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NOTE

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to:	Permanent Representatives Committee
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Subject:	Proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products - Preparation for the first informal trilogue

I. INTRODUCTION

1. The Commission submitted its proposal to the Council and the European Parliament on 12 June 2009.

2. The European Economic and Social Committee adopted its opinion on 17 February 2010 [1].
The Committee of the Regions decided not to deliver an opinion.

3. The European Parliament adopted its position at first reading on 22 September 2010 [2].

[1] OJ C 347, 18.12.2010, p. 62.
[2] doc. 13881/10.

4. The Council adopted its position at first reading on 21 June 2011.

5. The Committee on the Environment, Public Health and Food Safety of the European Parliament (ENVI), on 4 October 2011, adopted a draft recommendation [3], suggesting 179 amendments to the Council position at first reading, and notably a package of compromise and consolidated amendments on the major political issues.

6. The Presidency has been in informal contact with the European Parliament with the aim to pave the way for a second reading agreement. The European Parliament has indicated its willingness to enter into negotiations for such an agreement. The Commission has also informally declared its readiness to facilitate such an agreement between the European Parliament and the Council.

II. EXAMINATION OF DRAFT AMENDMENTS

7. Based on the examination of a number of ENVI amendments at the meeting of the Working Party on the Environment, on 6 October 2011, the Presidency suggests that the first trilogue identifies priority issues and sets the agenda for the negotiations. The Presidency intends to follow the approach set out below:

- On the main political issues, the Council confirms its position at first reading, namely in relation to:

  - the definition of biocidal products (AM 11),
  - exclusion criteria (AM 25),
  - derogations to mutual recognition (AM 82),
  - the scope of Union authorisation (AM 83),
  - derogations from Union authorisation (AM 87),
  - treated Articles (AM 105),
  - transitional measures (AM 4, 133 and 134) and
  - the reinstatement of a list of approved active substances in "Annex -I" (AM 2, 23, 33, 34, 39, 40, 42, 44, 130 and 140).

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[3] See document A7-0336/2011.

- Other amendments could be already considered for negotiations based on the suggestions for a Council position set out in the third column of Annex I to this note. In particular, this concerns the amendments on:

  - substitution criteria (AM 35 and 36),
  - sustainable use of biocidal products (AM 49 and 127),
  - comparative assessment (AM 58 and 59),
  - simplified authorisation procedure (AM 61 and 62),
  - data sharing and compensation arrangements (AM 107, 108, 110 and 111), and
  - fees (AM 129).

8. Given the large number of amendments on the table and the tight timeline for finalising the negotiations, the first informal trilogue should furthermore agree to refer the examination of more technical amendments to tripartite meetings at technical level. This group of amendments, set out in Annex II, include those related to clarifications on fees, to the Register for Biocidal products and to the Annexes of the Regulation.

9. Additionally, for greater clarity, a full table with all the amendments voted by the ENVI Committee will be established and will serve as basis for the negotiations.

III. CONCLUSION

10. Based on the approach described above, the Permanent Representatives Committee is invited to mandate the Presidency to enter into negotiations with the European Parliament with the aim of reaching an agreement at second reading.

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 11 **Article 3 – paragraph 1 – point a**			
(a) 'biocidal product' means any substance, mixture or article, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the ***primary*** intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action;	(a) 'biocidal product' means any substance, mixture or article, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action; ***A treated article that has a primary biocidal function shall be considered a biocidal product.***	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 25 **Article 5**			
1. Subject to paragraph 2, the following active substances shall not be approved: (a) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B; (b) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B; (c) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B; (d) active substances identified in accordance with Articles 57(f) and	1. Subject to paragraph 2, the following active substances shall not be approved: (a) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B; (b) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B; (c) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B; (d) active substances ***which, on the basis of the assessment of Union***	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties***;***	***or internationally agreed test guidelines or other peer-reviewed scientific data and information, including a review of the scientific literature, reviewed by the Agency, are considered as having endocrine-disrupting properties that may cause adverse effect in humans, or which are*** identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties**.**		
(e) active substances which fulfil the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) according to Annex XIII to Regulation (EC) No 1907/2006.	(e) active substances which fulfil the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) according to Annex XIII to Regulation (EC) No 1907/2006.		
2. Without prejudice to Article 4(1), active substances referred to in paragraph 1 of this Article may be approved if it is shown that at least one of the following conditions is met:	2. Without prejudice to Article 4(1), active substances referred to in paragraph 1 of this Article may be approved if it is shown that at least one of the following conditions is met:		
(a) the ***risk to*** humans or the	(a) the ***exposure of*** humans or the		

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environment ***from exposure*** to the active substance in a biocidal product, under ***realistic worst case*** conditions of use, is negligible, ***in particular where*** the product is used in closed systems or ***strictly controlled*** conditions; (b) the active substance is ***essential*** to prevent or ***to*** control a serious danger to public or animal health or the environment***;*** or	environment to the active substance in ***question in*** a biocidal product, under ***normal*** conditions of use, is negligible, ***meaning that*** the product is used in closed systems or ***under other*** conditions ***excluding contact with humans***; (b) ***it is shown by evidence that*** the active substance is ***necessary*** to prevent or control a serious danger to public or animal health or ***to*** the environment***, to food and feed safety,*** or ***to the public interest and that there are no effective alternative substances or technologies available.*** ***The use of any biocidal product containing active substances included in Annex -I pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment is minimised.*** ***Member State authorising a biocidal product containing an active substance included in Annex I pursuant to this***		

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	paragraph shall draw up a substitution plan concerning the control of the serious danger by other means including non-chemical methods, which are as effective as the biocidal product concerned and shall without delay transmit that plan to the Commission. The use of the biocidal product with the active substance concerned shall be restricted to those Member States where the serious danger has to be prevented or, if it occurs, controlled.		
(c) not approving the active substance would cause disproportionate negative impacts for society when compared with the risk to human health or the environment arising from the use of the substance. ***When deciding whether an active substance may be approved in accordance with the first subparagraph, the availability of suitable and sufficient alternative substances or technologies shall***			

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
also be taken into account.			
3. ***The*** Commission shall ***be empowered to*** adopt delegated acts in accordance with Article 82 specifying scientific criteria for the determination of endocrine disrupting properties.	3. ***No later than 13 December 2013, the*** Commission shall adopt delegated acts in accordance with Article 82 specifying scientific criteria for the determination of endocrine disrupting properties.		
Pending the adoption of those criteria, active substances that are classified in accordance with the provisions of Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as, carcinogen category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties.	Pending the adoption of those criteria, active substances that are classified in accordance with the provisions of Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as, carcinogen category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties.		
Substances such as those that are classified in accordance with the provisions of Regulation (EC) No 1272/2008 as, or that meet the criteria to be classified as, toxic for reproduction category 2 and that have toxic effects on the endocrine organs, may be considered as having endocrine-disrupting properties.	Substances such as those that are classified in accordance with the provisions of Regulation (EC) No 1272/2008 as, or that meet the criteria to be classified as, toxic for reproduction category 2 and that have toxic effects on the endocrine organs, may be considered as having endocrine-disrupting properties.		

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 82 **Article 36 paragraphs 1 and 2**			
1. By way of derogation from Article 31(2), any of the Member States concerned may ***propose to*** refuse to grant an authorisation or ***to*** adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of: (a) the protection of the environment; (b) public policy or public security; (c) the protection of health and life of humans, animals or plants; (d) the protection of national treasures possessing artistic, historic or archaeological value; or (e) the target organisms not being present in harmful quantities.	1. By way of derogation from Article 31(2), any of the Member States concerned may refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of: (a) the protection of the environment; (b) public policy or public security; (c) the protection of health and life of humans, ***particularly of vulnerable groups, or of*** animals or plants; (d) the protection of national treasures possessing artistic, historic or archaeological value; or (e) the target organisms not being present in harmful quantities. ***(ea) implementation of other Union legislation, and in***	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
	particular Directive 98/83/EC.		
Any of the Member States concerned may, in particular, ***propose*** in accordance with the first subparagraph ***to*** refuse to grant an authorisation or ***to*** adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or 10(1) applies.	Any of the Member States concerned may, in particular, in accordance with the first subparagraph***,*** refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or 10(1) applies.		
2. The Member State concerned shall communicate to the applicant a detailed statement of the grounds for seeking a derogation pursuant to paragraph 1 and shall seek to reach an agreement with the applicant on the proposed derogation.	2. The Member State concerned shall communicate to the applicant a detailed statement of the grounds for seeking a derogation pursuant to paragraph 1 and shall seek to reach an agreement with the applicant on the proposed derogation.		
If the Member State concerned is unable to reach agreement with the applicant or receives no reply from the applicant within 60 days of that communication it shall inform the Commission. ***In that case, the Commission:***	If the Member State concerned is unable to reach agreement with the applicant or receives no reply from the applicant within 60 days of that communication it shall ***without delay*** inform ***other Member States and*** the Commission ***of any decision taken in this respect and its justification***.		

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
(a) may ask the Agency for an opinion on scientific or technical questions raised by the applicant or the Member State concerned; ***(b) shall adopt a decision on the derogation in accordance with the examination procedure referred to in Article 81(3).*** ***The Commission's decision shall be addressed to the Member State concerned and the Commission shall inform the applicant thereof.*** ***The Member State concerned shall take necessary measures to comply with the Commission's decision within 30 days of its notification.***			

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Amendment 83 **Article 41**			
1. Applicants may apply for Union authorisation for biocidal products which have similar conditions of use across the Union ***and which fall within the following categories of biocidal products:*** ***(a) biocidal products of product-types 6, 7, 9, 10, 12, 13 and 22; and*** ***(b) with effect from 1 January 2020, all other biocidal products except for those of product-types 14, 15, 17, 20 and 21.*** ***2. The Commission shall report to the European Parliament and the Council on the application of this Article by 31 December 2017. It shall, if appropriate, accompany its report with relevant proposals for adoption in accordance with the ordinary legislative procedure.***	1. Applicants may apply for Union authorisation for biocidal products which have similar conditions of use across the Union ***with the exception of biocidal products that contain active substances that fall under Article 5***: ***a) from 2013 the Union authorisation may be granted to biocidal products containing one or more new active substances;*** ***b) from 2017 the Union authorisation may be granted to all categories of biocidal products.*** ***No later than 31 December 2012, the Commission shall adopt delegated acts in accordance with Article 82 concerning the definition of "similar conditions of use across the Union".***	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 87 **Article 43 – paragraph 3a (new) and 4**			
	3a. Within 30 days of the submission of its opinion to the Commission, the Agency shall transmit, in all the official languages of the European Union, the draft summary of the biocidal product characteristics, as referred to in Article 21(2), as applicable;	***Not acceptable***	
4. On receipt of the opinion of the Agency, the Commission shall adopt, by means of implementing acts, a decision on the Union authorisation of the biocidal product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3). ***As soon as the Commission has taken a decision to grant a Union authorisation, it shall enter the information referred to in Article 29(4) in the Register for Biocidal Products.***	4. On receipt of the opinion of the Agency, the Commission shall adopt a decision on the Union authorisation of the biocidal product in accordance with the examination procedure referred to in Article 81(3).		
The Commission may, at the request of a Member State***, decide*** to adjust certain conditions of a Union authorisation specifically for	***A*** Member State ***shall inform the Commission if it decides*** to adjust certain conditions of a Union authorisation specifically for the		

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
the territory of that Member State or ***decide*** that a Union authorisation shall not apply in the territory of that Member State, provided that such a ***request*** can be justified on one or more of the grounds referred to in Article 36(1).	territory of that Member State or ***decides*** that a Union authorisation shall not apply in the territory of that Member State, provided that such a ***decision*** can be justified on one or more of the grounds referred to in Article 36(1).		

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 105 **Article 57 – paragraph 3-5**			
3. Where ***the release of the active substances contained in the biocidal products with which*** a treated article ***was treated or which it incorporates, is intended or expected under normal or reasonably foreseeable conditions of use,*** the person responsible for the placing on the market of that treated article shall ensure that the label provides the following information: (a) a statement that the treated article incorporates biocidal products; (b) where substantiated, the biocidal property attributed to the treated article; (c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products;	3. Where a treated article ***contains a biocidal product,*** the person responsible for the placing on the market of that treated article shall ensure that the label provides the following information: (a) a statement that the treated article incorporates biocidal products; (b) where substantiated, the biocidal property attributed to the treated article; (c) without prejudice to Article 24 of Regulation (EC) No 1272/2008, the name of all active substances contained in the biocidal products; ***(ca) the name of all nanomaterials, followed by the word "nano" in***	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
	brackets;		
(d) any relevant instructions for use, including any precautions to be taken because of the biocidal products ***with*** which a treated article ***was treated or which it*** incorporates.	(d) any relevant instructions for use, including any precautions to be taken because of the biocidal products which a treated article incorporates.		
4. Where the release of the active substances contained in the biocidal products with which a treated article was treated or which it incorporates, is not intended or expected under normal or reasonably foreseeable conditions of use, the person responsible for the placing on the market of the treated article shall ensure that the label provides the following information:	***This paragraph shall not apply where at least equivalent labelling requirements for biocidal products in treated articles to meet information requirements concerning those active substances already exist under sector-specific legislation.***		
(a) a statement that the treated article was treated with biocidal products; and			
(b) the address of a website containing the name of all active substances used for the treatment, without prejudice to Article 24 of			

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Regulation (EC) No 1272/2008. The label of such a treated article shall not lay claim to any biocidal property.			
5. The labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty.	5. The labelling shall be clearly visible, easily legible and appropriately durable. Where necessary because of the size or the function of the treated article, the labelling shall be printed on the packaging, on the instructions for use or on the warranty ***in the national language or languages of the Member State on whose market the treated article is to be placed. In the case of treated goods which are not produced as part of a series, but rather designed and manufactured to meet a specific order, the manufacturer may agree other methods of providing the customer with the relevant information.***		

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 4 **Recital 65**			
(65) ***It*** is appropriate to provide for ***a deferred application of this Regulation so as to facilitate the smooth transition to the new systems*** for the approval of active substances and authorisation of biocidal products.	(65) ***To ensure a smooth transition, it*** is appropriate to provide for ***procedures so that the applications submitted*** for the approval of active substances and authorisation of biocidal products ***before the application of this Regulation are assessed against the requirements of this Regulation.***	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 133 **Article 89 – paragraph 2 – subparagraph 1**			
Dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by …* shall ***continue to*** be evaluated by the competent authorities in accordance with the provisions of ***Directive 98/8/EC*** and, where relevant, Regulation (EC) No 1451/2007.	Dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by …* shall be evaluated by the competent authorities in accordance with the provisions of ***this Regulation*** and, where relevant, Regulation (EC) No 1451/2007. ***To ensure a smooth transition, the Commission shall, no later than ... *, adopt a delegated act in accordance with Article 82 regarding the evaluation of dossiers submitted in accordance with Directive 98/8/EC.*** ***This delegated act shall be based on the following principles:*** ***1) the evaluation shall be carried out on the basis of the information provided in the dossier as submitted under Directive 98/8/EC;*** ***2) where the evaluation identifies***	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
	concerns arising from the application of provisions of the present Regulation, which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information; ***3) every effort shall be made to avoid additional testing on vertebrate animals;*** ***4) every effort shall be made to avoid causing delays to the review programme laid down in Regulation (EC) No 1451/2007 as a result of these transitional arrangements.***		
* OJ: Insert the date - the day of application of this Regulation	* OJ: Insert the date - the day of application of this Regulation		

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
	Amendment 134 **Article 89 a (new)**		
	Transitional measures concerning applications for biocidal product authorisations submitted under Directive 98/8/EC ***Dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by …*shall be evaluated by the competent authorities in accordance with this Regulation.*** ***To ensure a smooth transition, the Commission shall, no later than ... *, adopt a delegated act in accordance with Article 82 regarding the evaluation of dossiers submitted in accordance with Directive 98/8/EC. This delegated act shall be based on the following principles:*** ***1) the evaluation shall be carried out on the basis of the information provided in the dossier as submitted under Directive 98/8/EC;***	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
	2) where the evaluation identifies concerns arising from the application of provisions of the present Regulation, which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information; ***3) every effort shall be made to avoid additional testing on vertebrate animals.*** **** OJ: Insert the date - the day of application of this Regulation***		

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 2 **Recital 10**			
(10) In order to ensure legal certainty, it is necessary to establish a Union list of active substances approved for use in biocidal products. A procedure should be laid down for assessing whether or not an active substance can be entered in that list. The information that interested parties should submit in support of an application for approval of an active substance and its inclusion in the list should be specified.	(10) In order to ensure legal certainty ***and transparency,*** it is necessary ***to maintain, within this Regulation,*** a Union list of active substances ***which are*** approved for use in biocidal products. A procedure should be laid down for assessing whether or not an active substance can be entered in that list. The information that interested parties should submit in support of an application for approval of an active substance and its inclusion in the list should be specified.	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 23 **Article 4 – paragraph 1**			
1. An active substance shall be ***approved*** for an initial period not exceeding 10 years if at least one biocidal product containing that active substance ***may be expected to meet*** the ***criteria*** laid down in point (b) of Article 18(1) taking into account the factors set out in Article 18(2) and (5).	1. An active substance shall be ***included in Annex -I*** for an initial period not exceeding 10 years if at least one biocidal product containing that active substance ***fulfils*** the ***conditions*** laid down in point (b) of Article 18(1) taking into account the factors set out in Article 18(2) and (5). ***An active substance referred to in Article 5 may only be included in Annex -I for an initial period of 5 years.*** *(Note: This amendment applies throughout the text. If adopted, reference to "approval of an active substance" is to be replaced by reference to "inclusion of an active substance in Annex -I", reference to "approval" by "inclusion in Annex -I", reference to "approved" by "included in Annex -I" etc. throughout the text.)*	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 33 **Article 9 – paragraph 1**			
1. The Commission shall, on receipt of the opinion of the Agency referred to in Article 8(4), ***either:*** ***(a) adopt an implementing Regulation providing that an active substance is approved, and under which conditions, including the dates of approval and of expiry of the approval; or*** ***(b) in cases where the requirements of Article 4(1) or, where applicable, Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, adopt an implementing decision that an active substance is not approved.*** ***Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).***	1. The Commission shall, on receipt of the opinion of the Agency referred to in Article 8(4), ***adopt, by means of delegated acts in accordance with Article 82, a decision on the inclusion of the active substance in Annex -I, including the conditions of the inclusion, the dates of inclusion and of expiry of inclusion, or on the non-inclusion of the active substance in Annex I.***	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 34 **Article 9 – paragraph 2**			
2. Approved active substances shall be included in a Union list of authorised active substances. The Commission shall keep the list up to date and make it electronically available to the public.	***deleted*** *(Note: This amendment applies throughout the text. If adopted, any reference to Article 9(2) is to be deleted, and any reference to "the list drawn up in accordance with Article 9(2)" or the "list referred to in Article 9(2)" is to be replaced by a reference to "Annex -I".)*	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 39 **Article 14 – paragraph 4**			
4. The Commission shall, on receipt of the opinion of the Agency, adopt*:* ***(a) an implementing Regulation providing that the approval of an active substance is renewed for one or more product-types, and under which conditions; or*** ***(b) an implementing decision that the approval of an active substance is not renewed.*** ***Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).*** ***Article 9(2) shall apply.***	4. The Commission shall, on receipt of the opinion of the Agency, adopt***, by means of delegated acts in accordance with Article 82, a decision on the renewal of the inclusion of the active substance in Annex -I for one or more product-types, or of the non-renewal of inclusion. In the event that the inclusion is renewed, the decision shall state the conditions of renewal and the dates of renewal and of expiry of inclusion.***	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 40 **Article 14 – paragraph 6**			
6. Where the Commission decides not to renew the ***approval*** of an active substance for one or more product-types ***it may grant a period of grace for the disposal, making available on the market and use of existing stocks*** of biocidal products of the product-type(s) concerned containing that active substance. ***The period of grace shall not exceed 180 days for making available on the market and an additional maximum of 180 days for disposal and use of existing stocks of biocidal products of the product-type(s) concerned containing that active substance.***	6. Where the Commission decides not to renew ***or to amend*** the ***inclusion*** of an active substance ***in Annex -I*** for one or more product-types***, the Member States or, in the case of a Union authorisation, the Commission shall cancel or, where appropriate, amend the authorisations*** of biocidal products of the product-type(s) concerned containing that active substance. ***Article 51 shall apply accordingly.***	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 42 **Article 15 – paragraph 1 - subparagraph 2**			
Where those indications are confirmed the Commission shall adopt ***an implementing Regulation*** amending the conditions of ***approval*** of an active substance or cancelling its ***approval***. ***That implementing Regulation shall be adopted in accordance with the examination procedure referred to in Article 81(3). Article 9(2) shall apply.*** The Commission shall inform the initial applicant(s) for the ***approval*** accordingly.	Where those indications are confirmed the Commission shall adopt ***delegated acts in accordance with Article 82*** amending the conditions of ***inclusion*** of an active substance ***in Annex -I*** or cancelling its ***inclusion***. The Commission shall inform the initial applicant(s) for the ***inclusion in Annex -I that it is carrying out a review and shall provide an opportunity for the applicant to submit comments. The Commission shall take due account of those comments in its review***.	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 44 **Article 15 – paragraph 3 a (new)**			
	3a. Where the Commission decides to cancel or amend the inclusion of an active substance in Annex -I for one or more product-types, the Member States or, in the case of a Union authorisation, the Commission shall cancel or, where appropriate, amend the authorisations of biocidal products of the product-type(s) concerned containing that active substance. Article 29 and Article 43, as appropriate, shall apply mutatis mutandis.	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 130 **Article 88 – paragraph 1 – subparagraph 3**			
In order to facilitate a smooth transition from Directive 98/8/EC to this Regulation, during the work programme the Commission shall adopt ***either implementing regulations providing that an active substance is approved, and under which conditions, or,*** in cases where the requirements of Article 4(1) or, where applicable, 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, ***implementing decisions stating that an active substance is not approved. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3). Regulations approving an active substance shall specify the date of approval. Article 9(2) shall apply.***	The Commission shall adopt***, by means of delegated acts in accordance with Article 82, decisions on the inclusion of an active substance in Annex -I, including the conditions of the inclusion, the dates of inclusion and of expiry of inclusion, or on the non-inclusion of the active substance in Annex -I.*** In cases where the requirements of Article 4(1) or, where applicable, 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, ***the active substance shall not be included in Annex -I***.	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 140 Annex -I (new)			
	Annex -I ***List of active substances with requirements for inclusion in biocidal products*** *(The full text of Annex I of Parliament's Position at first reading (EP-PW-TC1-COD(2009)0076) shall be re-inserted as Annex -I (new).)*	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 35 **Article 10 – paragraph 1 – point a a (new)**			
	(a a) it meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser;	***Acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 36 **Article 10 – paragraph 1 – point d**			
(d) there are reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures;	(d) there are reasons for concern linked to the nature of the critical effects***, in particular developmental neurotoxic or immunotoxic effects*** which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures;	***Not acceptable*** *Already covered by Council text*	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 49 **Article 17 a (new)**			
	Measures geared to the sustainable use of biocidal products ***Member States shall establish and implement mandatory measures on the basis of a Union framework directive in order to achieve the sustainable professional use of biocidal products, including the introduction of National Action Plans, integrated pest management, risk reduction measures and the promotion of alternatives.*** ***By ...*, the Commission shall submit a legislative proposal for the framework directive referred to in paragraph 1 to the European Parliament and the Council.*** _____ **** Please insert date two years after adoption of this Regulation.***	***Not acceptable / further clarification required***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 127 **Article 75 – paragraph 1 – point j a (new)**			
	(ja) providing guidance and tools for the use phase, particularly: ***- measures for integrated pest management, for specified vermin,*** ***- monitoring biocidal product use,*** ***- best practice of biocidal product use to limit use of such products to the minimum necessary dose,*** ***- pest management in sensitive areas like schools, workplaces, kindergartens, public spaces, lakes, canals, riversides and geriatric care centres,*** ***- technical equipment for biocidal product application and its inspection.***	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 58 **Article 22 – paragraph 3 a (new)**			
	3a. The Commission shall be empowered to adopt delegated acts in accordance with Article 82 defining the criteria and algorithms to be used in the comparative assessments referred to in paragraph 3, in order to ensure that there is a uniform application throughout the Union.	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 59 **Article 22 – paragraph 7**			
7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or amendment of the authorisation shall take effect ***five*** years after that decision. However, where the approval of the active substance which is a candidate for substitution expires on an earlier date, the cancellation of the authorisation shall take effect on that earlier date.	7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or amendment of the authorisation shall take effect ***three*** years after that decision. However, where the approval of the active substance which is a candidate for substitution expires on an earlier date, the cancellation of the authorisation shall take effect on that earlier date.	***To be discussed***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 61 **Article 24 – paragraph 1 – point b a (new)**			
	(b a) the biocidal product does not contain a nanomaterial;	***Acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 62 **Article 24 – point c a (new)**			
	(ca) the biocidal product meets the criteria laid down in Article 18(1)(b)(ii) to (iv); and	***Not acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 107 **Article 58 – paragraph 1 – introductory part**			
1. Without prejudice to Articles 61 and 62, data submitted for the purposes of this Regulation shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except where:	1. Without prejudice to Articles 61 and 62, data submitted for the purposes of ***Directive 98/8/EC or of*** this Regulation shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except where:	***Acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 108 **Article 58 – paragraph 1 – point a**			
(a) the subsequent applicant has a letter of access; or	(a) the subsequent applicant has ***and submits*** a letter of access; or	***Acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 110 **Article 61 – paragraph 2**			
		Partly acceptable. The text should read:	
2. Any person intending to perform tests or studies involving vertebrate animals or non-vertebrate animals ("the prospective applicant") shall ***ask the Agency whether such tests or studies have already been submitted in connection with a previous application under this Regulation or Directive 98/8/EC.***	2. Any person intending to perform tests or studies involving vertebrate animals or non-vertebrate animals, ("the prospective applicant"), shall ***submit a written request to the Agency to determine whether such tests or studies have already been submitted to the Agency, or to a competent authority in connection with a previous application under this Regulation or Directive 98/8/EC for an identical or technically equivalent product.*** ***The request shall be accompanied by fees in accordance with Article 79(1). If the applicant fails to pay the fees, the Agency shall not consider the request.***	2. Any person intending to perform tests or studies involving vertebrate animals or non-vertebrate animals, ("the prospective applicant"), shall submit a written request to the Agency to determine whether such tests or studies have already been submitted to the Agency, or to a competent authority in connection with a previous application under this Regulation or Directive 98/8/EC ~~*for an identical or technically equivalent product*~~. The request shall be accompanied by fees in accordance with Article 79(1). If the applicant fails to pay the fees, the Agency shall not consider the request.	
The ***competent authority or the*** Agency shall verify whether such tests or studies have already been submitted.	The Agency shall verify whether such tests or studies have already been submitted.	The Agency shall verify whether such tests or studies have already been submitted.	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Where such tests or studies have already been submitted in connection with a previous application, under this Regulation or Directive 98/8/EC, ***the competent authority or*** the Agency shall, without delay, communicate the name and contact details of the data ***owner*** to the prospective applicant.	Where such tests or studies have already been submitted ***to the Agency, or to a competent authority*** in connection with a previous application, under this Regulation or Directive 98/8/EC, the Agency shall, without delay, communicate the name and contact details of the data ***submitter(s)*** to the prospective applicant. ***The data submitter(s) shall where relevant, facilitate contacts between the prospective applicant and the data owner(s)***	Where such tests or studies have already been submitted to the Agency, or to a competent authority in connection with a previous application, under this Regulation or Directive 98/8/EC, the Agency shall, without delay, communicate the name and contact details of the data ***submitter(s) and data owners*** to the prospective applicant. The data submitter(s) shall, where relevant, facilitate contacts between the prospective applicant and the data owner(s).	
Where the data acquired under those tests or studies are still protected under Article 59, the prospective applicant: (a) shall, in the case of data involving tests on vertebrate animals, ***request from the data owner the right to refer to those tests or studies***; and (b) may, in the case of data not involving tests on vertebrate	Where the data acquired under those tests or studies are still protected under Article 59, the prospective applicant: (a) shall, in the case of data involving tests on vertebrate animals; and (b) may, in the case of data not involving tests on vertebrate	Where the data acquired under those tests or studies are still protected under Article 59, the prospective applicant: (a) shall, in the case of data involving tests on vertebrate animals; and (b) may, in the case of data not involving tests on vertebrate	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
animals, request from the ***data owner the right to refer to those*** tests or studies.	animals, request from the ***data owner(s) all the scientific and technical data related to the*** tests and studies ***concerned as well as the right to refer to these data when submitting applications within the framework of this Regulation***.	animals, request from the data owner(s) all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications within the framework of this Regulation.	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 111 **Article 62 - paragraphs 1-3**			
		Partly acceptable; (Clarification required for the reference in paragraph 1) **The text should read:**	
1. Where a request has been made in accordance with Article 61(2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.	1. Where a request has been made in accordance with ***the sixth subparagraph of*** Article 61(2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.	1. Where a request has been made in accordance with Article 61(2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.	
2. Where such agreement is reached, the data owner shall make the data available to the prospective applicant ***and*** shall give the prospective applicant permission to refer to the data owner's tests or studies.	2. Where such agreement is reached, the data owner shall make ***all*** the ***scientific and technical*** data ***related to the tests and studies concerned*** available to the prospective applicant ***or*** shall give the prospective applicant permission to refer to the data owner's tests or studies ***where***	2. Where such agreement is reached, the data owner***(s)*** shall make all the scientific and technical data related to the tests and studies concerned available to the prospective applicant or shall give the prospective applicant permission to refer to the data owner's tests or studies where	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
	submitting applications under this Regulation.	submitting applications under this Regulation.	
3. Where no ***such*** agreement is reached ***within 60 days of a request made according to Article 61(2)*** with respect to ***data involving*** tests ***on*** vertebrate animals, the prospective applicant shall***, without delay,*** inform the Agency***, competent authority*** and the ***data owner accordingly.*** Within 60 days of being informed ***about the failure to reach an agreement***, the Agency shall give the prospective applicant ***the right*** to refer to ***those*** tests ***or*** studies. ***Where the prospective applicant and data owner cannot agree, national courts shall decide on the*** proportionate share of the cost ***that the prospective applicant shall pay to the data owner***.	3. Where no agreement is reached with respect to tests ***and studies*** involving ***vertebrate animals,*** the prospective applicant shall inform the Agency and the ***data owner(s) thereof at the earliest one month after receipt, from the Agency, of the name and address of the data submitter(s).*** Within 60 days of being informed, the Agency shall give the prospective applicant ***permission*** to refer to ***the requested*** tests ***and*** studies ***involving vertebrate animals provided that the prospective applicant demonstrates that it has paid the data owner(s) for these tests and studies a share of cost incurred, and that every effort has been made to reach an agreement on the sharing of these tests and studies. The data owner(s) shall have a claim on the prospective applicant for*** a proportionate share of the cost ***incurred by it***.	3. Where no agreement is reached with respect to ***data concerning*** tests and studies involving vertebrate animals, the prospective applicant shall inform the Agency and the data owner(s) thereof at the earliest one month after receipt, from the Agency~~, of the name and address of the data submitter(s)~~. Within 60 days of being informed, the Agency shall give the prospective applicant permission to refer to the requested tests and studies involving vertebrate animals provided that the prospective applicant demonstrates that it has paid the data owner(s) for these tests and studies a share of cost incurred, and that every effort has been made to reach an agreement on the sharing of these tests and studies. ~~The data owner(s) shall have a claim on the prospective applicant for a proportionate share of the cost incurred by it.~~ ***Where the prospective applicant and data***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
		owners cannot agree, national courts shall decide on the proportionate share of the cost that the prospective applicant shall pay to the data owners.	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
Amendment 129 **Article 79**			
1. The Commission shall adopt, on the basis of the principles set out in paragraph 3, ***an implementing Regulation*** specifying: (a) the fees payable to the Agency, including an annual fee; (b) the rules defining conditions for reduced fees, fee waivers and the reimbursement of the member of the Biocidal Products Committee who acts as a rapporteur; and (c) conditions of payments. ***That implementing Regulation shall be adopted in accordance with the examination procedure referred to in Article 81(3). It*** shall apply only with respect to fees paid to the Agency. The Agency may collect charges for other services it provides. The fees payable ***to the Agency*** shall be set at such a level as to	1. The Commission shall adopt, on the basis of the principles set out in paragraph 3, ***delegated acts pursuant to Article 82*** specifying: (a) the fees payable to the Agency, including an annual ***and a submission*** fee; (b) the rules defining conditions for reduced fees, fee waivers and the reimbursement of the member of the Biocidal Products Committee who acts as a rapporteur; and (c) conditions of payments. ***These delegated acts*** shall apply only with respect to fees paid to the Agency. The Agency may collect charges for other services it provides. The fees payable shall be set at such a level as to ensure that the revenue	***Partly acceptable: last sentence of paragraph 1 subparagraph 4 to be discussed; paragraph 3 point f acceptable***	

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
ensure that the revenue derived from the fees, when combined with other sources of the Agency's revenue pursuant to this Regulation, is sufficient to cover the cost of the services delivered.	derived from the fees, when combined with other sources of the Agency's ***and competent authorities'*** revenue pursuant to this Regulation, is sufficient to cover the cost of the services delivered. ***The fees payable shall be published by the Agency.***		
2. Member States shall directly charge applicants fees for services that they provide with respect to the procedures under this Regulation, including the services undertaken by Member States' competent authorities when acting as evaluating competent authority.	2. Member States shall directly charge applicants fees for services that they provide with respect to the procedures under this Regulation, including the services undertaken by Member States' competent authorities when acting as evaluating competent authority.		
Based on the principles set out in paragraph 3, the Commission ***may*** issue guidance concerning a harmonised structure of fees. ***Member States may levy annual fees with respect to biocidal products made available on their markets.*** ***Member States may collect charges for other services they provide.*** Member States shall set and publish the amount of fees payable to their	Based on the principles set out in paragraph 3, the Commission ***shall*** issue guidance concerning a harmonised structure of fees. Member States shall set and publish the amount of fees payable to their competent authorities.		

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
competent authorities.			
3. Both the ***implementing Regulation*** referred to in paragraph 1 and Member States' own rules concerning fees shall respect the following principles:	3. Both the ***delegated acts*** referred to in paragraph 1 and Member States' own rules concerning fees shall respect the following principles:		
(a) fees shall be set at such a level as to ensure that the revenue derived from the fees is, in principle, sufficient to cover the cost of the services delivered and shall not exceed what is necessary to cover those costs;	(a) fees shall be set at such a level as to ensure that the revenue derived from the fees is, in principle, sufficient to cover the cost of the services delivered and shall not exceed what is necessary to cover those costs***, The level should also reflect the fact that (the funding of) the evaluation and authorisation procedure shall not be entirely financed by these fees;***		
(b) partial reimbursement of the fee if the applicant fails to submit the information requested within the specified time limit;	(b) partial reimbursement of the fee if the applicant fails to submit the information requested within the specified time limit;		
(c) the specific needs of ***SMEs*** shall be taken into account, as appropriate;	(c) the specific needs of ***small and medium sized enterprises*** shall be taken into account, ***with respect to a fee payment system,*** as appropriate; ***this shall have no bearing on the***		

Council position at first reading (adopted on 21 June 2011)	Draft EP Recommendation at second reading (voted by ENVI Committee on 4 October 2011)	Draft Council position on draft EP recommendation	EP position
	responsibility of the relevant competent authority to carry out a careful assessment in accordance with the provisions of this Regulation;		
(d) the structure and amount of fees shall take into account whether information has been submitted jointly or separately;	(d) the structure and amount of fees shall take into account whether information has been submitted jointly or separately;		
(e) in duly justified circumstances, and where it is accepted by the Agency or the competent authority, the whole fee or a part of it may be waived; and	(e) in duly justified circumstances, and where it is accepted by the Agency or the competent authority, the whole fee or a part of it may be waived; and		
(f) ***as regards Member States' rules only,*** the deadlines for the payment of fees ***to competent authorities*** shall be fixed taking due account of the deadlines of the procedures provided for in this Regulation.	(f) the deadlines for the payment of fees shall be fixed taking due account of the deadlines of the procedures provided for in this Regulation.		

ANNEX II

Amendments for examination by tripartite meetings at technical level

Fees (clarification related to Article 79 paragraphs 1 and 2):
AM 28, 29, 30, 38, 64, 65, 71, 72, 74, 84, 85, 88, 94, 98 and 99

Register for Biocidal Products – AM 63, 66, 69, 73, 87 (partly), 89, 92, 93, 97, 103 (partly), 126

Reporting: 114, 115, 116, 117, 118, 119, 120

Electronic public access: 121, 122, 123, 124, 128, 131, 132, 138

Annex I: 141, 142, 143
Annex II+III: AM 144 - 170
Annex V: 171, 172, 173
Annex VI: AM 174 - 179

AM 3, 10, 12, 13, 14, 15, 16, 17, 18, 20, 21, 24 (partly), 26, 31, 32, 40 (partly), 41, 42 (partly), 44 (partly), 45 (partly), 47, 48, 51, 52, 54 (partly), 56, 57, 60, 67, 68, 70, 90, 95, 96 (partly), 100, 101, 104, 106, 109, 112, 113, 135, 137, 139