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NOTE

from :	General Secretariat
to :	Permanent Representatives Committee
Subject :	Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market - Approval of the final compromise text with a view to a second reading agreement with the European Parliament

1. On 19 July 2006 the Commission forwarded the above proposal[1] to the Council based on Articles 37(2), 95 and 152(4)(b) of the EC Treaty. The draft Regulation will replace the existing legislation in this domain (Council Directive 91/414/EEC) thoroughly revising the procedures for considering the safety of active substances and for the authorisation of plant protection products.

2. The Committee of the Regions delivered its opinion on 13 February 2007[2]. The Economic and Social Committee delivered its opinion on 31 May 2007[3].

3. The European Parliament appointed Hiltrud Breyer as rapporteur for the Environment Committee and delivered its opinion at first reading on 23 October 2007, adopting 247 amendments to the Commission proposal[4].

[1] 11755/06
[2] OJ C 146, 30.6.2007, p. 48
[3] OJ C 175, 27.7.2007, p. 44
[4] 14184/07

4. The Commission submitted an amended proposal[1] under Article 250(2) of the EC Treaty on 11 March 2008.

5. After a very detailed examination of the proposal by the Working Party of Agricultural Questions (Pesticides/Plant Protection Products) for almost two years, the Council reached political agreement on 23 June 2008. On 15 September 2008 the Council adopted its common position[2] and transmitted it to the European Parliament for its plenary session of 22-25 September 2008.

6. On 5 November the European Parliament's Environment Committee adopted a draft recommendation for the second reading of the Council's common position including 177 amendments.

7. With a view to reaching a second reading agreement four trilogues and other technical meetings were held between the European Parliament, the Presidency and the Commission and a draft compromise package was agreed between the three Institutions on 17 December 2008.

8. The Permanent Representative Committee is therefore invited to:

– confirm the agreement on the text set out in the Annex to this note;

– give the Chairman of the Permanent Representatives Committee a mandate to inform the Chairman of the European Parliament Committee on Environment, Public Health and Food Safety by letter that, should the European Parliament adopt the amendments to the common position in the exact form as set out in the Annex, the Council would, in accordance with Article 251, paragraph 3, of the Treaty, and subject, if necessary, to revision by the legal linguists of both institutions, approve the amendments of the European Parliament. This would permit the act in question to be deemed to have been adopted in the form of the common position thus amended.

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1 7538/08
2 11119/8/08 REV 8

ANNEX

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL CONCERNING THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET

Common position	Draft Council position
Amendment **1** Citation 1	
Having regard to the Treaty establishing the European Community, and in particular Articles 37(2) and 95 thereof,	Having regard to the Treaty establishing the European Community, and in particular ***Articles*** **37(2), 95** ***and 152(4)(b)*** **[…]** thereof,
New amendment from the Council Recital 8	
(8) In order to remove as far as possible obstacles to trade in plant protection products existing due to the different levels of protection in the Member States, this regulation should lay down harmonised rules for the approval of active substances and the placing on the market of plant protection products, including rules on the mutual recognition of authorisations and on parallel trade. The purpose of this Regulation is thus also to increase the free movement of such products and availability of these products in the Member States.	**(9)** In order to remove as far as possible obstacles to trade in plant protection products existing due to the different levels of protection in the Member States, this regulation should **also** lay down harmonised rules for the approval of active substances and the placing on the market of plant protection products, including rules on the mutual recognition of authorisations and on parallel trade. The purpose of this Regulation is thus also to increase the free movement of such products and availability of these products in the Member States.

New amendment from the Council Recital 9	
(9) The purpose of this Regulation is also to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.	**(8)** The purpose of this Regulation is **[…]** to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.
Amendment **3** Recital 10b (new)	
	See AM 15
Amendment **4** Recital 10c (new)	
	Recital (38a) ***(10c) The development of non-animal*** **[...]** ***test methods should be promoted in order to produce safety data*** **[…]** ***relevant to humans and*** **[…]** **to replace** ***animal studies currently in use.***
Amendment **5** Recital 14	
(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. **[…]** **The renewal of the approval should be for a period not exceeding fifteen years.**

Amendment **6** Recital 15	
(15) The possibility of amending or withdrawing the approval of an active substance in cases where the criteria for approval are no longer satisfied should be provided for.	(15) The possibility of amending or withdrawing the approval of an active substance in cases where the criteria for approval are no longer satisfied**,** ***or where compliance with Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy […]*** **is** ***compromised,*** should be provided for **under certain conditions.**
Amendment **7** Recital 18	
(18) Some active substances may only be acceptable when extensive risk mitigation measures are taken. Such substances should be identified at Community level as candidates for substitution. Member States should regularly re-examine whether plant protection products containing such active substances can be replaced by plant protection products containing active substances which require less risk mitigation.	(18) Some active substances ***with certain properties*** should be identified at Community level as candidates for substitution. Member States should regularly ***examine*** plant protection products containing such active substances ***with the aim of replacing them*** by plant protection products containing active substances which require **[…]** less **[…]** risk mitigation ***or by*** **[…]** ***non-chemical*** **control or prevention methods […].**
Amendment **8** Recital 19a (new)	
	Addition to Recital (16) **Incentives should be given for placing on the market of low risk plant protection products.**
Amendment **10** Recital 26b (new)	
	(26b) Good administrative cooperation between Member States should be increased during all steps of the authorisation procedure. **[…]**

Amendment **11** Recital 27	
(27) The principle of mutual recognition is one of the means of ensuring the free movement of goods within the Community. To avoid any duplication of work, to reduce the administrative burden for industry and for Member States and to provide for more harmonised availability of plant protection products, authorisations granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. Therefore, the Community should be divided into zones with such comparable conditions in order to facilitate such mutual recognition. However, environmental or agricultural circumstances specific to the territory of a Member State might require that, on application, Member States recognise an authorisation issued by another Member State, amend it or refrain from authorising the plant protection product in their territory, if justified because of specific agricultural circumstances or if the high level of protection of both human and animal health and the environment set out in this Regulation can not be achieved.	(27) The principle of mutual recognition is one of the means of ensuring the free movement of goods within the Community. To avoid **any** duplication of work, to reduce the administrative burden for industry and for Member States and to **provide for** more harmonised availability of plant protection products, authorisations granted by one Member State should be **accepted by** other Member States **where agricultural, plant health and environmental (including climatic) conditions are comparable. Therefore, the Community should be divided into zones with such comparable conditions in order to facilitate such mutual recognition. However, environmental or agricultural circumstances specific to the territory of one or more Member States 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 environmental or 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.** **Appropriate conditions may also be imposed with regard to the objectives laid down in the national action plan adopted in accordance with Directive 2008/…/EC of the European Parliament and of the Council of … [establishing a framework for Community action to achieve a sustainable use of pesticides].**

Amendment **12** Recital 30	
(30) In exceptional cases, Member States should be permitted to authorise plant protection products not complying with the conditions provided for in this Regulation, where it is necessary to do so because of a danger or threat to plant production which cannot be combatted by any other means. Such authorisations should be reviewed at Community level.	(30) In exceptional cases, **[…]** **Member States** should be permitted to authorise plant protection products not complying with the conditions provided for in this Regulation, where it is necessary to do so because of a danger or threat to plant production **[…]** **or** ***ecosystems*** which cannot be ***contained*** by any other **reasonable** means. Such ***temporary*** authorisations should be reviewed at Community level.
Amendment **13** Recital 33	
(33) In order to ensure a high level of protection of human health and the environment, plant protection products should be used properly having regard to the principles of integrated pest management. The Council should include in the statutory management requirement referred to in Council Regulation (EC) No 1782/2003 of 29 September 2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers the principles of integrated pest management, including good plant protection practice.	(33) In order to ensure a high level of protection of human health and the environment, plant protection products should be used properly***, in accordance with their authorisation,*** having regard to the principles of integrated pest management ***and giving priority to non-chemical and natural alternatives wherever possible.*** The Council should include in the statutory management requirement referred to in ***Annex III of*** Council Regulation (EC) No 1782/2003 of 29 September 2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers**,** the principles of integrated pest management, including good plant protection practice ***and non-chemical methods of plant protection and pest and crop management*** **[…].**

Amendment **14** Recital 37	
(37) Studies represent a major investment. This investment should be protected in order to stimulate research. For this reason, studies lodged by one applicant with a Member State should be protected against use by another applicant. This protection should, however, be limited in time in order to allow competition. It should also be limited to studies which are genuinely necessary for regulatory purposes, to avoid applicants artificially extending the period of protection by submitting new studies which are not necessary.	(37) Studies represent a major investment. This investment should be protected in order to stimulate research. For this reason, studies***, other than those involving tests on vertebrate animals,*** **which are subject to obligatory data sharing,** lodged by one applicant with a Member State should be protected against use by another applicant. This protection should, however, be limited in time in order to allow competition. It should also be limited to studies which are genuinely necessary for regulatory purposes, to avoid applicants artificially extending the period of protection by submitting new studies which are not necessary.
Amendment **15** Recital 38	
(38) Rules should be laid down to avoid duplication of tests and studies. In particular, repetition of studies involving vertebrates should be prohibited. In this context, there should be an obligation to allow access to studies on vertebrates on reasonable terms. In order to allow operators to know what studies have been carried out by others, Member States should keep a list of such studies even where they are not covered by the above system of compulsory access.	**(38) […] The use of non-animal test methods and other risk assessment strategies should be promoted. Animal testing for the purposes of this regulation should be minimised and tests on vertebrates should be undertaken as a last resort. In accordance with Council Directive 86/609/EEC... regarding the protection of animals used for experimental and other scientific purposes, tests on vertebrate animals must be replaced, restricted or refined.** **Therefore, rules should be laid down to avoid duplicative tests and duplication of tests on vertebrates should be prohibited. For the purpose of developing new plant protection products, there should be an obligation to allow access to studies on vertebrates on reasonable terms and the results and the costs of tests and studies on animals should be shared. In order to allow operators to know what studies have been carried out by others, Member States should keep a list of such studies even where they are not covered by the above system of compulsory access.**

Amendment **16** Recital 41	
(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.
Amendment **17** Recital 43a (new)	
	to be added to recital (37) **<u>Business operators, in particular small and medium sized enterprises, should have the same opportunities in respect of market access.</u>**
Amendment **18** Recital 44a (new)	
	To be added to recital (44) : ***The bureaucratic burden on farmers should be as limited as possible.***
Amendment **19** Recital 45	
(45) Close coordination should be ensured with other Community legislation, in particular Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, and with Community legislation on the protection of workers and anyone concerned with the contained use and deliberate release of genetically modified organisms.	(45) ***The measures provided for in this Regulation should apply without prejudice to*** **[…]** **<u>other</u>** Community legislation, in particular ***Directive 2008/.../EC [establishing a framework for Community action to achieve a sustainable use of pesticides], Directive 2000/60/EC,*** Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residues levels of pesticides in or on food and feed of plant and animal origin [2]and Community legislation on the protection of workers and anyone concerned with the contained use and deliberate release of genetically modified organisms. [+] ***OJ: please insert number*** [2] OJ L 70, 16.3.2005, p. 1. *Regulation as amended by Commission Regulation (EC) No 178/2006 (OJ L 29, 2.2.2006, p. 3).*

Amendment **20** Recital 53	
(53) In particular, the Commission should be empowered to adopt Regulations concerning labelling requirements, controls and rules for adjuvants, establishing a work programme for safeners and synergists, including their data requirements, postponing the expiry of the approval period, extending the date for provisional authorisations, setting the information requirements for parallel trade and on inclusion of co-formulants, as well as amendments to the Regulations on data requirements and on uniform principles for evaluation and authorisation and to the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, inter alia by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.	53) In particular, the Commission should be empowered to adopt **[…]** ***harmonised methods to determine the nature and quantity of active substances, safeners and synergists, and where appropriate of relevant impurities and co-formulants,*** **[…],** ***and*** to adopt Regulations concerning labelling requirements, controls and rules for adjuvants, establishing a work programme for safeners and synergists, including their data requirements, postponing the expiry of the approval period, extending the date for provisional authorisations, setting the information requirements for parallel trade and on inclusion of co-formulants, as well as amendments to the Regulations on data requirements and on uniform principles for evaluation and authorisation and to the Annexes. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, inter alia by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
Amendment **22** Article 1	
Subject matter This Regulation lays down rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the Community. This Regulation lays down both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants.	Subject matter ***and purpose*** ***1.*** This Regulation lays down rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the Community. ***2.*** This Regulation lays down both rules for the approval of active substances, safeners and synergists, which plant protection products contain or consist of, and rules for adjuvants and co-formulants. ***3. The purpose of this Regulation is*** **[…] to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on**

	the market of plant protection products including active substances, while improving agricultural production. 4. Its provisions are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human, animal health or the environment posed by the plant protection products to be authorised in their territory.
Amendment **23** Article 2 – paragraph 2	
2. This Regulation shall apply to substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products, hereinafter referred to as "active substances".	Cf. AM 162
Amendment **25** Article 3 – point 3	
3) "preparations" Mixtures composed of two or more substances intended for use as a plant protection product or as an adjuvant;	3) "preparations" Mixtures ***or solutions*** composed of two or more substances **[…]** intended for use as a plant protection product or as an adjuvant

Amendment **26** Article 3 – point 4	
4) "substance of concern" Any substance which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a plant protection product in sufficient concentration to present risks of such an effect. Such substances include, but are not limited to, substances meeting the criteria to be classified as dangerous in accordance with Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, and present in the plant protection product at a concentration leading the product to be regarded as dangerous within the meaning of Article 3 of Directive 1999/45/EC;	See New amendments of the Council on Article 23 and Annex II.5
Amendment **34** Article 3 – point 12b (new)	
	(12b) "vulnerable groups" ***Persons needing specific consideration when assessing the acute and chronic health effects of plant protection products. These include pregnant and nursing women,*** **[…]** **unborns,** ***infants and children, the elderly*** **[…]** ***and workers and residents subject to high pesticide exposure over the long term;***
Amendment **37** Article 3 – point 15b (new)	
	7a. "non-chemical methods" **[...]** **Alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques such as those referred to in annex III. 1 of the Directive 2008/…/EC establishing a framework for Community action to achieve a sustainable use of pesticides, or physical, mechanical or biological pest control methods.**

Amendment **40** Article 3 – point 19a (new)	
	(19a) "rapporteur Member State" ***The Member State which*** **undertakes the task of evaluating an active substance, or safener, or synergist. […]*;***
Amendment **41** Article 3 – point 19b (new)	
	(19b) "tests and studies" ***Investigations or experiments whose purpose is to determine the properties and behaviour of an active substance or of plant protection products, predict exposure to active substances and/or their relevant metabolites, determine safe levels of exposure and establish conditions for the safe use of plant protection products;***
Amendment **42** Article 4 – paragraph 2 – point a	
(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***,*** **[…]** **including** vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the ~~**established**~~ **scientific** methods **accepted by the Authority** to assess such effects are ***available,*** or on groundwater;
Amendment **44** Article 4 – paragraph 3 – point b	
(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,*** **including for […]** ***vulnerable groups,*** or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, **[…]** or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the **scientific** methods **accepted by the Authority** to assess such effects are ***available;*** or on **[…]** groundwater;

Amendment **45** Article 4 – paragraph 3 – point e	
(e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations: (i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil; (ii) its impact on non-target species; (iii) its impact on biodiversity.	(e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations **where the scientific methods accepted by the Authority to assess such effects are** ***available***: (i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters **[…]** groundwater, air and soil **taking into account locations distant from its use following long-range environmental transportation**; (ii) its impact on non-target species***, including on the*** **ongoing** ***behaviour of those species***; (iii) its impact on biodiversity ***and the ecosystem;*** **[…]**
Amendment **46** Article 4 –paragraph 7	
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. 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.	7. By way of derogation from paragraph 1, where **[…]** on the basis of documented evidence **included in the application** an active substance is necessary to control a serious danger to plant health **[…]** which cannot be contained by other available means ***including non-chemical*** **methods, […] such** active substance may be approved for a time limited period ***necessary to control that serious danger but*** not exceeding **five** years **[…]** even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. **[…].** For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005. This derogation shall not apply to active substances which are or have to be classified in accordance with Directive 67/548/EEC, as carcinogenic category 1**,** ***carcinogenic category 2 without a threshold*****,** or toxic for reproduction category 1. **[…]**

	Members States may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control that serious danger to plant health in their territory. **At the same time, they shall elaborate a phasing out plan on how to control the serious danger by other means, including non-chemical methods, and shall forthwith transmit it to the Commission. […]**
Amendment **47** Article 4a (new)	
	To be added to Article 62, new first paragraph **[…]** ***Testing on vertebrate animals for the purposes of this Regulation shall be undertaken*** **[…] only where no other methods are available. Repetition of tests and studies involving vertebrates undertaken for the purposes of this regulation shall be avoided in accordance with paragraphs 1 to 4.**
Amendment **48** Article 6 – point (ia) (new)	
	Addition to article 6 (h) (h) designation of areas where the use of plant protection products **including soil treatment products** containing the active substance may not be authorised or where the use may be authorised under specific conditions;
Amendment **51** Article 7 – paragraph 1b (new)	
	1b. Assessment of an application may be performed by a number of Member States together under a […] co-rapporteur system.

Amendment **52** Article 8 – paragraph 1 – point ca (new)	
	(ca) for each test or study involving vertebrate animals, a justification of the steps taken to avoid animal testing and duplicative testing on vertebrate animals;
Amendment **53** Article 8 – paragraph 4a (new)	
	4a.* […] S*cientific peer-reviewed open literature,* as determined by the Authority, *on the active substance and its* relevant *metabolites* dealing with […] *side-effects on health, the environment* and non-target species […] and published within the last ten years before the date of dossier submission *shall be added by the applicant to the dossier.
Amendment **55** Article 11 – paragraph 2	
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.
Amendment **56** Article 12 – paragraph 2 – sub-paragraph 2	
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 subparagraph above is organised, the 120- day period shall be extended by* […] 30 *days.***

Amendment **57** Article 12 – paragraph 6a (new)	
	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) N°396/2005 shall not apply and the provisions of Article 14 of that Regulation shall apply without delay.
Amendment **58** Article 12 – paragraph 6b (new)	
	6b. Where the conclusions of the Authority are 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 Article 11 and 14 of Regulation (EC) N°396/2005 shall apply without delay
Amendment **64** Article 18 – point b	
(b) the necessary data to be submitted;	(b) the necessary data to be submitted ***including measures to minimise animal testing, in particular the use of non-animal test methods and intelligent testing strategies***;
Amendment **66** Article 20 – paragraph 2	
2. Where the reasons for not renewing the approval permit it, the Regulation referred to in paragraph 1 shall provide for a grace period not exceeding one year for the placing on the market and in addition a maximum of one year for the disposal, storage, and use of existing stocks of the plant protection products concerned. In the case of a withdrawal of the approval or if the approval is not renewed because of the immediate concerns for human health or animal health or the environment, the plant protection products concerned shall be withdrawn from the market immediately.	2. Where the reasons for not renewing the approval ***do not concern the protection of health or the environment***, the Regulation referred to in paragraph 1 shall provide for a grace period not exceeding **[…]** **six months for the sale and distribution, and in addition a maximum of one year for the disposal, storage, and use of existing stocks of the plant protection products concerned. The first period shall take into account the normal period of use of the plant protection product but the total grace period shall not exceed 18 months.** In the case of a withdrawal of the approval or if the approval is not renewed because of **the immediate** concerns for human health or animal health or the environment, the plant protection products concerned shall be withdrawn from the market immediately.

Amendment **67** Article 21 – paragraph 1 – sub-paragraph 1	
1. The Commission may review the approval of an active substance at any time. It may take into account the request of a Member State to review the approval of an active substance.	1. The Commission may review the approval of an active substance at any time. **[…]** **It shall take into account the request of a Member State to review, in the light of new *scientific and technical knowledge and monitoring data,* the approval of an active substance, including where after the review of the authorisations pursuant to article 44 (1), there are indications that the achievement of the objectives established in accordance with Article 4(1)(a)(iv) and (b)(i) and Article 7(2) and (3) of Directive 2000/60/EC is compromised.**
Amendment **68** Article 21 – paragraph 1 – sub-paragraph 2a (new)	
	See AM 67
Amendment **71** Article 22 – paragraph 1 – sub-paragraph 1a (new)	
	Add "chemicals" in Annex II.5, first paragraph, 4th indent. - sensitising **chemicals**,
New Amendment from the Council **Artcile 23 – parapgraph 1 – sub-paragraph aa (new)**	
	See AM 26 **(aa) does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects, and**
Amendment **74** Article 23 – paragraph 1 - sub-paragraph 2a (new)	
	For the purpose of this Regulation, an active substance which fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 shall be considered as a basic substance.

Amendment **77** Article 24 – paragraph 1	
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, **for a period not exceeding seven years,** as a candidate for substitution if it meets one or more of the additional criteria laid down in point 4 of Annex II. By way of derogation from Article 14(2), the approval may be renewed once or more for a period not exceeding **seven** years.
Amendment **80** Article 26	
By …*, a Regulation shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4) establishing a work programme for the gradual review of synergists and safeners on the market when that Regulation enters into force. The Regulation shall include notification, evaluation, assessment and decision-making procedures. It shall require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a specified time period. * Note to OJ: 60 months from the date of entry into force of this Regulation.	By …*, a Regulation shall be adopted in accordance with the **regulatory** procedure **with scrutiny** referred to in **[…]** **Article 79(4)** establishing a work programme for the gradual review of synergists and safeners on the market when that Regulation enters into force. The Regulation shall include ***the establishment of data requirements, including measures to minimise animal testing***, notification, evaluation, assessment and decision-making procedures. It shall require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a specified time period. * Note to OJ: **[…]** **60 months** from the date of entry into force of this Regulation.
Amendment **85** Article 29 – paragraph 1 – point ca (new)	
	(ca) its (technical) formulation is such that user exposure or other risks are limited as much as possible without compromising the functioning of the product;
Amendment **87** Article 29 – paragraph 1 – point f	
(f) its residues, resulting from authorised uses, and which are of toxicological, ecotoxicological or environmental relevance, can be determined by appropriate methods in general use;	(f) its residues, resulting from authorised uses, **and which are of toxicological, ecotoxicological or environmental relevance,** can be determined by **[…]** **appropriate** methods in general use ***in all Member States***, **with appropriate limits of determination on relevant samples** **[…]*;***

Amendment **89** Article 29 – paragraph 4	
4. With respect to point (e) of paragraph 1, harmonised methods may be adopted in accordance with the regulatory procedure referred to in Article 79(3).	4. With respect to point (e) of paragraph 1, harmonised methods may be adopted in accordance with the regulatory procedure ***with scrutiny*** referred to in ***Article 79(4)***.
Amendment **90** Article 29 – paragraph 6 - sub-paragraph 1a (new)	
	Addition to point 6. **Following these principles interaction between the active substance, safeners, synergists and co-formulants shall be taken into account in the evaluation of plant protection products.**
Amendment **91** Article 30 – paragraph 1 – point a	
The decision on approval could not be finalised within a time period of 30 months from the date of admissibility of the application, extended with any additional time period set in accordance with article 92 (2), article 11 (3) or article 12 (3); and	The decision on approval could not be finalised within a time period of 30 months from the date of admissibility of the application, extended with any additional time period set in accordance with article **9 […]** (2), article 11 (3) or article 12 ***(2) or*** (3); and
Amendment **93** Article 31 – paragraph 2 – sub-paragraph 1a (new)	
	Paragraph 2a (new) **2a.** ***These requirements shall also include where applicable:*** ***a) the maximum dose per hectare in each application;*** ***b) the period between the last application and harvest;*** ***c) the maximum number of applications per year.***

Amendment **95** Article 31 – paragraph 2 - sub-paragraphs 2a et 2b (new)	
	Article 31 – paragraph **3 (ba) (new)** **(ba) [...]** ***indications for proper use according to the principles of integrated pest management*** **[…] as referred to in article 13 and in Annex III to the Directive 2008/…/EC establishing a framework for Community action to achieve a sustainable use of pesticides*;***
Amendment **96** Article 31 – paragraph 3 – point a	
(a) a restriction with respect to the distribution and use of the plant protection product taking into consideration requirements imposed by other community provisions in order to protect the health of the distributors, users, bystanders and workers concerned and the environment; such restriction shall be indicated on the label;	(a) a restriction with respect to the distribution and use of the plant protection product in order to protect the health of the distributors, users, bystanders, ***residents,*** **[…] consumers or** workers concerned, **[…]** ***or*** the environment, ***taking into consideration requirements imposed by other Community provisions***; such restriction shall be indicated on the label;
Amendment **99** Article 31 – paragraph 3 – point (e)	
(e) the maximum dose per hectare in each application;	***Deleted***
Amendment **100** Article 31 – paragraph 3 – point (f)	
(f) the maximum number of applications per year and interval between applications;	**(f) the interval between applications;**
Amendment **101** Article 31 – paragraph 3 – point (h)	
(h) the pre-harvest interval, where applicable;	***Deleted***
Amendment **104** Article 33 – paragraph 3 – point c	
(c) for each test or study involving vertebrate animals, a justification of the steps taken to avoid unnecessary testing;	(c) for each test or study involving vertebrate animals, a justification of the steps taken to avoid ***animal testing and duplicative*** testing ***on vertebrate animals***;

Amendment **112** Art. 36, paragraph 3	
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 therefore. Member States shall provide for a possibility to challenge decision refusing the authorisation of such product before the national courts or other instances of appeal.	3. By way of derogation from paragraph 2 and subject to Community law**, […]** appropriate conditions **may be imposed** with respect to the requirements referred to in Article 31 **(2a) and** (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 refuse authorisation of the plant protection product in its territory if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk to human or animal health or the environment.** It shall immediately inform the applicant and the Commission of its decision and provide a technical or scientific justification therefore. Member States shall provide for a possibility to challenge **[…]** decision **[…]** refusing the authorisation of such product **[…]** before the national courts or other instances of appeal.
Amendment **113** Article 37 – paragraph 4	
4. The other Member States concerned shall at the latest within 90 days of the receipt of the assessment report and the copy of the authorisation of the Member State examining the application decide on the application as referred to in Article 36(2) and (3).	4. The other Member States concerned shall at the latest within **120** days of the receipt of the assessment report and the copy of the authorisation of the Member State examining the application decide on the application as referred to in Article 36(2) and (3).

Amendment **118** Art. 41, paragraph 1	
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, **after having examined the application and the accompanying documents referred to in Article 42(1), as appropriate with regard to the circumstances in its territory,** authorise the plant protection product concerned under the same conditions as the Member State examining the application **except where** Article 36(3) **applies**.
Amendment **123** Article 42 – paragraph 2	
2. The Member State to which an application under Article 40 is submitted shall decide on the application within 90 days.	2. The Member State to which an application under Article 40 is submitted shall decide on the application within **120** ***days***
Amendment **126** Article 44 – paragraph 3 – point ca (new)	
	(ca) on the basis of developments in scientific and technical knowledge the manner of use and amounts used can be modified;
Amendment **128** Article 46 – paragraph 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 ***are not related to the protection of human and animal health or the environment,*** **[…]** **the grace period shall be limited and not exceed six months for the sale and the distribution and an additional maximum of one year for the disposal, storage, and use of existing stocks of the plant protection products concerned.**

Amendment **132** Article 50 – paragraph 1 - introduction and points (a) and (b)	
1. A comparative assessment shall be performed by Member States when evaluating an application for authorisation for a plant protection product containing an active substance approved as a candidate for substitution. Member States shall not authorise or shall restrict the use of a plant protection product containing a candidate for substitution where the comparative assessment weighing up the risks and benefits, as set out in Annex IV, demonstrates that: (a) for the uses specified in the application an authorised plant protection product, or a non-chemical control or prevention method, already exists which is significantly safer for human or animal health or the environment; and (b) the plant protection product or non-chemical control or prevention method referred to in point (a) does not present significant economic or practical disadvantages; and (c) the chemical diversity of the active substances is adequate to minimize the occurrence of resistance in the target organism; and	1. A comparative assessment shall be performed by Member States when evaluating an application for authorisation for a plant protection product containing an active substance approved as a candidate for substitution. Member States shall not authorise or shall restrict the use of a plant protection product **[…]** containing a candidate for substitution **for use on a given crop** where the comparative assessment weighing up the risks and benefits, as set out in Annex IV, demonstrates that: (a) for the uses specified in the application an authorised plant protection product, or a non-chemical control or prevention method, already exists which is significantly safer for human or animal health or the environment; and (b) the ***substitution by*** plant protection ***products*** or non-chemical control or prevention ***methods*** referred to in point (a) does not present significant economic or practical disadvantages; and (c) the chemical diversity of the active substances, ***where relevant, or methods and practices of crop management and pest prevention are*** adequate to minimise the occurrence of resistance in the target organism; and
Amendment **133** Article 50 – paragraph 3 – sub-paragraph 2	
Such authorisations shall be granted for a period not exceeding five years.	Such authorisations shall be **once** granted for a period not exceeding **five** **[…]** years**.**
Amendment **135** Article 50 – paragraph 5	
5. Where a Member State decides to withdraw or amend an authorisation pursuant to paragraph 4, that withdrawal or amendment shall take effect five years after the decision of the Member State or at the end of the approval period of the candidate for substitution where that period ends earlier.	5. Where a Member State decides to withdraw or amend an authorisation pursuant to paragraph 4, that withdrawal or amendment shall take effect **[…]** **three** ***years*** after the decision of the Member State or at the end of the approval period of the candidate for substitution where that period ends earlier.

Amendment **136** Article 51 – paragraph 2a (new)	
	2a. ***Member States may*** **[…]** **take** ***measures to facilitate*** **or encourage** ***the submission of applications*** **[…]** **to extend the authorisation of already authorised plant protection products to** ***minor uses.***
Amendment **138** Article 51 – paragraph 4a (new)	
	Extensions on the basis of this Article shall be separately identified and separate reference shall be made to liability restrictions.
Amendment **139** Article 51 – paragraph 6	
6. Member States shall establish and regularly update a list of minor uses.	Article 57, 1st paragraph, **h) (new)** **h) The list of minor uses as referred to in Article 51, paragraph 6**
Amendment **140** Article 51 – paragraph 6a (new)	
	6a. Not later than [two years after the entry into force of this regulation], the Commission shall present a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal.
Amendment **143** Article 52 – paragraph 10a (new)	
	10a. Without prejudice to Article 63, Member State authorities shall make publicly available information about parallel trade permits
Amendment **144** Article 54 – paragraph 5	
5. Detailed rules for the application of this Article, in particular the maximum quantities of plant protection products that may be released during experiments or tests and the minimum data to be submitted in accordance with paragraph 2, may be adopted in accordance with the regulatory procedure referred to in **Article 79(3)**.	5. Detailed rules for the application of this Article, in particular the maximum quantities of plant protection products that may be released during experiments or tests and the minimum data to be submitted in accordance with paragraph 2, may be adopted in accordance with the regulatory procedure ***with scrutiny*** referred to in ***Article 79(4)***.

Amendment **145** Article 56 – paragraph 1 – sub-paragraph 3	
To this end the authorisation holder shall record and report all suspected adverse reactions in humans related to the use of the plant protection product.	To this end the authorisation holder shall record and report all suspected adverse reactions in humans***, in animals and the environment*** related to the use of the plant protection product.
Amendment **151** Article 61 – paragraph 2	
2. The competent authority of the Member State, where satisfied that the prospective applicant intends to apply for an authorisation, shall provide him with the name and address of the holder or holders of previous relevant authorisations and shall at the same time inform the holders of the authorisations of the name and address of the applicant.	2. The competent authority of the Member State, where satisfied that the prospective applicant intends to apply for an authorisation, ***or the renewal or review thereof,*** shall provide him with the name and address of the holder or holders of previous relevant authorisations and shall at the same time inform the holders of the authorisations of the name and address of the applicant.
Amendment **152** Article 61 – paragraph 3	
3. The prospective applicant for the authorisation and the holder or holders of relevant authorisations shall take all reasonable steps to reach agreement on the sharing of any test and study reports protected under Article 59 that are required by the applicant for authorisation of a plant protection product.	3. The prospective applicant for the authorisation, ***or the renewal or review thereof,*** and the holder or holders of relevant authorisations shall take all reasonable steps to reach agreement on the sharing, of any test and study reports protected under Article 59, **in a fair, transparent and non-discriminatory way.**
Amendment **155** Article 62 – paragraph 3a (new)	
	3a. Not later than [seven years after the entry into force of this Regulation], the Commission shall report on the effects of the provisions in this Regulation concerning data protection of tests and studies involving vertebrate animals. The Commission shall submit this report accompanied, if necessary, by an appropriate legislative proposal, to the European Parliament and the Council.

New Amendment of the Council Article 62 – paragraph 4	
4. The holder or holders of the relevant authorisation shall have a claim on the prospective applicant for an equal share of the costs incurred by him. The competent authority of the Member State may direct the parties involved to resolve the matter by formal and binding arbitration administered under national law. Otherwise the parties may resolve the matter through litigation in the courts of the Member States. Awards from arbitration or litigation shall have regard to the principles determined in paragraph 2 and shall be enforceable in the courts of the Member States.	4. The holder or holders of the relevant authorisation shall have a claim on the prospective applicant for **[…]** **a fair** share of the costs incurred by him. The competent authority of the Member State may direct the parties involved to resolve the matter by formal and binding arbitration administered under national law. Otherwise the parties may resolve the matter through litigation in the courts of the Member States. Awards from arbitration or litigation shall have regard to the principles determined in paragraph 2 and shall be enforceable in the courts of the Member States.
Amendment **159** Article 66 – paragraph 2a (new)	
	2a. Member States may prohibit or restrict the advertising of plant protection products in certain media **subject to Community law.**
Amendment **160** Article 67 - paragraph 1	
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. They shall make the relevant information contained in these records available to the competent authority on request. Third parties such as the drinking water industry may request access to this information by addressing the competent authority.	1. Producers, suppliers, distributors, importers, **and** exporters **[…]** of plant protection products shall keep records of the plant protection products they produce, import, export, store, or place on the market for at least **five years** […]. **Professional users of plant protection products shall keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used, for at least three years**. They shall make the **relevant** information contained in these records available to the competent authority **on request**. **Third parties such as the drinking water industry, retailers or residents, may request access to this information by addressing the competent authority.** **The competent authorities shall provide access to such information in accordance with applicable national or Community law.**

	By [3 years], the Commission shall present a report to the European Parliament and the Council on costs and benefits of the traceability of the information from users to retailers concerning the plant protection products' applications on agricultural products accompanied, if necessary, with appropriate legislative proposals.
Amendment **161** Article 67 – paragraph 1a (new)	
	***1a. Producers of plant protection products shall undertake post-*[…] authorisation *monitoring* on request of the competent authorities*. They shall notify the competent authorities of* […] the relevant results.**
Amendment of the Council **Article 74 – paragraph 2**	
(b) correspond to the actual cost of the work involved except if it is in public interest to lower the fees or charges	(b) correspond to the actual **total** cost of the work involved except if it is in public interest to lower the fees or charges
Amendment **162** Article 77	
The Commission may, in accordance with the advisory procedure referred to in Article 79(2), adopt or amend technical and other guidance documents for the implementation of this Regulation. The Commission may ask the Authority to prepare or to contribute to such guidance documents.	The Commission may, in accordance with the […] **advisory** procedure referred to in ***Article 79*** […] **(2),** adopt or amend technical and other guidance documents **such as explanatory notes or guidance documents on the content of the application concerning micro-organisms, pheromones and biological products,** for the implementation of this Regulation. The Commission may ask the Authority to prepare or to contribute to such guidance documents. […]
Amendment **163** Article 78 – paragraph 1 – point f	
(f) a Regulation establishing a work program for safeners and synergists referred to in Article 26;	Not accepted For consistency with AM 89, addition of a new point : **(fa) (new) adoption of the harmonised methods as referred to in Article 29(4)**

Amendment **165** Article 80 – paragraph 7	
7. By …*, the Commission shall establish a list of substances included in Annex I of Directive 91/414/EEC which satisfy the criteria set out in point 4 of Annex II to this Regulation and to which the provisions of Article 50 of this Regulation shall apply. * Note to OJ: **78 months** from the date of entry into force of this Regulation.	7. By …*, the Commission shall establish a list of substances included in Annex I of Directive 91/414/EEC which satisfy the criteria set out in point 4 of Annex II to this Regulation and to which the provisions of Article 50 of this Regulation shall apply. * Note to OJ: **48 *months*** from the date of entry into force of this Regulation.
Amendment **168** Annex II - point 3.6.1	
3.6.1. Where relevant, an ADI, AOEL and ARfD shall be established. When establishing such values an appropriate safety margin of at least 100 shall be ensured taking into account the type and severity of effects and the vulnerability of specific groups of the population.	3.6.1 Where relevant, an ADI, AOEL and ARfD shall be established. When establishing such values an appropriate safety margin of at least 100 shall be ensured taking into account the type and severity of effects **[…]** and the vulnerability of **specific** groups **of the population. When the critical effect is judged of particular significance such as developmental neurotoxic or immunotoxic effects, an increased margin of safety shall be considered, and applied if necessary.**
Amendment **169** Annex II - point 3.6.5	
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 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. **[…]** **Within 4 years from the entry into force of this Regulation, the Commission shall present to the Committee referred to in**

	Article 79 (1) a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties […] to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4). **Pending the adoption of these criteria, substances, that are or have to be classified, in accordance with the provisions of Directive 67/548/EEC, as carcinogen category 3 and toxic for reproduction category 3, shall be considered to have disrupting endocrine properties.** **In addition, substances, such as those that are or have to be classified, in accordance with the provisions of Directive 67/548/EEC, as toxic for reproduction category 3 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.**
Amendment **174** Annex II - point 3.8.2. a (new)	
	3.8.2a. An active substance, safener or synergist shall **be approved only if** ***it is established*** **following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist :** **- will result in a negligible exposure of honeybees […], or** **- […] there are no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae, honeybee behaviour.**
New amendment from the Council **Annex II – fifth paragraph - second subparagraph – third indent and new fourth indent**	
- it is deemed to be an endocrine disrupter.	See AM 26 - it is deemed to be an endocrine disrupter […] **or,** **- it has neurotoxic or immunotoxic effects.**

Amendment **177** Annexe IV – point 3 – sub-paragraph 2a (new)	
	The comparative assessment shall take authorised minor uses into account.

Commission declaration :

ad Annex II 3.8.2 a)

"When revising the provisions on that requirements, as referred to in Article 8.1. b) and c) of this Regulation, the Commission will pay particular attention to study protocols allowing to assess the real risk of pesticides for bees, in particular through nectar and pollen."