EUROPEAN PARLIAMENT

2004 *2009*

Committee on the Environment, Public Health and Food Safety

2006/0136(COD)

16.10.2008

AMENDMENTS
215 - 325

Draft recommendation for second reading
Hiltrud Breyer
(PE412.104v01-00)

Council common position for adopting a regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Council common position
(11119/8/2008 – C6-0326/2008 – 2006/0136(COD))

AM_Com_LegRecomm

Amendment 215
Liam Aylward

Council common position
Recital 6

Council common position	*Amendment*
(6) Plant production has a very important place in the Community. One of the most important ways of protecting plants and plant products against harmful organisms, including weeds, and of improving agricultural production is the use of plant protection products.	(6) Plant production has a very important place in the Community. One of the most important ways of protecting plants and plant products against harmful organisms, including weeds, and of improving agricultural production is the use of plant protection products. ***It should be ensured that a complete impact assessment, including the impact of any cut-off system on agricultural activity, has been undertaken.***

Or. en

Justification

Having analysed the initial impact assessment of the Commission, no data could be found on the impact of changing from a risk-based authorisation system to a hazard-based one. This is absent vital information which should be provided to the institutions in order to make an informed decision.

Amendment 216
Robert Sturdy, Caroline Jackson, Richard Seeber

Council common position
Recital 6 a (new)

Council common position	*Amendment*
	(6a) Therefore, as the Regulation could have an impact on the landscape and the supply and price of plants and food, the Commission should carry out a thorough and broad-reaching EU-wide impact assessment of all aspects of this Regulation on all industry sectors affected

including agriculture, horticulture, gardening, landscaping and public and private amenities prior to its implementation.

Or. en

Justification

This recognizes the importance of plant protection products. The extent to which this legislation will affect member states production practices and capabilities should be fully understood and evaluated in the interest of consumers, public health, farmers and industry.

Amendment 217
Caroline Lucas

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.***

Or. en

Justification

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

Amendment 218
Caroline Lucas

Council common position
Recital 17

Council common position	*Amendment*
(17) Certain substances which are not predominantly used as plant protection products may be of value for plant protection, but the economic interest of applying for approval may be limited. Therefore, specific provisions should ensure that such substances, as far as their risks are acceptable, may also be approved for plant protection use.	(17) Certain substances which are not predominantly used as plant protection products may be of value for plant protection, but the economic interest of applying for approval may be limited. Therefore, specific provisions should ensure that such substances, as far as their risks are ***deemed*** acceptable ***by all relevant stakeholders,*** may also be approved for plant protection use.

Or. en

Justification

It is supposed to be society that designates what is an "acceptable risk" and so if society feels that a risk is not acceptable, then what is considered acceptable is redefined and the risk assessed accordingly. Therefore risks can only be deemed acceptable by all relevant Stakeholders. This must include representatives of rural residents and communities, farmers groups, (both organic and conventional) and environmental and consumer groups as well as the public in general.

Reinstating first reading Amendment 13.

Amendment 219
Caroline Lucas

Council common position
Recital 25

Council common position	*Amendment*
(25) In case the decision on approval cannot be finalised within the period of time provided for due to reasons not falling under the responsibility of the applicant, Member States should be able to grant the provisional authorisations for	***deleted***

a limited period of time in order to facilitate the transition to the approval procedure provided for under this Regulation. In the light of the experience gained with the approval of the active substances under this Regulation, the provisions on provisional authorisations should cease to apply or be extended after the period of five years, if necessary.

Or. en

Justification

There seems little point in having a Regulation with high standards if it gives the option to depart from those standards. There shouldn't be any reason for a delay in making a regulatory decision, as that is what the regulators are there for. Therefore this recital should be deleted.

Amendment of a new recital introduced by Council.

Amendment 220
Hiltrud Breyer

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 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***	(27) The principle of mutual recognition is one of the means of ensuring the free movement of goods within the 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

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.	because of specific agricultural ***or environmental*** circumstances, ***that may, 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 Pesticide Action Plan.***

Or. en

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 221
Kathy Sinnott

Council common position
Recital 28 a (new)

Council common position	*Amendment*
	(28a) Imported food should be subject to the same standards with regard to plant protection and should not be treated with substances that have not been approved in accordance with the provisions of this Regulation.

Or. en

Justification

In order to protect human health it is important that imported food is not exposed to plant protection substances that are not approved by the EU. Importing foods not subject to the same standards would be a double standard for the health of external producers and disadvantage EU farmers.

Amendment 222
Caroline Lucas

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.

Or. en

Justification

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

Reinstating first reading Amendment 26.

Amendment 223
Hanne Dahl

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	***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.	the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants. ***3. Member States may not be prevented from applying the precautionary principle in restricting or prohibiting pesticides.*** ***4. 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.*** ***5. Member States may impose a ban on the use and marketing of EU-authorised pesticides where they are found in measurable quantities outside the root zone.***

Or. en

Justification

Paragraph 3 is to make the provisions of this Regulation minimum rule, thereby enabling individual Member States to make further progress with the development of pesticides.

Paragraphs 4 and 5 are important to ensure that the achievements secured in the groundwater directive are carried over into this Regulation in order to safeguard drinking water.

Amendment 224
Mojca Drčar Murko

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;***

Or. en

Justification

Reintroduction of amendment adopted in 1st reading.

Amendment 225
Caroline Lucas

Council common position
Article 3 – point 23

Council common position	*Amendment*
23) "greenhouse"	23) "greenhouse"
A walk-in, static, closed place of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and ***prevents*** release of plant protection products into the environment.	A walk-in, static, closed place of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and ***reduces*** release of plant protection products into the environment.
For the purpose of this Regulation, closed places of plant production where the outer shell is not translucent (e.g. for production of mushrooms or witloof) are also considered as greenhouses;	For the purpose of this Regulation, closed places of plant production where the outer shell is not translucent (e.g. for production of mushrooms or witloof) are also considered as greenhouses;

Or. en

Justification

Whilst use of pesticides in greenhouses may well reduce the release of pesticides into the environment it cannot be stated categorically that it will prevent it altogether, as greenhouses often have windows which may be opened and doors may also be left open for any length of time which could result in release of pesticides into the environment.

Amendment of new text introduced by Council.

Amendment 226
Pilar Ayuso

Council common position
Article 3 –point 23 a (new)

Council common position	*Amendment*
	23a) 'area of application'
	Specific plants, plant species or plant products together with those harmful organisms against which plants and plant products shall be protected or any other purpose for which the plant protection product shall be used;

Or. en

Justification

There is a need for clarification. "Area" is for example used in Article 6h.

Amendment 227
Anja Weisgerber

Council common position
Article 4 – paragraph 1 – subparagraph 2

Council common position	*Amendment*
The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.	The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied***, including points 3.6.5 and 3.8.2 once specific scientific criteria have been adopted for these annex points in accordance with Article 78(2)***.

Or. en

Justification

This sentence has been newly added by Council. The proposed changes acknowledge that endocrine disruption has not been defined in this regulation and therefore can not be used to ban an active substance until clear implementation rules have been adopted and enforced.

Amendment 228
Johannes Blokland

Council common position
Article 4 – paragraph 1 – subparagraph 2

Council common position	*Amendment*
The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.	The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied***, including points 3.6.5 and 3.8.2 once specific scientific criteria have been adopted for these annex points in accordance with Article 78(2)***.

Or. en

Justification

This sentence has been newly added by Council. The proposed changes acknowledge that endocrine disruption has not been defined in this regulation and therefore can not be used to ban an active substance until clear implementation rules have been adopted and enforced.

Amendment 229
Liam Aylward, Christa Klaß, Anne Laperrouze

Council common position
Article 4 – paragraph 1 – subparagraph 2

Council common position	*Amendment*
The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.	The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of annex II are satisfied***, including points 3.6.5 and 3.8.2 once specific scientific criteria have been adopted for these annex points in accordance with Article 78(2)***.

Or. en

Justification

This sentence has been newly added by Council. The proposed changes acknowledge that endocrine disruption has not been defined in this regulation and therefore can not be used to ban an active substance until clear implementation rules have been adopted and enforced

Amendment 230
Caroline Lucas

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***,*** or on ***surface water or***

groundwater;

Or. en

Justification

All the various population subgroups at risk of exposure to pesticides must be protected. This includes professional and non-professional users, residents, bystanders, workers, specific vulnerable groups and consumers, directly or indirectly exposed through air, food, feed, water and the environment. Considering agricultural pesticides are often used in mixtures, then the potential adverse health effects of mixtures, including any synergistic effects, must be assessed prior to their approval.

Reinstating first reading Amendment 296.

Amendment 231
Hiltrud Breyer

Council common position
Article 4 – paragraph 2 – subparagraph 2

Council common position	*Amendment*
For residues ***which are of toxicological, ecotoxicological, environmental or drinking water relevance,*** there shall be methods in general use for measuring them. Analytical standards shall be commonly available.	For residues ***of all approved substances***, there shall be ***standardised*** methods in general use for measuring them ***which are sufficiently sensitive with respect to any technically detectable levels that could be present in any environmental and biological media or be of drinking water relevance. The residues shall be detectable with the common multi-residue methods as applied by Community reference laboratories.*** Analytical standards shall be commonly available.

Or. en

Justification

This amendment introduces two dimensions into this article. Firstly, that for all authorised pesticides there shall be methods available to identify residues. This is currently not the case, as standard laboratory equipment is capable of identifying only a limited number of substances' residues. Secondly, the methods used to assess health effects 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 detected by methods in general use.

Reinstating first reading Amendment 62. Replaces amendment 56 by the rapporteur.

Amendment 232
Caroline Lucas

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 cumulative and synergistic effects**,** or on ***surface water and*** groundwater;

Or. en

Justification

All the various subgroups at risk of exposure to pesticides must be protected, particularly residents, who can be regularly exposed to pesticides from various sources. These include long term exposure to airborne pesticides, exposure to vapours, which can occur days, weeks, even months after application, reactivation, precipitation, pesticides transported from outdoor applications and redistributed indoors, as well as long-range transportation, as pesticides can travel in the air for miles.

Reinstating first reading Amendment 297.

Amendment 233
Anne Ferreira, Stéphane Le Foll

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 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.***	7. By way of derogation from paragraph 1, where on the basis of documented evidence***, particularly an analysis of the scientific documentation,*** an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means, such active substance may be approved for a period ***limited to two*** 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.
	This approval may be renewed once, in accordance with the provisions of the previous subparagraph.
	In the case of these substances, the maximum limits applicable to residues have been laid down 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*** toxic for reproduction ***category 1***.	This derogation shall not apply to active substances which are or have to be classified in accordance with Directive 67/548/EEC, as carcinogenic ***or genotoxic, substances*** toxic for reproduction ***of Categories 1 and 2 or substances classified as endocrine disruptors***.

Or. fr

Justification

It must be possible to authorise certain active substances in order to control a serious danger to plant health which cannot be contained by other available means. This authorisation must

be subject to strict conditions and should be granted for a shorter period, allowing this temporary authorisation to be renewed twice.

This possible derogation cannot extend to carcinogenic or genotoxic substances or substances toxic for reproduction of Categories 1 and 2 or substances classified as endocrine disruptors.

Amendment 234
Diana Wallis

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 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.	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 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 , ***3.7.1*** or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.
This derogation shall not apply to active substances which are or have to be classified in accordance with Directive 67/548/EEC, as carcinogenic category 1 or toxic for reproduction category 1.	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 toxic for reproduction category 1.
	Member States should submit applications with supporting evidence to the Commission for approval.

Or. en

Justification

The derogation should also apply to active substances which do not meet the environmental criteria. This would include in particular pendimethalin which is used in the treatment of land for pea growing.

Amendment 235
Marianne Thyssen

Council common position
Article 4 – paragraph 7 – subparagraph 1

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 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.	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 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, ***3.7.2, 3.7.3, 3.8.1*** 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.

Or. en

Justification

The derogation should be extended to cover more cut-off criteria than those specified in the common position. All means necessary should be available to member states to control and contain threats to plant health that may arise.

Amendment 236
Anja Weisgerber

Council common position
Article 4 – paragraph 7 – subparagraph 1

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 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.	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, ***including the development of resistance,*** which cannot be contained by other ***appropriate*** 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.

Or. en

Justification

This clause has newly been added by Council. Development of resistance is one of the key issues that should be taken into account when looking at 'serious danger to plant health'.

Not all available means are suitable for reaching the anticipated goal of controlling a serious danger to plant health. Therefore the wording should be clarified to better reflect the purpose of the clause

Amendment 237
Liam Aylward, Christa Klaß

Council common position
Article 4 – paragraph 7 – subparagraph 1

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 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.	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 cannot be contained by other ***appropriate*** 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.

Or. en

Justification

This clause has newly been added by Council. Not all available means are suitable for reaching the anticipated goal of controlling a serious danger to plant health. Therefore the wording should be clarified to better reflect the purpose of the clause.

Amendment 238
Johannes Blokland

Council common position
Article 4 – paragraph 7 – subparagraph 1

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 on the basis of documented evidence an active substance is necessary to control a serious danger to plant health, ***including***

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.	***the development of resistance,*** which cannot be contained by other ***appropriate*** 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.

Or. en

Justification

This clause has newly been added by Council. Development of resistance is one of the key issues that should be taken into account when looking at 'serious danger to plant health'. Furthermore not all available means are suitable for reaching the anticipated goal of controlling a serious danger to plant health. Therefore the wording should be clarified to better reflect the purpose of the clause.

Amendment 239
Liam Aylward, Christa Klaß

Council common position
Article 4 – paragraph 7 – subparagraph 1

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 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	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, ***including the development of resistance,*** which 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

environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.	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.

Or. en

Justification

This clause has newly been added by Council. Development of resistance is one of the key issues that should be taken into account when looking at 'serious danger to plant health'.

Amendment 240
Robert Sturdy, Richard Seeber

Council common position
Article 4 - paragraph 7 - subparagraph 1

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 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.	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 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, ***3.7.2, 3.7.3, 3.8.1*** 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.

Or. en

Justification

The derogation must be extended to cover more cut-off criteria than those specified in the common position. All means necessary must be available to member states to control and

contain threats to plant health that may arise

Amendment 241
Liam Aylward

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 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.	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 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 ***3.6.2,*** 3.6.3, 3.6.4, 3.6.5, ***3.7.2, 3.7.3*** or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.
This derogation shall not apply to active substances which are or have to be classified in accordance with Directive 67/548/EEC, as carcinogenic category 1 or toxic for reproduction category 1.	This derogation shall not apply to active substances which are or have to be classified in accordance with Directive 67/548/EEC, as ***mutagenic category 1,*** carcinogenic category 1 or toxic for reproduction category 1.

Or. en

Justification

This clause has newly been added by Council. If a Member State faces a situation of serious danger to plant health on it territory it should have the appropriate means to prevent serious damage to crops under threat. Therefore the derogation should be extended to further criteria then those mentioned by the common position.

Amendment 242
Christa Klaß

Council common position
Article 4 – paragraph 7 – subparagraph 1 a (new)

Council common position	*Amendment*
	If a Member State applies for a derogation under this paragraph the Commission shall, within two months, put forward the measures as proposed in this application to the Standing Committee for opinion and take a decision in accordance with the regulatory procedure referred to in Art. 79 (3). The derogation may in some cases be limited to only that Member State making the application.

Or. en

Justification

This clause has newly been added by Council. The Commission should be required to transmit the measures as proposed by the applying Member State to the Standing Committee for a decision.

Amendment 243
Liam Aylward, Neil Parish

Council common position
Article 4 – paragraph 7 – subparagraph 1 a (new)

Council common position	*Amendment*
	If a Member State applies for a derogation under this paragraph the Commission shall, within two months, put forward the measures as proposed in this application to the Standing Committee for opinion and take a decision in accordance with the regulatory procedure referred to in Art. 79 (3). The derogation may in some cases be limited to only that Member State making the application.

Or. en

Justification

This clause has newly been added by Council. The Commission should be required to transmit the measures as proposed by the applying Member State to the Standing Committee for a decision.

Amendment 244
Anja Weisgerber

Council common position
Article 4 – paragraph 7 – subparagraph 1 a (new)

Council common position	*Amendment*
	If a Member State applies for a derogation under this paragraph the Commission shall, within two months, put forward the measures as proposed in this application to the Standing Committee for opinion and take a decision in accordance with the regulatory procedure referred to in Art. 79 (3). The derogation may in some cases be limited to only that Member State making the application.

Or. en

Justification

This clause has newly been added by Council. The Commission should be required to transmit the measures as proposed by the applying Member State to the Standing Committee for a decision.

Amendment 245
Caroline Lucas

Council common position
Article 8 – paragraph 1 – point c

Council common position	*Amendment*
(c) for each point of the data requirements	(c) for each point of the data requirements

for the plant protection product, the summaries and results of tests and studies, the name of their owner and of the person or institute that carried out the tests and studies, relevant to the assessment of the criteria provided for in Article 4(2) and (3) for one or more plant protection products which are representative of the uses referred to in point (a), taking into account the fact that data gaps in the dossier, as provided for in paragraph 2 of this Article, resulting from the proposed limited range of representative uses of the active substance, ***may*** lead to ***restrictions in the approval;***	for the plant protection product, the summaries and results of tests and studies, the name of their owner and of the person or institute that carried out the tests and studies, relevant to the assessment of the criteria provided for in Article 4(2) and (3) for one or more plant protection products which are representative of the uses referred to in point (a), taking into account the fact that ***any*** data gaps in the dossier, as provided for in paragraph 2 of this Article, resulting from the proposed limited range of representative uses of the active substance, ***shall*** lead to ***non-approval of the active substance***;

Or. en

Justification

Dossiers with incomplete or wrong information should be rejected.

Reinstating first reading Amendment 74.

Amendment 246
Erna Hennicot-Schoepges

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.

Or. en

Justification

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

Amendment 247
Hiltrud Breyer

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

Or. en

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 248
Erna Hennicot-Schoepges

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.

Or. en

Justification

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

Amendment 249
Erna Hennicot-Schoepges

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.

Or. en

Justification

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

Amendment 250
Hiltrud Breyer

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***.

Or. en

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 251
Françoise Grossetête

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 the Regulation referred to in Article 13(4) ***following their approval or its renewal pursuant to this Regulation***.

Or. fr

Justification

The common position requires the drawing-up of a list of substances which ought to be replaced. This Regulation should therefore specify a precise date by which a substance must, if appropriate, be included in this list. It is logical that, for a given substance, the decision as to whether or not to include it in this list should be taken on the basis of Community re-examination.

Amendment 252
Bogusław Sonik

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 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.

Or. en

Amendment 253
Liam Aylward

Council common position
Article 30 – paragraph 1 - subparagraph 1 a (new)

Council common position	*Amendment*
	If no decision concerning the active substance has been made before the provisional period of authorisation for the plant protection product has expired, the Member State may extend this authorisation upon application up to the date when a decision is made on the authorisation of the active substance.

Or. en

Justification

The law has to cover a provision what has to happen if the Commission does not make a decision on the active substance in the three years provisional authorisation period of the plant protection product.

Amendment 254
Pilar Ayuso

Council common position
Article 30 – paragraph 1 - subparagraph 1 a (new)

Council common position	*Amendment*
	If no decision concerning the active substance has been made before the provisional period of authorisation for the plant protection product has expired, the Member State may extend this authorisation upon application up to the date when a decision is made on the

authorisation of the active substance.

Or. en

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.

The law has to cover a provision what has to happen if the Commission does not make a decision on the active substance in the three years provisional authorisation period of the plant protection product.

Amendment 255
Anja Weisgerber

Council common position
Article 30 – paragraph 1 - subparagraph 1 a (new)

Council common position	*Amendment*
	If no decision concerning the active substance has been made before the provisional period of authorisation for the plant protection product has expired, the Member State may extend this authorisation upon application up to the date when a decision is made on the authorisation of the active substance.

Or. en

Justification

The law has to cover a provision what has to happen if the Commission does not make a decision on the active substance in the three years provisional authorisation period of the plant protection product.

Amendment 256
Pilar Ayuso

Council common position
Article 30 – paragraph 2

Council common position	*Amendment*
2. In such cases the Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorisation, giving at least the information provided for in Article 57 (1).	2. In such cases the Member State ***may start its evaluation regarding a 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).

Or. en

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 257
Anja Weisgerber

Council common position
Article 30 – paragraph 2

Council common position	*Amendment*
2. In such cases the Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorisation, giving at least the information provided for in Article 57 (1).	2. In such cases the Member State ***may start its evaluation regarding a 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).

Or. en

Justification

Reintroduction of amendment adopted in 1st reading.

Amendment 258
Liam Aylward

Council common position
Article 30 – paragraph 2

Council common position	*Amendment*
2. In such cases the Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorisation, giving at least the information provided for in Article 57 (1).	2. In such cases the Member State ***may start its evaluation regarding a 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).

Or. en

Justification

Reintroduction of amendment adopted in 1st reading.

Amendment 259
Johannes Blokland

Council common position
Article 30 – paragraph 2

Council common position	*Amendment*
2. In such cases the Member State shall	2. In such cases the Member State ***may***

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).	***start its evaluation regarding a 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).

Or. en

Justification

Reintroduction of amendment adopted in 1st reading.

Amendment 260
Johannes Blokland

Council common position
Article 30 – paragraph 2 a (new)

Council common position	*Amendment*
	2a. If no decision concerning the active substance has been made before the provisional period of authorisation for the plant protection product has expired, the Member State may extend this authorisation upon application up to the date when a decision is made on the authorisation of the active substance.

Or. en

Justification

The law has to cover a provision what has to happen if the Commission does not make a decision on the active substance in the three years provisional authorisation period of the plant protection product.

Amendment 261
Liam Aylward

Council common position
Article 30 – paragraph 3 a (new)

Council common position	*Amendment*
	3a. By way of derogation from Article 29(1)(a), Member States may, on the basis of documented evidence, authorise for a provisional period not exceeding three years the placing on the market of a plant protection product containing an active substance that does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 and 3.8.2 of Annex II and which is not approved, provided the plant protection product is necessary to control a serious danger to plant health, including the development of resistance, which cannot be controlled by other available means and an application for the approval of the active substance according to Article 4(7) has been submitted. The use of the plant protection product has to be subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised.* ***Following the approval of the active substance, the validity of the plant protection product authorisation shall be adjusted so that it does not exceed the expiry date of the active substance approval. ***If a decision on the possible approval of the active substance has not been made by the time the provisional authorisation expires, Member States may extend the authorisation until a decision on the active substance has been taken.*** ***For such substances, exemptions from maximum residue levels shall be arranged in accordance with the procedure set out in Article 18(4) of Regulation (EC) No***

396/2005.

Or. en

Justification

The new regulation will lead to a significant decrease in the availability of plant protection solutions. Point 7 of Article 4 was added by the European Council to allow for the possibility to approve active substances not meeting criteria set out in points 3.6.3, 3.6.4, 3.6.5 and 3.8.2 of Annex II but that are indispensable to keep some agricultural production in Europe (no other solution available). However the European approval of an active substance may take several years. The amendment above allows Member States to provisionally authorize plant protection products containing active substances while these are being evaluated/approved under Article 4 point 7 in situations where no other control solutions exist.

Amendment 262
Robert Sturdy, Richard Seeber

Council common position
Article 30 - paragraph 3 a (new)

Council common position	*Amendment*
	3a. By way of derogation from Article 29(1)(a), Member States may, on the basis of documented evidence, authorise for a provisional period not exceeding three years the placing on the market of a plant protection product containing an active substance that does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 and 3.8.2 of Annex II and which is not approved, provided the plant protection product is necessary to control a serious danger to plant health, including the development of resistance, which cannot be controlled by other available means and an application for the approval of the active substance according to Article 4(7) has been submitted. The use of the plant protection product has to be subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised.* ***Following the approval of the active

substance, the validity of the plant protection product authorisation shall be adjusted so that it does not exceed the expiry date of the active substance approval.

If a decision on the possible approval of the active substance has not been made by the time the provisional authorisation expires, Member States may extend the authorisation until a decision on the active substance has been taken.

For such substances, exemptions from maximum residue levels shall be arranged in accordance with the procedure set out in Article 18(4) of Regulation (EC) No 396/2005.

Or. en

Justification

The new regulation will lead to a significant decrease in the availability of plant protection solutions. Point 7 of Article 4 was added by the European Council to allow for the possibility to approve active substances not meeting criteria set out in points 3.6.3, 3.6.4, 3.6.5 and 3.8.2 of Annex II but that are indispensable to keep some agricultural production in Europe (no other solution available). However the European approval of an active substance may take several years. The amendment above allows Member States to provisionally authorize plant protection products containing active substances while these are being evaluated/approved under Article 4 point 7 in situations where no other control solutions exist.

Amendment 263
Hiltrud Breyer

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.

Or. en

Justification

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

Reinstating first reading Amendment 124.

Amendment 264
Caroline Lucas

Council common position
Article 31 – paragraph 2 – subparagraphs 2 a and 2 b (new)

Council common position	*Amendment*
	The authorisation shall also include:
	(a) indications for proper use according to the principles of integrated pest management as defined in Article 3, to apply from 2012 onwards;
	(b) the obligation before the product is used to inform any neighbours who could be exposed to the spray drift and who have requested to be informed.

Or. en

Justification

Reinstating part of first reading Amendment 305.

Amendment 265
Hiltrud Breyer

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

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

Or. en

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 266
Hiltrud Breyer

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***

Or. en

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 267
Hiltrud Breyer

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

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

Or. en

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 268
Anja Weisgerber

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. The Member States concerned shall grant authorisations ***within 180 days of receiving an application*** 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.

Or. en

Amendment 269
María Sornosa Martínez, María Isabel Salinas García

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, 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.
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 therefor.	
Member States shall provide for a possibility to challenge the decision refusing the authorisation of such product before the national courts or other instances of appeal.	

Or. es

Amendment 270
Anja Weisgerber

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, 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 ***taking into account non-comparable agricultural, plant health or environmental conditions.***
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***.	***In very exceptional cases***, where the concerns of a Member State related to human health 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 health.
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.
	The Commission shall within 90 days present a report with a conclusion concerning the decision of the Member State to refuse authorisation of the plant protection product in its territory.
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 refusing the authorisation of such product before the national courts or other instances of appeal.

Or. en

Amendment 271
Johannes Blokland

Council common position
Article 40 – paragraph 2 – subparagraph 2

Council common position	*Amendment*
In case the authorisation holder refuses its consent, the competent authority of the Member State concerned may accept the application, on grounds of public interest.	***deleted***

Or. en

Justification

Newly added sentence by the Council. A mutual recognition authorisation for third parties is not acceptable for the "original" authorisation holder without his liability exemption as it is in the law in cases of minor use extensions for third parties.

Amendment 272
Dorette Corbey

Council common position
Article 40 – paragraph 2 a (new)

Council common position	*Amendment*
	2a. Member States may refuse to recognise a plant protection product if a prima facie case can be made that the use of the plant protection product in their territory will have a different impact on the environment than in the reference Member State or if refusal to authorise it accords with the established environmental policy of the Member State concerned;

Or. nl

Justification

Member States must have the opportunity to decide for themselves about the authorisation of plant protection products.

Amendment 273
Anja Weisgerber

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 ***except where*** Article 36(3) ***applies.***	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. ***Where the agricultural, plant health or environmental conditions are non-comparable,*** Article 36***(2) and*** (3) ***shall apply.***

Or. en

Amendment 274
Pilar Ayuso

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;

Or. en

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 275
Anja Weisgerber

Council common position
Article 46

Council common position	*Amendment*
Where a Member State withdraws or amends an authorisation or does not renew it, it may grant a grace period for the disposal, storage, placing on the market and use of existing stocks.	Where a Member State withdraws or amends an authorisation or does not renew it, it may grant a grace period for the disposal, storage, placing on the market and use of existing stocks ***in line with Article 20(2)***.
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 permit it, the grace period shall not exceed ***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.
	If the authorisation is withdrawn or not renewed because of immediate concerns for human or animal health or the environment, the plant protection products concerned shall be withdrawn from the market immediately.

Or. en

Justification

Council has introduced new provisions regarding periods of grace. The proposed change would achieve a consistent approach to periods of grace for active substances (Art 20 (2)) and plant protection products.

Amendment 276
Liam Aylward

Council common position
Article 50 – paragraph 2

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

Or. en

Justification

The term "exceptional cases" is undefined and is jeopardizing the predictability and workability of the authorisation process.

Amendment 277
Anja Weisgerber, Christa Klaß

Council common position
Article 50 – paragraph 2

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

State.

Or. en

Justification

The term "exceptional cases" is undefined and is jeopardizing the predictability and workability of the authorisation process.

Amendment 278
Christofer Fjellner

Council common position
Article 51 – paragraph 1

Council common position	*Amendment*
1. The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations or professional users may ask for the ***authorisation*** of a plant protection product already authorised in the Member State concerned to be extended to minor uses not yet covered by that authorisation.	1. The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations or professional users may ask for the ***approval*** of a plant protection product already authorised in the Member State concerned to be extended to minor uses not yet covered by that authorisation.

Or. en

Justification

Clarification: for minor uses the full authorisation procedure is not applicable. Therefore it is not an application for an authorisation but an application for an approval to extend an existing authorisation.

Amendment 279
Bogusław Sonik

Council common position
Article 51 – paragraph 4 – subparagraph 3

Council common position	*Amendment*
The official publication or where	The official publication or where

applicable the label shall include a reference to the liability of the person using the plant protection product with respect to failures on the efficacy or to phytotoxicity of the product for which the minor use was granted. The minor use extension shall be separately identified in the label.	applicable the label shall include a reference to the liability of the person using the plant protection product with respect to failures on the efficacy or to phytotoxicity of the product for which the minor use was granted. ***Without prejudice to Article 73, the authorisation holder shall not be liable for any losses arising from use in accordance with extensions of authorisation.*** The minor use extension shall be separately identified in the label.

Or. en

Amendment 280
Liam Aylward, Anne Laperrouze

Council common position
Article 52 – paragraph 3 – point (c)

Council common position	*Amendment*
(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.***	(c) they are either the same or equivalent in the co-formulants present

Or. en

Justification

Council has newly introduced these provisions on packaging of parallel traded products. Clarification to emphasise that re-packaging should not be allowed in order to prevent any opportunity for the import of counterfeited and unevaluated products.

Amendment 281
Liam Aylward, Anne Laperrouze

Council common position
Article 52 – paragraph 3 – point (c) a (new)

Council common position	*Amendment*
	(ca) they have not been repackaged and their packaging is the same as or equivalent to that of the reference products in terms of size, material and form.

Or. en

Justification

Council has newly introduced these provisions on packaging of parallel traded products. Clarification to emphasise that re-packaging should not be allowed in order to prevent any opportunity for the import of counterfeited and unevaluated products.

Amendment 282
Erna Hennicot-Schoepges

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 assessment 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 or a co-formulant substance which has not been assessed,

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

(d) the product does not feature different nominal concentrations of co-formulants with essential functions or co-formulant substances 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.

Or. de

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 283
Liam Aylward, Anne Laperrouze

Council common position
Article 52 – paragraph 4 – point (h)

Council common position	*Amendment*
(h) a sample of the product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;	(h) a sample of the product ***and packaging*** which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;

Or. en

Justification

Council has newly introduced these provisions on packaging of parallel traded products. Clarification to emphasise that re-packaging should not be allowed in order to prevent any opportunity for the import of counterfeited and unevaluated products.

Amendment 284
Anja Weisgerber

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..

Or. en

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 285
Kathy Sinnott

Council common position
Article 54– paragraph 3 a (new)

Council common position	*Amendment*
	3a. Research and development should take into account the needs and experiences of agricultural stakeholders such as farmers as they have a significant contribution to make regarding maximising crop outputs and day-to-day implementation of plant protection practices.

Or. en

Justification

Agricultural stakeholders should be recognised as people who can contribute to this field and to best practice and not just as those who implement plant protection as directed by others.

Amendment 286
Mojca Drčar Murko

Council common position
Article 56 – paragraph 1 – subparagraph 2

Council common position	*Amendment*
In particular, potentially harmful effects of that plant protection product, or of residues of an active substance, its metabolites, a safener, synergist or co-formulant contained in it, on human or animal health or on groundwater, or their potentially unacceptable effects on ***plants*** or ***plant*** products or the environment shall be notified.	In particular, potentially harmful effects of that plant protection product, or of residues of an active substance, its metabolites, a safener, synergist or co-formulant contained in it, on human or animal health or on groundwater, or their potentially unacceptable effects on ***crops*** or ***crop*** products or the environment shall be notified.

Or. en

Justification

The obligation to notify potentially unacceptable effects on - all - plant products is not in line with the principle of proportionality. This has to be limited to crops.

Amendment 287
Anja Weisgerber

Council common position
Article 58

Council common position	*Amendment*
1. An adjuvant shall not be placed on the market or used ***unless it has been authorised in the Member State concerned in accordance with the conditions established in the Regulation referred to in paragraph 2.***	An adjuvant shall not be placed on the market or used ***if it contains a co-formulant which has been prohibited in accordance with Article 27.***
2. Detailed rules for the authorisation of adjuvants, including data requirements, notification, evaluation, assessment and decision making procedure shall be adopted in accordance with the procedure referred to in Article 79(4).	
3. Article 81(3) shall apply.	

Or. en

Justification

The content of this article has been changed by Council. Indicating that an adjuvant shall not be placed on the market or used if it contains a co-formulant which has not been approved in accordance with the co-formulant article should suffice. Adjuvants shall be registered and documented under REACH and detailed rules are therefore not needed under Article 58.

Amendment 288
Liam Aylward, Christa Klaß, Anne Laperrouze

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 2 years and 6 months. The first to fourth subparagraphs shall apply with due changes.***	A study ***submitted for the renewal or review of an authorisation shall not be protected except where required for the purposes of legislative changes or updates to scientific and technical knowledge, in which case the time period of protection shall be equivalent to that set out in the fourth subparagraph.***

Or. en

Justification

Retables amendment adopted in 1st reading and clarifies it.

Amendment 289
Alessandro Foglietta, Amalia Sartori

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 also be protected if it was necessary for the renewal or review of an authorisation.

Or. en

Justification

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

reading)

Amendment 290
Anja Weisgerber

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 2 years and 6 months. The first to fourth subparagraphs shall apply with due changes.***	A study ***submitted for the renewal or review of an authorisation shall not be protected except where required for the purposes of legislative changes or updates to scientific and technical knowledge, in which case the time period of protection shall be equivalent to that set out in the fourth subparagraph.***

Or. en

Justification

Retables amendment adopted in 1st reading.

Amendment 291
Robert Sturdy, Richard Seeber

Council common position
Article 63 – paragraph 2 - introduction

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:

Or. en

Justification

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

Amendment 292
Pilar Ayuso

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:

Or. en

Justification

From the juridical point of view "normally" is indefinite and opens the door for arbitrariness.

Amendment 293
Caroline Lucas

Council common position
Article 66 – paragraph 4

Council common position	*Amendment*
4. Advertisements shall not contain any visual representation of potentially dangerous practices, such as mixing or application without sufficient protective clothing, ***not*** any use near food or use by or in the vicinity of children.	4. Advertisements shall not contain any visual representation of potentially dangerous practices, such as mixing or application without sufficient protective clothing, ***nor*** any use near food or use by or in the vicinity of children ***or residential or other public areas.***

Or. en

Justification

Children and other vulnerable groups may also be situated in homes and gardens near fields that are sprayed as well as in other public areas and so spraying near such areas should also not be advertised.

Amendment of new text introduced by Council.

Amendment 294
Pilar Ayuso

Council common position
Article 67 – paragraph 1 – subparagraph 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 ***and*** importers of plant protection products shall keep records of the plant protection products they place on the market for at least 3 years.

Or. en

Justification

The provisions have to be reduced because they are a not proportional administrative burden.

Amendment 295
Pilar Ayuso

Council common position
Article 80 – paragraph 2 to 4

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

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

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

(c) for a period of five years from the date of the renewal of the inclusion or renewal of the approval, for active substances whose inclusion in Annex I to Directive 91/414/EEC expires by …. This provision shall only apply to data necessary for the renewal of the approval and which were certified as compliant with the principles of good laboratory practice by that date.

3. Where Article 13 of Directive 91/414/EEC applies by virtue of paragraph 1 or paragraph 2 of this Article, it shall be subject to any special rules concerning Directive 91/414/EEC laid down in the Act of Accession by which a Member State joined the Community.

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

3. Where Article 13 of Directive 91/414/EEC applies by virtue of paragraph 1 or paragraph 2 of this Article, it shall be subject to any special rules concerning Directive 91/414/EEC laid down in the Act of Accession by which a Member State joined the Community.

Or. en

Justification

The subparagraphs under paragraph 2 and paragraph 4 have to be deleted because they violate the legitimate expectations of the authorisation holders and the equal treatment of similar cases.

Amendment 296
Christofer Fjellner

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.	***deleted***

Or. en

Justification

These provisions have been newly added by Council. Clarification that it is not necessary to repeat the establishment of such a list here as it is already covered under Art 24(2) and the review clause in Art 82.

Amendment 297
Françoise Grossetête

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.	By …, the Commission shall ***plan a programme of work with a view to drawing up*** a list of substances 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.

Or. fr

Justification

This provision is new and was inserted by the Council. A programme of work is required in

order to determine how this list should be drawn up.

Amendment 298
Robert Sturdy, Richard Seeber

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 accompanied, if necessary, by the appropriate legislative proposals to amend those provisions.	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 ***minor uses, raw material availability,*** the diversification and competitiveness of agriculture ***and the wider socio-economic context (i.e. food demand, evolution of food prices, availability of agricultural land)*** as well as on human health and on the environment. The report may be accompanied, if necessary, by the appropriate legislative proposals to amend those provisions.

Or. en

Justification

Just recently the Commission explained why it did not conduct an assessment of the impact of the criteria on food production and farmers. At the time of its original proposal it was supposedly not possible to anticipate which substances would remain on the market at the end of the review programme under Directive 91/414/EEC. An increasing number of reports, however, confirm that the additional criteria adopted by the European Parliament in its 1st reading will have serious consequences on product quality and availability as well as the economic viability of certain crops.

Amendment 299
Pilar Ayuso

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 accompanied, if necessary, by the appropriate legislative proposals to amend those provisions.	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 in Article 50 (2), the division of the ***European Union*** into three zones and on the ***likely future impact of the*** application of the criteria for the approval of active substances, safeners and synergists as set out in Annex II and the impact thereof on the diversification and competitiveness of agriculture as well as on human health and on the environment. The report may be accompanied, if necessary, by the appropriate legislative proposals to amend those provisions.
	The criteria as set out in Annex II shall not be applied until after the completion of the process set out in this article.
***** Note to OJ: ***60 months*** from the date of entry into force of this Regulation	***** Note to OJ: ***48 months*** from the date of entry into force of this Regulation

Or. en

Justification

The review clause has been newly added by Council. As the full functioning of the new regulatory framework can only be recognized over a longer period of time the co-legislators need a clear view on the future impact of the suggested measures.

Amendment 300
Inés Ayala Sender

Council common position
Annex II - point 3.6.2.

Council common position	*Amendment*
3.6.2 An active substance, safener or synergist shall only be approved if, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or *has not to* be classified, in accordance with the provisions of Directive 67/548/EEC, as mutagen category 1 or 2.	3.6.2 An active substance, safener or synergist shall only be approved if, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or ***should not*** be classified, in accordance with the provisions of Directive 67/548/EEC, as mutagen category 1 or 2***, as the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance concerned on food and feed do not exceed the limit of determination using the most sensitive methods.***

Or. es

Amendment 301
Anja Weisgerber

Council common position
Annex II - point 3.6.3.

Council common position	*Amendment*
3.6.3. An active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the	3.6.3. An active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the

Authority, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as carcinogen category 1 or 2, 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.***	Authority, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as carcinogen category 1 or 2, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, i.e. ***the margin of safety for humans under realistic proposed conditions of all uses is higher than 200.***

Or. en

Justification

Council has introduced a new definition of the term "negligible exposure". This definition should be based on a proper assessment of the risk involved in using a product under realistic field conditions.

Amendment 302
Liam Aylward, Neil Parish

Council common position
Annex II - point 3.6.3.

Council common position	*Amendment*
3.6.3. An active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as carcinogen category 1 or 2, unless the exposure of humans to that active	3.6.3. An active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as carcinogen category 1 or 2, 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.***	substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, i.e. ***the margin of safety for humans under realistic proposed conditions of all uses is higher than 200.***

Or. en

Justification

Council has introduced a new definition of the term "negligible exposure". This definition should be based on a proper assessment of the risk involved in using a product under realistic field conditions.

Amendment 303
Marianne Thyssen

Council common position
Annex II - point 3.6.3.

Council common position	*Amendment*
3.6.3. An active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as carcinogen category 1 or 2, 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***	3.6.3. An active substance, safener or synergist shall only be approved, if, on the basis of assessment of carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as carcinogen category 1 or 2, 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.	***margin of safety for humans under realistic proposed conditions of all uses is higher than 200.***

Or. en

Justification

Council has introduced a new definition of the term "negligible exposure". This definition should be based on a proper assessment of the risk involved in using a product under realistic field conditions.

Amendment 304
Anja Weisgerber

Council common position
Annex II - point 3.6.4.

Council common position	*Amendment*
3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as toxic for reproduction category 1 or 2, 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***	3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as toxic for reproduction category 1 or 2, 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 margin of safety for humans under realistic proposed conditions of all uses is***

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.	***higher than 200.***

Or. en

Justification

Council has introduced a new definition of the term "negligible exposure". This definition should be based on a proper assessment of the risk involved in using a product under realistic field conditions.

Amendment 305
Marianne Thyssen

Council common position
Annex II - point 3.6.4.

Council common position	*Amendment*
3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as toxic for reproduction category 1 or 2, 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***	3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as toxic for reproduction category 1 or 2, 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 margin of safety for humans under realistic proposed conditions of all uses is higher than 200***

point (b) of Article 18(1) of Regulation (EC) No 396/2005.

Or. en

Justification

Council has introduced a new definition of the term "negligible exposure". This definition should be based on a proper assessment of the risk involved in using a product under realistic field conditions.

Amendment 306
Liam Aylward

Council common position
Annex II - point 3.6.4.

Council common position	*Amendment*
3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as toxic for reproduction category 1 or 2, 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.***	3.6.4. An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as toxic for reproduction category 1 or 2, 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 margin of safety for humans under realistic proposed conditions of all uses is higher than 200.***

Or. en

Justification

Council has introduced a new definition of the term "negligible exposure". This definition should be based on a proper assessment of the risk involved in using a product under realistic field conditions.

Amendment 307
Liam Aylward, Christa Klaß

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 Article 18(1) (b) of Regulation (EC) No 396/2005.	3.6.5. An active substance, safener or synergist shall only be approved, if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information including a review of the scientific literature, reviewed by the Authority, it is not***, on the basis of specific scientific criteria once they are adopted in accordance with Article 78(2),*** 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 Article 18(1) (b) of Regulation (EC) No 396/2005.

Or. en

Justification

A newly introduced derogation for these substances has been set out in Article 4(7) which specifically refers to Annex II points 3.6.5 and 3.8.2 and this requires further clarity on the criteria to be applied.

Amendment 308
Anja Weisgerber

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 Article 18(1) (b) of Regulation (EC) No 396/2005.	3.6.5. An active substance, safener or synergist shall only be approved, if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information including a review of the scientific literature, reviewed by the Authority, it is not***, on the basis of specific scientific criteria once they are adopted in accordance with Article 78(2),*** 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 Article 18(1) (b) of Regulation (EC) No 396/2005.

Or. en

Justification

A newly introduced derogation for these substances has been set out in Article 4(7) which specifically refers to Annex II points 3.6.5 and 3.8.2 and this requires further clarity on the criteria to be applied.

Amendment 309
Avril Doyle

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 396/2005.	3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties ***for which there is scientific evidence of probable serious effects for human health,*** 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.

Or. en

Justification

This wording is consistent with Article 57(f) of Regulation 1907/2006 "REACH". It would set

a more realistic standard for implementing measures on endocrine disruptors.

Amendment 310
Robert Sturdy, Richard Seeber, Alyn Smith

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 396/2005.	3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans ***such that it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as toxic for 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 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.

Or. en

Justification

This amendment reflects what appears to be the Commission's interpretation of this provision, and is similar to the interpretation adopted in the report published by KEMI (the Swedish Chemicals Agency) on 22 September 2008 . It would clarify that adverse effects of endocrine disruption in humans are those involving reproductive toxicity. Substances classified as toxic to reproduction category 1 and 2 are already subject to the provisions of paragraph 3.6.4; this paragraph therefore extends to substances classified as category 3, i.e.

those remaining substances for which there is some evidence of potential to have adverse effects on hormone systems.

Amendment 311
Glenis Willmott, Dorette Corbey

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 396/2005.	3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans ***such that it is not or has not to be classified, in accordance with the provisions of Directive 67/548/EEC, as toxic for 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 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.

Or. en

Justification

This amendment reflects what appears to be the Commission's interpretation of this provision, and is similar to the interpretation adopted in the report published by KEMI (the Swedish Chemicals Agency) on 22 September 2008 http://www.kemi.se/templates/News____5415.aspx . It would clarify that adverse effects of

endocrine disruption in humans are those involving reproductive toxicity. Substances classified as toxic to reproduction category 1 and 2 are already subject to the provisions of paragraph 3.6.4; this paragraph therefore extends to substances classified as category 3, i.e. those remaining substances for which there is some evidence of potential to have adverse effects on hormone systems

Amendment 312
Liam Aylward

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 396/2005.***	3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible.

Or. en

Justification

This process is too prescriptive and restrictive given the variety of substances that may fall into category 1 and category 2 . It would be advisable that experts should decide scope of negligibility .

Amendment 313
Liam Aylward

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 396/2005.***	3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, i.e. ***the margin of safety for humans under realistic proposed conditions of all uses is higher than 200.***

Or. en

Justification

Council has introduced a new definition of the term "negligible exposure". This definition should be based on a proper assessment of the risk involved in using a product under realistic field conditions.

Amendment 314
Marianne Thyssen

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 396/2005.***	3.6.5. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, i.e. ***the margin of safety for humans under realistic proposed conditions of all uses is higher than 200.***

Or. en

Justification

Council has introduced a new definition of the term "negligible exposure". This definition should be based on a proper assessment of the risk involved in using a product under realistic field conditions.

Amendment 315
Johannes Blokland

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

Council common position	*Amendment*
	3.6.5a. An active substance shall only be approved if, on the basis of the assessment or other available data and information including a review of the scientific literature, it is not considered to cause a significant risk (affecting 1 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.

Or. en

Justification

Partly reinstating Am 300 of first reading, in order to seek for a compromise with the Council. Neurotoxic and immunotoxic substances interfering at the developmental stage of life pose a serious threat to society. Exposure to such chemicals should be prevented, but limited to cases of serious concern. Amendment 300 of the EP is therefore adapted in such a way that not every risk will lead to non-approval but only in cases of significant risk.

Amendment 316
Dorette Corbey

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

Council common position	*Amendment*
	3.6.5a. An active substance, safener or synergist shall only be approved, if, on the basis of evaluation of other available data and information, including an overview of the scientific literature, it is not considered to give rise to a risk of neurotoxic or immunotoxic developmental

disorders in humans, taking into account exposure during embryonic/foetal life and/or childhood or combined 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, in horticultural greenhouses or in conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned in 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 and if the emissions into surface waters, soil and outside air are kept to a minimum. On the basis of risk analyses, a Member State may however permit the use of these substances.

Or. nl

Justification

Substances which cause neurodevelopmental or immunotoxic developmental disorders must not be permitted except in closed systems or in situations where people do not come into contact with the substances or if they are used in modern horticultural greenhouses where emissions into surface waters, soil and outside air have been minimised.

Amendment 317
Anne Laperrouze, Dan Jørgensen

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

Council common position	*Amendment*
	3.6.5.a. An active substance shall only be approved if:
	- tests of behaviour of the active substance, its metabolites and degradation and reaction products in response to different drinking water treatment processes have not highlighted the

formation of potentially harmful by-products for human health

- tests of treatability based on common drinking water treatment processes have demonstrated that drinking water produced from raw waters (ground and surface waters) containing the active substance, its metabolites and degradation and reaction products will comply with the value of 0,1µg/l set in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption[1] and not involve risks for human health.

The tests will be carried out according to common protocols established at EU level and recognised by both water suppliers and pesticide manufacturers.

[1] OJ L 330, 5.12.1998, p. 32.

Or. en

Justification

To be consistent with Article 4.3 b), tests are needed to prove that use of an active substance contained in a plant protection product will not lead to the formation of harmful by-products for human health during drinking water treatment.

The case of the substance called "Tolylfluanid" in 2007 (Commission Decision n°2007/322/EC) has clearly showed the need to include such tests in the procedure of evaluation and justifies the introduction of this new amendment.

Amendment 318
Hiltrud Breyer

Council common position
Annex II - point 3.7.1. – 3.7.1.1. – 3.7.1.2.

Council common position	*Amendment*
3.7.1. An active substance, safener or synergist shall only be approved where it ***is*** not considered to be ***a*** persistent organic	3.7.1. An active substance, safener or synergist shall only be approved where it***, and its transformation products or***

pollutant (POP).	***residues, are*** not considered to be persistent organic ***pollutants (POPs)***.
A substance that fulfils all three of the criteria of the sections below is a POP.	A substance that fulfils all three of the criteria of the sections below is a POP.
3.7.1.1. Persistence	3.7.1.1. Persistence
An active substance, safener or synergist fulfils the persistence criterion where there is evidence that the time it takes for a degradation of 50 % (DT50) in water is greater than two months, or that its DT50 in soil is greater than six months, or that its DT50 in sediment is greater than six months.	An active substance, safener or synergist fulfils the persistence criterion where there is***:***
	- evidence that the time it takes for a degradation of 50 % (DT50) in water is greater than two months, or that its DT50 in soil is greater than six months, or that its DT50 in sediment is greater than six months; ***or***
	- evidence that the active substance is otherwise sufficiently persistent to be considered in the context of the POPs Convention;
3.7.1.2. Bioaccumulation	3.7.1.2. Bioaccumulation
An active substance, safener or synergist fulfils the bioaccumulation criterion where there is:	An active substance, safener or synergist fulfils the bioaccumulation criterion where there is:
- evidence that its bio-concentration factor or bioaccumulation factor in aquatic species is greater than ***5 000*** or, in the absence of such data, that the partition coefficient n-octanol/water (log Ko/w) is greater than 5; or	- evidence that its bio-concentration factor or bio accumulation factor in aquatic species is greater than ***2 000*** or, in the absence of such data, that the partition coefficient n-octanol/water (log Ko/w) ***or the partition coefficient n-octanol/air (log Ko/a)*** is greater than 5; or
- evidence that the active substance, safener or synergist present other reasons for concern, such as high bioaccumulation in other non-target species, high toxicity or ecotoxicity.	- evidence that the active substance, safener or synergist present other reasons for concern, such as high bioaccumulation in other non-target species, high toxicity or ecotoxicity; ***or***
	- evidence based on monitoring data in biota indicating that the bio-accumulation potential of the active substance is sufficient for it to be considered under the

POPs Convention.

Or. en

Justification

This amendment brings the Regulation in line with the provisions of Annex D of the Stockholm Convention, which also allows for other evidence than just certain tests.

Partially reinstating first reading Amendment 230. Replaces amendment 195 by the rapporteur.

Amendment 319
Pilar Ayuso

Council common position
Annex II - point 3.8.1. a (new)

Council common position	*Amendment*
	3.8.1.a. An active substance, safener or synergist shall only be approved if, used under realistic conditions, it does not result in adverse effects on bee colonies.
	Evaluation must take into account the severity of effects observed under field conditions and the level at which adverse effects are observed on colonies.
	Uses of an active substance, safener or synergist shall not be authorised if there is evidence, under normal condition of use, that exposure will result in adverse effects on bee colonies.

Or. en

Justification

As Council has not accepted the additional criterion on bee toxicity proposed by Parliament in first reading. This proposal would offer a compromise to take account of the concerns of both institutions. Specific uses of a plant protection product shall not be authorized when it is demonstrated that they have or are expected to have adverse and irreversible effects on bee

colonies.

Amendment 320
Anja Weisgerber

Council common position
Annex II - point 3.8.2.

Council common position	*Amendment*
3.8.2. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.	3.8.2. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not***, on the basis of specific scientific criteria once they are adopted in accordance with Article 78(2),*** considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.

Or. en

Justification

A newly introduced derogation for these substances has been set out in Article 4(7) which specifically refers to Annex II points 3.6.5 and 3.8.2 and this requires further clarity on the criteria to be applied.

Amendment 321
Liam Aylward, Christa Klaß

Council common position
Annex II - point 3.8.2.

Council common position	*Amendment*
3.8.2. An active substance, safener or	3.8.2. An active substance, safener or

synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.	synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not***, on the basis of specific scientific criteria once they are adopted in accordance with Article 78(2),*** considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.

Or. en

Justification

A newly introduced derogation for these substances has been set out in Article 4(7) which specifically refers to Annex II points 3.6.5 and 3.8.2 and this requires further clarity on the criteria to be applied.

Amendment 322
Liam Aylward

Council common position
Annex II - point 3.8.2.

Council common position	*Amendment*
3.8.2. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product ***under realistic proposed conditions of use*** is negligible.	3.8.2. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product is negligible, ***i.e. under realistic proposed conditions of use the product does not lead to unacceptable negative effects in the environment.***

Or. en

Justification

Council has introduced a new definition of the term "negligible exposure". This definition should be based on a proper assessment of the risk involved in using a product under realistic field conditions.

Amendment 323
Marianne Thyssen

Council common position
Annex II - point 3.8.2.

Council common position	*Amendment*
3.8.2. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product ***under realistic proposed conditions of use*** is negligible.	3.8.2. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product is negligible, ***i.e. under realistic proposed conditions of use the product does not lead to unacceptable negative effects in the environment.***

Or. en

Justification

Council has introduced a new definition of the term "negligible exposure". This definition should be based on a proper assessment of the risk involved in using a product under realistic field conditions.

Amendment 324
Erna Hennicot-Schoepges

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 if the hazard quotients (HQ) for oral or contact exposure of honeybees resulting from direct or indirect exposure via spray drift or dust are greater than 50, unless it is established that under realistic proposed conditions of use:
	- the exposure of honeybees to that active substance in a plant protection product is negligible,
	- or if it is clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on honeybee larvae, honeybee behaviour, or colony survival and development.

Or. en

Justification

Bee toxicity and realistic exposure routes should be taken into consideration.

Amendment 325
Caroline Lucas

Council common position
Annex IV - point 1 – point (a)

Council common position	*Amendment*
(a) substitution shall be applied only where other methods or the ***chemical*** diversity of the active substances is sufficient to minimise the occurrence of resistance in the target organism; and	(a) substitution shall be applied only where other methods***, including non-chemical methods of crop protection and pest prevention,*** or the diversity of the active substances is sufficient to minimise the occurrence of resistance in the target

organism; and

Or. en

Justification

Non-chemical methods and practices of crop management and pest prevention shall be taken into account in the comparative assessment. The priority should always be given to non-chemical methods.

Reinstating first reading Amendment 251.