment suggested at Article 4, paragraph 2 and the related justification.

Methods to detect all residues of active substances should be sufficiently sensitive with respect to levels of concern in various environmental and biological media in order not to overlook effects that are not easily detected by methods in general use.

Reinstating first reading Amendment 116.

Amendment 88

Council common position
Article 29 – paragraph 1 – point (h a) (new)

Council common position	*Amendment*
	(ha) its authorisation does not counteract the national plans developed under Directive 2008/.../EC [establishing a framework for Community action to achieve a sustainable use of pesticides]*.
	**** Note to OJ: please insert number.***

Justification

Member States should not be forced to accept pesticides which pollute ground water or cause unnecessary risks and hazards for humans, animals and the environment in conflict with their national environmental and health policies. Member states should be allowed to take regional conditions into account before authorising plant protection products.

Reinstating first reading Amendment 117.

Amendment 89

Council common position
Article 29 – paragraph 4

Council common position	*Amendment*
4. With respect to point (e) of paragraph 1, harmonised methods may be adopted in accordance with the regulatory procedure referred to in ***Article 79(3).***	4. With respect to point (e) of paragraph 1, harmonised methods may be adopted in accordance with the regulatory procedure ***with scrutiny*** referred to in ***Article 79(4)***.

Justification

This amendment is necessary to bring the text into line with the provisions of the new decision on comitology.

Reinstating first reading Amendment 119.

Amendment 90

Council common position
Article 29 – paragraph 6 – subparagraph 1 a (new)

Council common position	*Amendment*
	The uniform principles shall take due account of the interaction between the active substance, safeners, synergists and co-formulants.

Justification

It shall be made clear that the interaction between different substances is taken into account in the authorisation process. It is not sufficient to look at the involved substances separately.

The amendment is mainly meant to clarify. It is already indirectly mentioned in Article 25 paragraph 2 in connection with Article 8 paragraph 1 point a), Article 29 paragraph 4 and in the uniform principles.

Reinstating first reading Amendment 121.

Amendment 91

Council common position
Article 30 - paragraph 1 – point a

Council common position	*Amendment*
(a) the decision on approval could not be finalised within a time period of 30 months from the date of admissibility of the application, extended with any additional time period set in accordance with Article 9(2), Article 11(3) or Article 12(3); and	(a) the decision on approval could not be finalised within a time period of 30 months from the date of admissibility of the application, extended with any additional time period set in accordance with Article 92 (2), Article 11 (3) or Article 12***(2) or*** (3); and

Amendment 92

Council common position
Article 30 – paragraph 2

Council common position	*Amendment*
2. In such cases the Member State shall immediately inform the other Member	2. In such cases the Member State ***may start its evaluation regarding a***

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).	***provisional authorisation as soon as there is evidence that the deadlines for the substance authorisation will not be met and*** 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).

Justification

Council has modified the text as adopted by Parliament in 1st reading and has introduced a new article regarding the provisional authorisation of products. This new article needs to be modified to reflect the proposed changes of the European Parliament in 1st reading.

Amendment 93

Council common position
Article 31 – paragraph 2 – subparagraph 1 a (new)

Council common position	*Amendment*
	These requirements shall also include:
	(a) the maximum dose per hectare in each application;
	(b) the period between the last application and harvest;
	(c) the number of applications per year.

Justification

It should be compulsory to indicate the information above in every authorisation.

Reinstating first reading Amendment 124.

Amendment 94

Council common position
Article 31 –paragraph 2 – subparagraph 2

Council common position	*Amendment*
The authorisation shall include a classification of the plant protection product for the purpose of Directive	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 case, they shall immediately inform the competent authority thereof.	1999/45/EC. Member States ***shall*** 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 case, they shall immediately inform the competent authority thereof.

Justification

It should be obligatory on Member States to make provisions that authorisation holders update the label.

Amendment of a new passage introduced by Council.

Amendment 95

Council common position
Article 31 - paragraph 2 - subparagraph 2a

Council common position	*Amendment*
	The authorisation shall include indications for proper use in accordance with the principles of integrated pest management as defined in Article 3, to apply from 2012 onwards;

Justification

Reinstating first reading Amendment 305.

Amendment 96

Council common position
Article 31 –paragraph 3 – point (a)

Council common position	*Amendment*
(a) a restriction with respect to the distribution and use of the plant protection product ***taking into consideration requirements imposed by other***	(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***

community provisions in order to protect the health of the distributors, users, bystanders and workers concerned and the environment; such restriction shall be indicated on the label;	and workers concerned and ***consumers or animal health or*** the environment, ***taking into consideration requirements imposed by other Community provisions***; such restriction shall be indicated on the label;

Justification

Reinstatement of amendment 303 from first reading, and rearrangement of new Council text to address other community provisions as an addition and not as a limitation.

Reinstating first reading Amendment 126.

Amendment 97

Council common position
Article 31 – paragraph 3 – point (b a) (new)

Council common position	*Amendment*
	(ba) any restrictions or prohibitions of pesticide use in and around areas used by the general public or by vulnerable groups, such as residential areas, parks, public gardens, sports grounds, school grounds, children's playgrounds;

Justification

The statutory conditions of use in the approval for all pesticides should contain detailed requirements for any prohibition of pesticide use in and around areas used by the general public or by sensitive population, such as residential areas, parks, public gardens, sports grounds, school grounds, children's playgrounds etc.

Reinstating first reading amendment 127.

Amendment 98

Council common position
Article 31 – paragraph 3 – point (b b) (new)

Council common position	*Amendment*
	(bb) other restrictions or conditions relevant to the issue of an authorisation

	and to the use of the plant protection product, particularly where these are intended to protect the health of distributors, users, workers, residents, bystanders and consumers or animal health or the environment;

Justification

This new point would enable Member States to include other restrictions or conditions, particularly for the protection of distributors, users, workers, residents, bystanders and consumers, or animal health or the environment.

Reinstatement of am 303 of first reading.

Amendment 99

Council common position
Article 31 – paragraph 3 – point (e)

Council common position	*Amendment*
(e) the maximum dose per hectare in each application;	***deleted***

Justification

This amendment is linked to the amendment to Article 31, paragraph 2, subparagraph 1a by the rapporteur. This amendment should fall in case that amendment is not adopted.

In line with the reinstatement of first reading Amendment 124.

Amendment 100

Council common position
Article 31 – paragraph 3 – point (f)

Council common position	*Amendment*
(f) the maximum number of applications per year and interval between applications;	***deleted***

Justification

This amendment is linked to the amendment to Article 31, paragraph 2, subparagraph 1a by the rapporteur. This amendment should fall in case that amendment is not adopted.

In line with the reinstatement of first reading Amendment 124.

Amendment 101

Council common position
Article 31 – paragraph 3 – point (h)

Council common position	*Amendment*
(h) the pre-harvest interval, where applicable;	***deleted***

Justification

This amendment is linked to the amendment to Article 31, paragraph 2, subparagraph 1a by the rapporteur. This amendment should fall in case that amendment is not adopted.

In line with the reinstatement of first reading Amendment 124.

Amendment 102

Council common position
Article 33 – paragraph 2 – point (a) and (b)

Council common position	*Amendment*
(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;	(a) a list of intended uses 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 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 considering 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;	

Amendment 103

Council common position
Article 33 – paragraph 3 – point b

Council common position	*Amendment*
(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;	(b) for each active substance, safener and synergist, ***co-formulant and adjuvant*** 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, ***co-formulant and adjuvant***, ***as well as a complete and a summary dossier on the combined effect of the active substance(s), safener(s) and synergist(s), co-formulant(s) and adjuvant(s) contained in the plant protection product*;**

Justification

Clearly safeners, synergists, co-formulants and adjuvants are added to enhance or modify the effect of the active substance, making the combined effect different from the added-on effect of the individual substances. Therefore, the combined effect should also be evaluated.

Reinstating first reading Amendment 129.

Amendment 104

Council common position
Article 33 – paragraph 3 – point c

Council common position	*Amendment*
(c) for each test or study involving vertebrate animals, a justification of the steps taken to avoid ***unnecessary*** testing;	(c) for each test or study involving vertebrate animals, a justification of the steps taken to avoid ***animal testing and duplicative*** testing ***on vertebrate animals***;

Justification

In order to facilitate that animal testing for the purposes of this Regulation is kept to an absolute minimum, applications should also be required to provide a justification of the steps taken to avoid animal testing in general.

Reinstating first reading Amendment 130.

Amendment 105

Council common position
Article 33 – paragraph 6 a (new)

Council common position	*Amendment*
	6a. On request, the applicant shall provide any other Member States with the complete dossier referred to in paragraph 3(a).

Justification

Amendment 106

Council common position
Article 33 – paragraph 6 b (new)

Council common position	*Amendment*
	6b. Application forms shall be standard in all Member States.

Justification

Reinstating first reading Amendment 133.

Amendment 107

Council common position
Article 35

Council common position	*Amendment*
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.	The application shall be examined by the Member State proposed by the applicant**,** unless another Member State 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	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.	Member States 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.	
In case 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.	Member States evaluating the application shall agree on the evaluation of data which are not related to the environmental and agricultural conditions.

Justification

Amendment 108

Council common position
Article 35 a (new)

Council common position	*Amendment*
	Article 35 a
	Database of the Authority
	Upon being informed which Member State will examine the application, the applicant shall immediately forward to the Authority the complete and the summary dossiers referred to in Article 33(3)(a) and (b) and the information referred to in Article 33(3)(c).
	The Authority shall without delay make available to the public the summary dossiers, excluding any information which is confidential under Article 63, and the information referred to in Article 33(3)(c).

Justification

Conform the last subparagraph of Article 9(3) and Article 10. Linked to Amendments of Recital 32 and Articles 54(1), 57(1) and (2) and 58(-1). In order to facilitate data sharing it is necessary to establish one central database with all the information on tests and studies carried out previously for the purposes of this Regulation, managed by the Authority. Applicants would then have to consult only one database before carrying out any tests or studies. The information referred to in Article 32(3)(c) should also be publicly available to ensure transparency in relation to the steps taken by applicants to avoid animal testing.

Reinstating first reading Amendment 135.

Amendment 109

Council common position
Article 36 – paragraph 1

Council common position	*Amendment*
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.	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 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.	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, 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).***	The Member State examining the application shall make available its assessment to the other Member States. The format of the assessment report shall be established in accordance with the ***regulatory*** procedure referred to in ***Article 79(3).***

Justification

Amendment 110

Council common position
Article 36 – paragraph 2

Council common position	*Amendment*
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***.***	2. ***Within 180 days, the*** Member States concerned shall grant or refuse authorisations on the basis of the conclusions of the assessment of the Member State examining the application as provided for in Articles 31 and 32, ***and on the basis of any additional assessments, tests, and studies related to specific conditions in the Member States. The 180-day period cannot be extended.***

Justification

Amendment 111

Council common position
Article 36 – paragraph 2 a (new)

Council common position	*Amendment*
	2a A Member State may refuse authorisation of the plant protection product in its territory only if, due to specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question poses a risk to human or animal health or the environment.

Justification

Amendment 112

Council common position
Article 36 – paragraph 3

Council common position	*Amendment*
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 ***points (a) and (b) of*** Article 31(3) and other risk mitigation measures deriving from specific conditions of use.	3. By way of derogation from paragraph 2 and subject to Community law***, Member States may impose*** appropriate conditions with respect to the requirements referred to in Article 31(3) and other risk mitigation measures deriving from specific conditions of use.
Where the concerns of a Member State related to human or animal health or the environment cannot be controlled by the establishment of national risk mitigation measures referred to in the first subparagraph, a Member State may as a last resort refuse authorisation of the plant protection product in its territory if, due to its very specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question poses a serious risk to human or animal health or the environment.	
It shall immediately inform the applicant and the Commission of its decision and provide a technical or scientific justification therefore.	It shall immediately inform the applicant and the Commission of its decision and provide a technical or scientific justification therefore.
Member States shall provide for a possibility to challenge decision refusing the authorisation of such product before the national courts or other instances of appeal.	Member States shall provide for a possibility to challenge ***a*** decision ***accepting or*** refusing the authorisation of such product ***by any stakeholder*** before the national courts or other instances of appeal.

Amendment 113

Council common position
Article 37 – paragraph 4

Council common position	*Amendment*
4. The other Member States concerned shall at the latest within 90 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).	***deleted***

Justification

Deletion of new wording introduced by Council in line with Parliament's position to delete the concept of zones.

Amendment 114

Council common position
Article 39 – paragraph 1 – subparagraph 1 a (new)

Council common position	*Amendment*
	Not later than ...*, the Commission shall present a proposal introducing a standardised format for the documentation provided for in points (a), (b) and (c).
	**** 12 months after the entry into force of this Regulation.***

Justification

A system of work sharing should be put in place to facilitate the decision making process of Member States that authorise the same product within the EU.

Reinstating first reading Amendment 143.

Amendment 115

Council common position
Article 39 – paragraph 1 a (new)

Council common position	*Amendment*
	1a. Member States shall, without delay, make available to the Authority a file containing the documentation provided for in points (a), (b) and (c) of paragraph 1. The Authority shall maintain a register in which all authorisations in the different Member States are registered.

Justification

A central body, the Authority should keep track of the various authorisations granted to substances in the different Member States.

Reinstating first reading Amendment 144.

Amendment 116

Council common position
Article 39 – paragraph 2 a (new)

Council common position	*Amendment*
	2a. Within 12 weeks of a decision on the authorisation of a plant protection product, Member States shall make available a record of the administrative decisions as referred to in point (c) of paragraph 1 on a public website.

Justification

A system of work sharing should be put in place to facilitate the decision making process of Member States that authorise the same product within the EU.

Reinstating first reading Amendment 146.

Amendment 117

Council common position
Article 40 – paragraph 1

Council common position	*Amendment*
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:***	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.
(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.***	

Amendment 118

Council common position
Article 41 – paragraph 1

Council common position	*Amendment*
1. The Member State to which an application under Article 40 is submitted shall authorise the plant protection product concerned under the same conditions as the Member State examining the application	1. The Member State to which an application under Article 40 is submitted shall ***examine the assessment undertaken by the Member State where the authorisation was granted (reference***

except where Article 36(3) applies.	***Member State) against the circumstances in its own territory and shall within 180 days*** authorise the plant protection product concerned under the same conditions as the Member State examining the application ***or apply*** Article 36***(2a) or*** (3).

Amendment 119

Council common position
Article 41 – paragraph 1 a (new)

Council common position	*Amendment*
	1a. Where a Member State refuses the authorisation of a plant protection product in accordance with Article 36(2a), it shall notify the Commission, the other Member States and the applicant within 15 days of its decision and its substantiated reasons for that decision.

Amendment 120

Council common position
Article 41 – paragraph 2

Council common position	*Amendment*
By way of derogation from paragraph 1, the Member State may authorise the plant protection product where:	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;	***(a)*** it contains a candidate of substitution;
(c) Article 30 has been applied; or	***(b)*** Article 30 has been applied; or
(d) it contains a substance approved in accordance with Article 4(7).	***(c)*** it contains a substance approved in accordance with Article 4(7).

Amendment 121

Council common position
Article 41 – paragraph 2 a (new)

Council common position	*Amendment*
	2a. A Member State may also refuse authorisation of the plant protection product in its territory if it has substantiated reasons to consider that the authorisation of this product would counteract the objectives of its national action plan.

Amendment 122

Council common position
Article 42 – paragraph 1 - point a

Council common position	*Amendment*
(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;	(a) a copy of the authorisation granted by the reference Member State as well as, ***where requested,*** a translation of the authorisation into an official ***or national*** language of the Member State receiving the application;

Justification

Clarification to achieve consistency with translation requirements in Article 33(5). A general translation requirement without request undermines the efficiency of the process.

Amendment 123

Council common position
Article 42 – paragraph 2

Council common position	*Amendment*
2. The Member State to which an application under Article 40 is submitted shall decide on the application within ***90***	2. The Member State to which an application under Article 40 is submitted shall decide on the application within ***180***

days.	***days***.

Justification

We need to secure the fastest possible authorisation procedure compatible with a high protection of human health and the environment. This means, however, that if Member States are to take full account of the relevant and specific circumstances within their territory before authorising or refusing to authorise a product authorised in another Member State - rather than automatically approve the authorisation from another Member State - 90 days is inadequate.

Reinstating first reading Amendment 154.

Amendment 124

Council common position
Article 43 – paragraph 3 – subparagraph 2

Council common position	*Amendment*
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***.	The Member State referred to in Article 35 shall coordinate the compliance check and assessment of the information submitted ***to*** all Member States ***that received an application***.

Amendment 125

Council common position
Article 43 – paragraph 4

Council common position	*Amendment*
4. Guidelines on the authorisation of compliance checks may be established in accordance with the ***advisory*** procedure referred to in ***Article 79(2).***	4. Guidelines on the authorisation of compliance checks may be established in accordance with the ***regulatory*** procedure referred to in ***Article 79(3).***

Justification

Compromise proposal based on amendment 158 from first reading.

Amendment 126

Council common position
Article 44 – paragraph 3 – point (c a) (new)

Council common position	*Amendment*
	(ca) on the basis of developments in scientific and technical knowledge the manner of use and amounts used can be modified;

Justification

In the proposed text an important provision from Directive 91/414 Article 4(6) is missing. This Article states that the authorisation shall be modified if it is established that on the basis of developments in scientific and technical knowledge the manner of use and amount used can be modified. This obligation keeps the authorisation conditions up to date with scientific developments and is an example of a practical application of the precautionary principle.

Reinstating first reading Amendment 160.

Amendment 127

Council common position
Article 44 – paragraph 4

Council common position	*Amendment*
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 ***second to fourth subparagraphs of Article 36(3) have*** been applied. Article 46 shall apply where appropriate.	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 shall withdraw or amend the authorisation accordingly taking into account national conditions and risk mitigation measures except for cases where ***Article 36(2a) has*** been applied. Article 46 shall apply where appropriate.

Amendment 128

Council common position
Article 46 – paragraph 2

Council common position	*Amendment*
Where the reasons for withdrawal, amendment or not renewing the authorisation ***permit it the grace period shall be limited and not exceed six months for the placing on the market and an additional maximum of one year for the disposal, storage, and use of existing stocks of the plant protection products concerned.***	Where the reasons for withdrawal, amendment or not renewing the authorisation ***are not related to the protection of human and animal health or the environment, grace periods for using up stocks of the plant protection products concerned shall be granted for a period not longer than one season. If the reasons for withdrawal, amendment or not renewing the authorisation are related to the protection of human and animal health or the environment then there shall be no time period for using up stocks of the plant protection products concerned and all sales and use of such products shall cease with immediate effect once the decision of withdrawal or non-renewal has been taken***.

Justification

Where the reasons for withdrawal, amendment or not renewing the authorization are related to the protection of human and animal health and the environment then the sale and use of such pesticides should cease with immediate effect.

Reinstating first reaading Amendment 162.

Amendment 129

Council common position
Article 46 a (new)

Council common position	*Amendment*
	Article 46 a
	Disposal and destruction of unauthorised plant protection products
	Notwithstanding the provisions of Article 46, stocks of unauthorised plant

protection products shall be safely disposed of and destroyed under the responsibility of the former authorisation holder.

Justification

Stocks of obsolete pesticides pose serious hazards to human health and the environment in many Member States and third countries. The producers shall be required to assure safe disposal and destruction of these hazardous substances.

Reinstating first reading Amendment 163.

Amendment 130

Council common position
Article 46 b (new)

Council common position	*Amendment*
	Article 46b
	Imports
	Imported non-food materials or articles shall not contain residues of active substances that have not been approved in accordance with the provisions of this Regulation.

Justification

In order both to protect human health and the competitiveness of the European industry, imported non-food materials or articles should not contain active substances that have not been approved in the EU.

Reinstating first reading Amendment 164.

Amendment 131

Council common position
Article 47 a (new)

Council common position	*Amendment*
	Article 47a
	Placing on the market and use of

reduced-risk plant protection products

1. Notwithstanding Article 29, a plant protection product shall be authorised as a reduced-risk product if it meets the following requirements:

(a) at least one of the active substances that it contains is a substance as defined in Article 22;

(b) all the low-risk active substances, safeners and synergists contained in it have been approved under Chapter II;

(c) it entails, in the light of scientific or technical knowledge, considerably fewer risks to human or animal health or the environment than a comparable plant protection product that is already authorised;

(d) it is sufficiently effective;

(e) it complies with points (b), (c) and (e) to (h) of Article 29(1).

2. Applicants for authorisation of a reduced-risk plant protection product shall demonstrate that the requirements set out in paragraph 1 are met and shall accompany the application with a complete and 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 on whether to approve an application for authorisation of a reduced-risk plant protection product.

The period shall be 90 days where an authorisation has already been granted for the same reduced-risk plant protection product by another Member State.

Where the Member State needs additional information, it shall set a time limit for the applicant to supply it. In that case the period of 120 days shall be extended by the additional time limit granted by the Member State.

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

Justification

To encourage the development of less harmful plant protection products, this introduces a new category of low-risk plant protection products that present a lower risk than current products on the market and contain at least one low-risk active substance. This category of plant protection products should receive certain advantages such as a longer period of data protection and tax exemption.

Reinstating first reading Amendment 168.

Amendment 132

Council common position
Article 50 – paragraph 1 - introduction and points (a) and (b)

Council common position	*Amendment*
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 where the comparative assessment weighing up the risks and benefits, as set out in Annex IV, demonstrates that:	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 ***for use in a given crop*** containing a candidate for substitution 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; and	(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; and
(b) the plant protection ***product*** or non-chemical control or prevention ***method*** referred to in point (a) does not present significant economic or practical disadvantages; and	(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; and
(c) the chemical diversity of the active substances ***is*** adequate to minimize the	(c) the chemical diversity of the active substances, ***where relevant, or methods***

occurrence of resistance in the target organism; and	***and practices of crop management and pest prevention are*** adequate to minimise the occurrence of resistance in the target organism; and

Amendment 133

Council common position
Article 50 – paragraph 3 – subparagraph 2

Council common position	*Amendment*
Such authorisations shall be granted for a period not exceeding ***five years***.	Such authorisations shall be granted for a period not exceeding ***three years.***

Justification

Any authorisation of plant protection products containing a candidate for substitution without comparative assessment should be limited to three years maximum.

Reinstatement of the timeline proposed by the Commission.

Amendment 134

Council common position
Article 50 – paragraph 4 – subparagraph 1

Council common position	*Amendment*
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.***	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 ***four years after authorisation or renewal of the authorisation was granted.***

Justification

Comparative assessment should be done before the end of the authorisation period.

Reinstatement of the timeline proposed by the Commission.

Amendment 135

Council common position
Article 50 – paragraph 5

Council common position	*Amendment*
5. Where a Member State decides to withdraw or amend an authorisation pursuant to paragraph 4, that withdrawal or amendment shall take effect ***five years*** after the decision of the Member State or at the end of the approval period of the candidate for substitution where that period ends earlier.	5. Where a Member State decides to withdraw or amend an authorisation pursuant to paragraph 4, that withdrawal or amendment shall take effect ***two 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.

Justification

The proposed deadline of two years will speed up the process of substitution and give incentive for innovation.

Reinstating first reading Amendment 173.

Amendment 136

Council common position
Article 51 – paragraph 2 a (new)

Council common position	*Amendment*
	2a. Member States may, after authorisation by the Commission, adopt specific measures to facilitate the submission of applications to extend the authorisation for and the submission of applications relating to minor uses.

Justification

Simplification of bureaucracy and encouragement of those concerned to employ plant protection products for minor uses will resolve numerous problems in relation to certain crops. It has been noted that authorisation holders are reluctant to extend authorisations to minor uses owing to the lack of economic interest to industry. Measures are applied in some third countries, such as protection of data for a longer period, provided the authorisation has been extended to minor crops. Provision should be made for similar incentives in the EU in order to avoid a shortage of plant protection products for this type of crop.

Reinstating first reading Amendment 175.

Amendment 137

Council common position
Article 51 – paragraph 4 - subparagraph 1

Council common position	*Amendment*
4. 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.	4. When Member States grant an extension of authorisation for a minor use, they shall inform the authorisation holder, ***who shall*** change the labelling accordingly.

Justification

A correct labelling is pre-eminent for safe use off PPPs. The best way to inform the user is to indicate minor uses on the label and clearly indicate that liability for the indicated use patterns does not lie with the producer.

Partially reinstating first reading Amendment 179.

Amendment 138

Council common position
Article 51 – paragraph 4 a (new)

Council common position	*Amendment*
	Extensions on the basis of this Article shall be separately identified and separate reference shall be made to liability restrictions.

Justification

Regardless of how an extension of the authorisation for minor uses is granted in a Member State, it must be made clear that this is an extension under Article 49 in order to highlight the different legal status compared to an authorisation under Article 4.

Reinstating first reading Amendment 177.

Amendment 139

Council common position
Article 51 – paragraph 6

Council common position	*Amendment*
6. Member States shall establish and regularly update a list of minor uses.	6. Member States shall establish and regularly update a list of minor uses. ***This list shall be made available to the public through official websites of the Member State and of the Commission***.

Justification

To facilitate the exchange of information and improve the information of the interested public Member States and the Commission must make the list available on an official website.

Reinstating first reading Amendment 180.

Amendment 140

Council common position
Article 51 – paragraph 6 a (new)

Council common position	*Amendment*
	6a., Not later than ...*, the Commission shall present a proposal to the European Parliament and the Council for the establishment of a European promotion fund for minor uses. The Fund shall also be entitled to finance additional residue tests for minor uses.
	———
	**** One year after the entry into force of this Regulation.***

Justification

This proposal follows the ITRE line but deletes the reference to European Taxes.

Reinstating first reading Amendment 276.

Amendment 141

Council common position
Article 52 - paragraph 3 - points b and c

Council common position	*Amendment*
(b) they ***are identical in*** specification ***and content of the active substances, safeners and synergists, and in the type of formulation; and***	(b) they ***have either the same*** specification***, or specifications assessed as equivalent under the procedure referred to in Article 38.***
(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.	

Justification

The requirements to determine identity to the reference products are unnecessarily restrictive.

Partially reinstating first reading Amendment 286.

Amendment 142

Council common position
Article 52 – paragraph 3 – subparagraph 1 a (new)

Council common position	*Amendment*
	Plant protection products which do not comply with the condition referred to in subparagraph (a) but which do comply with the all the other conditions referred to in this paragraph shall be deemed to be identical to the reference product if a comparative assessment by a laboratory officially recognised in accordance with the Principles of Good Laboratory Practice, which is submitted to the competent authority of the importing Member State by the applicant, or a comparative assessment by the competent

authority, confirms that the plant protection product in respect of which an import permit is requested is, in substance, identical to the reference product and that the following requirements are met:

(a) the requirements of subparagraph 1, points (b) and (c),

(b) the plant protection product in respect of which an import permit is requested does not contain a co-formulant which has not been assessed,

(c) no co-formulants with essential functions are lacking,

(d) the product does not feature different nominal concentrations of co-formulants with essential functions which are more toxic or ecotoxic than the reference product or are less favourable from the point of view of effectiveness or stability than those of the reference product,

(e) no co-formulants are absent which serve to protect users or third parties.

Justification

Im EuGH Urteil vom 25.02.2008, Az. C-201/06, rügt der EuGH das Fehlen eines vereinfachten Zulassungsverfahrens für Generika, in welchem die wesentliche Übereinstimmung eines Generikums mit einem Referenzerzeugnis überprüft wird. Aufgrund der ausdrücklichen Forderung des Gerichtshofes nach Einführung eines solchen Verfahrens ist dessen Einführung in die vorliegende Verordnung dringend geboten, zumal der jetzt vorliegende Kompromissvorschlag eine solche Regelung vollständig vermissen lässt. Damit würde für die Paralleleinfuhr von Generika eine gesetzliche Lücke entstehen, die die Garantie des freien Warenverkehrs aus Art. 28 EG auch für solche Produkte verletzt.

Amendment 143

Council common position
Article 52 – paragraph 10 a (new)

Council common position	*Amendment*
	10a. Without prejudice to Article 63, Member State authorities shall make publicly available information about

parallel trade permits.

Justification

Council introduced new provisions concerning identicality of parallel traded pesticides. Under transparency considerations, the information about parallel trade permits should be made available.

Amendment 144

Council common position
Article 54 – paragraph 5

Council common position	*Amendment*
5. Detailed rules for the application of this Article, in particular the maximum quantities of plant protection products that may be released during experiments or tests and the minimum data to be submitted in accordance with paragraph 2, may be adopted in accordance with the regulatory procedure referred to in ***Article 79(3)***.	5. Detailed rules for the application of this Article, in particular the maximum quantities of plant protection products that may be released during experiments or tests and the minimum data to be submitted in accordance with paragraph 2, may be adopted in accordance with the regulatory procedure ***with scrutiny*** referred to in ***Article 79(4)***.

Justification

This amendment is necessary to bring the text into line with the provisions of the new decision on comitology.

Reinstating first reading Amendment 184.

Amendment 145

Council common position
Article 56 – paragraph 1 – subparagraph 3

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

Justification

The information should include possible adverse reactions in humans, animals and the environment.

Reinstating first reading Amendment 188.

Amendment 146

Council common position
Article 56 – paragraph 3 – subparagraph 1

Council common position	*Amendment*
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.	3. ***The Member State receiving such notification shall immediately pass it on to the other Member States.*** Without prejudice to the right of Member States to adopt interim protective measures, the Member State which granted an authorisation shall evaluate the information received and inform the other Member States, where it decides to withdraw or amend the authorisation under Article 44.

Justification

To provide a mechanism for Member States to share information on potentially harmful effects.

Reinstating first reading Amendment 189.

Amendment 147

Council common position
Article 57 – paragraph 1 – introduction

Council common position	*Amendment*
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:	1.Member States shall ***forward to the Authority, who shall make*** electronically available to the public, ***information*** on plant protection products authorised or withdrawn in accordance with this Regulation, containing at least:

Justification

In order to facilitate data sharing it is necessary to establish one central database with all the information on tests and studies carried out previously for the purposes of this Regulation, managed by the Authority. Applicants would then have to consult only one database before carrying out any tests or studies.

Reinstating first reading Amendment 191.

Amendment 148

Council common position
Article 59 – paragraph 1 – subparagraph 7

Council common position	*Amendment*
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 with due changes.***	A study shall ***not*** be protected if it was necessary for the renewal or review of an authorisation.

Justification

Reinstates Art. 56, par. 1 - subpar. 5 (COMM_2008_0093 not amended by EP in first reading)

Amendment 149

Council common position
Article 60 - paragraphs 1 and 2

Council common position	*Amendment*
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.***	1. For each active substance, safener and synergist and adjuvant, rapporteur Member States shall ***forward to the Authority, who shall make available to the public at the moment of publishing the draft assessment report in accordance with Article 12***, a list of the test and study reports necessary for first approval, amendment of approval conditions or renewal of the approval ***and a summary of the results of the test and study reports to***

	establish the efficacy of the substance and its harmlessness to humans, animals, plants and the environment.
2. For each plant protection product which they authorise, Member States shall ***keep and*** make available to ***any interested party upon request***:	2. For each plant protection product which they authorise, Member States shall ***forward to the Authority, who shall*** make available to ***the public, at the moment of publishing the draft assessment report in accordance with Article 12***:
(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	(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.	(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;
	(ba) a summary of the results of the test and study reports to establish the efficacy of the product and its harmlessness to humans, animals, plants and the environment.

Justification

In order to facilitate data sharing it is necessary to establish one central database with all the information on tests and studies carried out previously for the purposes of this Regulation, managed by the Authority. Applicants would then have to consult only one database before carrying out any tests or studies.

Reinstating first reading Amendment 299.

Amendment 150

Council common position
Article 61 – paragraph -1 (new)

Council common position	*Amendment*
	-1. Any persons intending to seek an authorisation for a plant protection product shall, before carrying out tests or studies, consult the database referred to in

Articles 35a and 57.

Justification

To ensure maximum data sharing, applicants should consult the Authority database in order to find all the necessary information on tests and studies carried out previously for the purposes of this Regulation.

Reinstating first reading Amendment 201.

Amendment 151

Council common position
Article 61 – paragraph 2

Council common position	*Amendment*
2. The competent authority of the Member State, where satisfied that the prospective applicant intends to apply for an authorisation, 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.	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.

Justification

Data protection must also be extended to data for renewal and review of an authorisation to protect medium-sized companies and the research based sectors of the plant protection industry.

Reinstating first reading Amendment 203.

Amendment 152

Council common position
Article 61 – paragraph 3

Council common position	*Amendment*
3. The prospective applicant for the authorisation and the holder or holders of relevant authorisations shall take all reasonable steps to reach agreement on the sharing of any test and study reports	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

protected under Article 59 that are required by the applicant for authorisation of a plant protection product.	sharing of any test and study reports protected under Article 59 that are required by the applicant for ***the*** authorisation***, or the renewal or review thereof,*** of a plant protection product. ***Such an agreement may be replaced by submission of the matter to an arbitration board and acceptance of the arbitration order. In an endeavour to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way, the Commission may, in accordance with the regulatory procedure referred to in Article 79(3), adopt cost-sharing guidelines based on those principles.***

Justification

Data protection must also be extended to data for renewal and review of an authorisation to protect medium-sized companies and the research based sectors of the plant protection industry.

In order to minimise unnecessary duplication of tests, it is necessary to put in place arbitration- and cost-sharing mechanisms that could help applicants and holders of authorisation to reach an agreement. These provisions have also been introduced in the REACH Directive.

Reinstating first reading Amendment 204.

Amendment 153

Council common position
Article 61 – paragraph 3 a (new)

Council common position	*Amendment*
	3a. Where the Member State considers that a monopoly might be created, and the prospective applicant and the holder or holders of the authorisations for plant protection products containing the same active substance, safener, or synergist cannot reach agreement on the sharing of any tests and studies involving vertebrate animals, the prospective applicant shall inform the competent authority of the Member State to that effect. The two parties shall nevertheless agree which

	courts and tribunals have jurisdiction for the purposes of of Article 62(4).

Justification

The new regulation should lay down special provisions to prevent monopolies being created on the market in plant protection products.

Reinstating first reading Amendment 205.

Amendment 154

Council common position
Article 62 - paragraph 2

Council common position	*Amendment*
2. The prospective applicant and the holder or holders of the relevant authorisations shall make every effort to ensure that they share tests and studies involving vertebrate animals. 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.	2. The prospective applicant and the holder or holders of the relevant authorisations shall make every effort to ensure that they share tests and studies involving vertebrate animals. The costs of sharing the test and study reports shall be determined in a fair, transparent and non-discriminatory way. The prospective applicant is required to share in the costs ***that accrue during the full process*** of ***generating the*** information he is required to submit to meet the authorisation requirements.

Justification

The cost of generating data is greater than the net cost of the study. The prospective applicant should be obliged to participate in the full costs of the data he is then entitled to use for his own registration purposes.

Reinstating first reading Amendment 207.

Amendment 155

Council common position
Article 62 - paragraph 3 a (new)

Council common position	*Amendment*
	3a. Not later than ...*, the Commission shall carry out a review of the provisions in this Regulation concerning data

protection for tests and studies involving vertebrate animals. The Commission shall submit this assessment, and any proposed amendments for limiting the data protection with regard to animal experiments, to the European Parliament and the Council.

**** Seven years after the entry into force of this Regulation.***

Justification

Under this proposal, the results from tests involving vertebrate animals enjoy data protection, but such data have to be shared. This compromise is at present necessary for practical reasons (otherwise many new products will not be marketable) but should be evaluated in due course. A less strict data protection regime will still reduce the number of tests on vertebrate animals.

Reinstating first reading Amendment 208.

Amendment 156

Council common position
Article 63 – paragraph 2 - introductory part

Council common position	*Amendment*
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:	2. Disclosure of the following information shall be deemed to undermine the protection of the commercial interests or of privacy and the integrity of the individuals concerned:

Justification

From a legal point of view "normally" is undefined and opens the door for arbitrariness.

Amendment 157

Council common position
Article 63 - paragraph 2 a (new)

Council common position	*Amendment*
	2a. For test data, including study reports,

which have been provided by an applicant to support a decision to authorise or amend a plant protection product under this Regulation, such data may be viewed by interested parties in specific locations identified by the Commission, the Authority or the Member States. Such data shall not be made public through the provision of copies or through any other means of publication (including electronic publication).

Justification

The public has a legitimate interest in the access to information, which should be guaranteed under this Regulation in accordance with the Aarhus Convention. The concept of informing the general public should however prevent misuse and unfair competition. The proposed reading room concept will strike the right balance as interested third parties have access to confidential information but potential competitors can not misuse the system to obtain sensitive commercial data.

Reinstating first reading Amendment 211.

Amendment 158

Council common position
Article 65 - paragraph 3 a (new)

Council common position	*Amendment*
	3a. Food products which do not comply with the provisions of Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children[1] shall be labelled "not suitable for infants and young children".
	[1] OJ L 339, 6.12.2006, p. 16.

Justification

Food containing residues of plant protection products, which are above the limits foreseen in Directive 2006/125/EC, should be clearly labelled with a respective warning message providing this information for the final consumer.

Reinstating first reading Amendment 214.

Amendment 159

Council common position
Article 66 - paragraph 2 a (new)

Council common position	*Amendment*
	2a. Member States may prohibit or restrict the advertising of plant protection products in certain media.

Justification

It is appropriate to retain any national restrictions which may exist in this area.

Reinstating first reading Amendment 215.

Amendment 160

Council common position
Article 67 - paragraph 1

Council common position	*Amendment*
1. Producers, suppliers, distributors***,*** importers, exporters and professional users of plant protection products shall keep records of the plant protection products they produce, import, export, store, use or place on the market for at least ***three years.***	1. Producers, suppliers, distributors, importers, exporters and professional users of plant protection products shall keep records of the plant protection products they produce, import, export, store, use or place on the market for at least ***ten years after the end of production or use.***
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 ***may*** request access to ***this information by addressing the competent authority.***	They shall make the information contained in these records available to the competent authority. ***They shall also keep this information available for neighbours and residents, retailers or*** the drinking water industry ***who*** request ***direct*** access to ***it. The information on all applications of plant protection products on a given agricultural product shall be provided to retailers and wholesalers using a standardised format.***
	The standardised format for the provision of the information referred to in the subparagraph above shall be established in accordance with the advisory procedure referred to in Article 79(2).

Justification

Amendment 161

Council common position
Article 67 - paragraph 1 a (new)

Council common position	*Amendment*
	1a. Producers of plant protection products shall undertake post-registration monitoring. They shall notify the competent authorities of any relevant information and keep the information available to relevant stakeholders on request.

Justification

The responsibility of producers of plant protection products should not end with the authorisation of their substance. To ensure protection of the environment and in particular of water resources, it is important that post-registration monitoring takes place and that this information is kept available for the competent authorities as well as relevant stakeholders (e.g. drinking water industry) who request access to it. It should not be for the downstream sectors to deal with potential negative effects of a substance on the aquatic environment.

Reinstating first reading Amendment 217.

Amendment 162

Council common position
Article 77

Council common position	*Amendment*
The Commission may, in accordance with the ***advisory*** procedure referred to in ***Article 79(2)***, adopt or amend technical and other guidance documents for the implementation of this Regulation. The Commission may ask the Authority to prepare or to contribute to such guidance documents.	The Commission may, in accordance with the ***regulatory*** procedure referred to in ***Article 79(3),*** adopt or amend technical and other guidance documents for the implementation of this Regulation. The Commission may ask the Authority to prepare or to contribute to such guidance documents. ***The Authority may initiate the preparation or revision of guidance documents for the risk assessment of active substances.***

Justification

EFSA should be allowed to initiate itself the preparation or revision of guidance documents related to risk assessment.

Compromise amendement based on first reading Amendment 224.

Amendment 163

Council common position
Article 78 – paragraph 1 – point (f)

Council common position	*Amendment*
(f) a Regulation establishing a work program for safeners and synergists referred to in Article 26;	***deleted***

Justification

This work programme should be adopted in codecision.

Amendment of a new paragraph introduced by Council, in line with amendment 108 of first reading.

Amendment 164

Council common position
Article 78 - paragraph 3

Council common position	*Amendment*
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.	3. In accordance with the ***regulatory*** procedure ***with scrutiny*** referred to in ***Article 79(4),*** a Regulation shall be adopted ***incorporating*** the list of active substances included in Annex I to Directive 91/414/EEC ***into Annex IIa of this Regulation***. Those substances shall be deemed to have been approved under this Regulation.

Justification

This amendment is necessary to bring the text into line with the provisions of the new decision on comitology.

Reinstating first reading Amendment 226, plus an additional modification to ensure coherence with the amendment to Article 13(2) which establishes an annex for the list of active substances.

Amendment 165

Council common position
Article 80 – paragraph 7

Council common position	*Amendment*
7. By …*, the Commission shall establish a list of substances included in Annex I of 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.	7. By …*, the Commission shall establish a list of substances included in Annex I of 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.
* Note to OJ: ***78 months*** from the date of entry into force of this Regulation.	* Note to OJ: ***36 months*** from the date of entry into force of this Regulation.

Justification

There is no good justification to wait for six and a half years to adopt the list of substances that are candidates for substitution. This should be done after 3 years at the latest.

Amendment of new paragraph introduced by Council.

Amendment 166

Council common position
Article 82

Council common position	*Amendment*
By ...*, 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	By ...*, 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(2a) and (3)*** and Article 50(2) 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***, including on food prices,*** as well as on human health and on the environment. The report may be accompanied, if necessary, by the

accompanied, if necessary, by the appropriate legislative proposals to amend those provisions.	appropriate legislative proposals to amend those provisions.

Justification

Amendment 167
Council common position
Annex I

Council common position	*Amendment*
Annex I	***deleted***
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	

Justification

The proposed zoning system is misleading because it refers to zones which do not have relatively similar agriculture, plant health and environmental conditions. The proposed zoning system undermines the national authorisation and it is not in line with the EC principle of proportionality and subsidiarity because it is going beyond what is necessary to speeding up the decision making process These objectives can be reached by amending the mutual recognition system without the concept of zoning.

Reinstating first reading Amendment 230.

Amendment 168

Council common position
Annex II - point 3.6.1

Council common position	*Amendment*
3.6.1. Where relevant, an ADI, AOEL and ARfD shall be established. When establishing such values an appropriate safety margin of at least 100 shall be ensured taking into account the type and severity of effects and the vulnerability of ***specific groups of the population***.	3.6.1. 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, ***possible combination effects*** and the vulnerability of ***vulnerable groups.***

Justification

Amendment 169

Council common position
Annex II - point 3.6.5

Council common position	*Amendment*
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, i.e. 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	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 ***, taking due account of likely combination effects,*** to have endocrine disrupting properties that may cause adverse effect in humans, ***so that, for example, it is not or does not have to be classified, in accordance with the provisions of Directive 67/548/EEC, as toxic to reproduction category 3,*** 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, i.e. the product is used in closed systems or in other conditions excluding contact with

396/2005.	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. ***Further specific scientific criteria for the determination of endocrine disrupting properties shall be adopted by ... * in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).*** **** Note to OJ: 18 months from the date of entry into force of this Regulation"***

Justification

Amendment 170

Council common position
Annex II - point 3.6.5a (new)

Council common position	*Amendment*
	3.6.5a. An active substance, safener or synergist shall only be approved if, on the basis of an assessment or other available data and information including a review of the scientific literature, it is not considered to cause a significant risk (affecting at least one in a million citizens) of developmental neurotoxic or immunotoxic properties in humans, taking into account exposure during embryonic/foetal life and/or during childhood as well as likely combination effects, 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, i.e. 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.

Justification

Amendment 171

Council common position
Annex II - point 3.7.2. - introduction - subparagraph 1

Council common position	*Amendment*
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***.	3.7.2. An active substance, safener or synergist shall only be approved if it, ***and its transformation products or residues, are*** not considered to be persistent, bioaccumulative and toxic (PBT) ***substances.***

Justification

It is important to include transformation products or residues.

Partially reinstating first reading Amendment 235.

Amendment 172

Council common position
Annex II - point 3.7.3. - introduction - subparagraph 1

Council common position	*Amendment*
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).	3.7.3. An active substance, safener or synergist shall only be approved if it ***or its transformation products or residues, are*** not considered to be very persistent and very bioaccumulative ***substances*** (vPvB).

Justification

It is important to include transformation products or residues.

Partially reinstating first reading Amendment 239.

Amendment 173

Council common position
Annex II - point 3.7.3.2. - subparagraph 1 a (new)

Council common position	*Amendment*
	It also fulfils the very bioaccumulative criterion when there is evidence of very high bioaccumulation in other species, or monitoring data in biota indicate that the bioaccumulation potential of the chemical is sufficient to be of concern.

Justification

The criteria in the Commission proposal are taken from REACH, even though the deficiency of those criteria has already been acknowledged within REACH, as they are subject to a review within 1 year. The REACH criteria for PBT and vPvB substances are so rigid that even well-known PBT substances, such as e.g. those listed by the Stockholm Convention on persistent organic pollutants, are not identified. In line with the provisions of that Convention, it is important to allow the use of equivalent evidence and not just tick-box test results that are often not available or not even applicable.

Reinstating first reading Amendment 241.

Amendment 174

Council common position
Annex II - point 3.8.2 a (new)

Council common position	*Amendment*
	3.8.2a. An active substance, safener or synergist shall not be approved unless it is established that under realistic proposed conditions of use:
	- the direct or indirect exposure of honeybees to that active substance in a plant protection product is negligible, or
	- it is clearly established through an appropriate risk assessment that there are no unacceptable acute or chronic, lethal or sublethal effects on honeybee larvae, honeybee behaviour, or colony survival and development.

Justification

Amendment 175

Council common position
Annex II - point 3.9 b (new)

Council common position	*Amendment*
	3.9b. Exclusion of priority hazardous substances
	Substances on the list of priority hazardous substances for water policy annexed to Directive 2000/60/EC, should not be approved.

Justification

This amendment brings the Regulation in line with existing legislation and in coherence with the Water Framework Directive.

Reinstating first reading Amendment 247.

Amendment 176

Council common position
Annex II a (new)

Council common position	*Amendment*
	Annex II a
	List of active substances approved for inclusion in plant protection products

Justification

The inclusion of approved substances in an Annex of the Regulation should be maintained.

Reinstating first reading Amendment 249.

Amendment 177

Council common position
Annex IV - point 3 - subparagraph 2 a (new)

Council common position	*Amendment*
	The comparative assessment shall take authorised minor uses into account.

Justification

Reinstating first reading Amendment 253.

PROCEDURE

Title	The placing of plant protection products on the market
References	11119/8/2008 – C6-0326/2008 – 2006/0136(COD)
Date of Parliament's first reading – P number	23.10.2007 T6-0445/2007
Commission proposal	COM(2006)0388 - C6-0245/2006
Amended Commission proposal	COM(2008)0093
Date receipt of common position announced in plenary	25.9.2008
Committee responsible Date announced in plenary	ENVI 25.9.2008
Rapporteur(s) Date appointed	Hiltrud Breyer 29.11.2005
Discussed in committee	6.10.2008
Date adopted	5.11.2008
Result of final vote	+: 39 –: 20 0: 6
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Margrete Auken, Liam Aylward, Pilar Ayuso, Irena Belohorská, Johannes Blokland, John Bowis, Frieda Brepoels, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Magor Imre Csibi, Chris Davies, Avril Doyle, Mojca Drčar Murko, Edite Estrela, Anne Ferreira, Karl-Heinz Florenz, Alessandro Foglietta, Matthias Groote, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Gyula Hegyi, Jens Holm, Marie Anne Isler Béguin, Caroline Jackson, Dan Jørgensen, Christa Klaß, Urszula Krupa, Marios Matsakis, Linda McAvan, Roberto Musacchio, Riitta Myller, Péter Olajos, Miroslav Ouzký, Vladko Todorov Panayotov, Vittorio Prodi, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Daciana Octavia Sârbu, Amalia Sartori, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Kathy Sinnott, Bogusław Sonik, Salvatore Tatarella, Antonios Trakatellis, Thomas Ulmer, Anja Weisgerber, Anders Wijkman, Glenis Willmott
Substitute(s) present for the final vote	Nicodim Bulzesc, Bairbre de Brún, Genowefa Grabowska, Miloš Koterec, Anne Laperrouze, Johannes Lebech, Caroline Lucas, Robert Sturdy, Andres Tarand, Lambert van Nistelrooij