EUROPEAN PARLIAMENT 2009 - 2014

Committee on the Environment, Public Health and Food Safety

2009/0076(COD)

14.9.2011

AMENDMENTS
231 - 358

Draft recommendation for second reading
Christa Klaß
(PE467.347v01-00)

The placing on the market and use of biocidal products

Council position at first reading
(05032/2/2011 – C7-0333/2010 – 2009/0076(COD))

AM_Com_LegRecomm

Amendment 231
Françoise Grossetête

Council position
Article 40

Council position	*Amendment*
A Union authorisation issued by the Commission in accordance with this Section shall be valid throughout the Union unless otherwise specified. It shall confer the same rights and obligations in each Member State as a national authorisation. ***For those categories of biocidal products referred to in Article 41(1), the applicant may apply for Union authorisation as an alternative to applying for a national authorisation and mutual recognition.***	A Union authorisation issued by the Commission in accordance with this Section shall be valid throughout the Union unless otherwise specified. It shall confer the same rights and obligations in each Member State as a national authorisation.

Or. fr

Justification

The concept of Union authorisation is a positive step towards a harmonised European biocidal products market, allowing for product authorisations to be valid throughout the 27 Member States. The Council's approach - both by product type and in stages - is overly restrictive. The possibility for products that are distributed widely across Europe to be authorised at Union level is crucial in order to prevent pointless barriers to their placing on the market.

Amendment 232
Julie Girling

Council position
Article 40

Council position	*Amendment*
A Union authorisation issued by the Commission in accordance with this Section shall be valid throughout the Union unless otherwise specified. It shall confer	A Union authorisation issued by the Commission in accordance with this Section shall be valid throughout the Union unless otherwise specified. It shall confer

the same rights and obligations in each Member State as a national authorisation***. For those categories of biocidal products referred to in Article 41(1), the applicant may apply for Union authorisation as an alternative to applying for a national authorisation and mutual recognition***.	the same rights and obligations in each Member State as a national authorisation.

Or. en

Justification

The introduction of the concept of Union authorisation is a positive step towards a harmonised European biocidal products market, allowing for product authorisations to be valid throughout the EU-27 Member States. Product types should be brought forward for authorisation after a risk based evaluation process has been undertaken.

Amendment 233
Julie Girling

Council position
Article 41

Council position	*Amendment*
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***:***	1. ***A*** Union authorisation ***may be granted to all categories of*** biocidal products ***with*** the ***exception*** of biocidal products ***that contain active substances that fall under Article 5.***
(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.	

Or. en

Justification

The introduction of the concept of Union authorisation is a positive step towards a harmonised European biocidal products market, allowing for product authorisations to be valid throughout the EU-27 Member States. Product types should be brought forward for authorisation after a risk based evaluation process has been undertaken.

Amendment 234
Françoise Grossetête

Council position
Article 41

Council position	*Amendment*
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:***	***An application*** for Union authorisation ***may be submitted*** for ***all categories of*** biocidal products ***with the exception of biocidal products that contain active substances that fall under Article 5.***
(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.	

Or. fr

Justification

The concept of Union authorisation is a positive step towards a harmonised European biocidal products market, allowing for product authorisations to be valid throughout the 27 Member States. The Council's approach - both by product type and in stages - is overly restrictive. The possibility for products that are distributed widely across Europe to be authorised at Union level is crucial in order to prevent pointless barriers to their placing on the market.

Amendment 235
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 41 – paragraph 1 – introductory part

Council position	*Amendment*
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:	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***, except any product that contains active substances that fall under Article 5 or 10***:

Or. en

(*Partial reinstatement of amendment of am 359 from first reading in a modified way with a view to find a compromise with Council.*)

Justification

The EP voted for a very limited scope of the Union authorisation (UA) in the first phase as of 2013. Council increased the scope by moving to certain product types (PTs). The rapporteur proposes to go way beyond the first reading. by adding PTs and by exchanging small ones for very big ones. As a true compromise, the larger scope of Council could be accepted, if substances that fall under Art.5 or 10, for which it is anyway impossible to find agreement at Union level, are excluded from the UA.

Amendment 236
Dan Jørgensen

Council position
Article 41 – paragraph 1 – subparagraphs 1a and 1b (new)

Council position	*Amendment*
	A product shall be considered a biocidal product with similar use conditions if all of the following criteria are met. The biocidal product:

(i) has similar conditions of use across the European Union, according to use instructions,

(ii) does not require personal protective equipment in conditions of use under their normal and realistic worst case condition of use according to Annex VI and

(iii) does not contain any substances of concern.

A Union authorisation may not be granted for biocidal products that contain active substances that fall under Article 5 or 10.

Or. en

Justification

The amendment underlines what is meant by similar conditions of use. When an applicant applies for a Union Authorisation we need to be sure that the biocidal product has similar conditions of use across the Union in order to ensure that the evaluation covers all circumstances and conditions. This will ensure a harmonised approach and fair completion

Amendment 237
Christa Klaß

Council position
Article 41 – paragraph 1 – point a

Council position	*Amendment*
(a) biocidal products of product-types 6, ***7, 9, 10, 12,*** 13 ***and 22***; and	(a) biocidal products of product-types ***1***, ***2***, ***3***, ***4***, ***5,*** 6, ***8,*** 13, ***18, 19***; and

Or. de

Justification

Introduction of stage-by-stage Union authorisations. For the product groups chosen by the Council, with the exception of product-types 6 and 13, the applications can be submitted from 2017 at the earliest, because on the basis of the review programme the decision on the inclusion of the active substance in Annex I will be taken from 2015 at the earliest. The proposed product-types are those which can take advantage of Community authorisation from 2013.

Amendment 238
Cristian Silviu Buşoi

Council position
Article 41 – paragraph 1 – point a

Council position	*Amendment*
(a) biocidal products of product-types ***6***, ***7***, ***9***, ***10***, ***12***, ***13 and 22***; and	(a) ***new*** biocidal products ***which have not yet been placed on the market and which provide additional benefits to the environment and human health compared to existing products and biocidal products containing one or more new active substances*** of product-types ***1***,***2***,***3***,***4***,***5***,***6,8, 18,19***; and

Or. en

Justification

For those products not yet placed on the market and which provide an added benefit for the environment and human health compared to existing products, being the result of innovation and investment, the market access of these should be encouraged. The Union authorisation procedure should therefore be available as soon as 2017 to allow all EU consumers to benefit equally from innovation and research.

Amendment 239
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 41 – paragraph 2 a (new)

Council position	*Amendment*
	2 a. No later than 13 December 2013, the Commission shall adopt delegated acts in accordance with Article 82 a definition of "similar conditions of use across the Union".

Or. en

Justification

The Council newly introduced the notion of "similar conditions of use across the Union". As this is the precondition for qualifying for Union authorisation, a clear definition needs to be provided before Union authorisation can be applied for.

Amendment 240
Rovana Plumb

Council position
Article 42 – paragraph 4 – subparagraph 3

Council position	*Amendment*
The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, part of the fee paid in accordance with Article 79 shall be reimbursed.	The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, part of the fee paid in accordance with Article 79***(1) and (2)*** shall be reimbursed.

Or. ro

Justification

This amendment is intended to improve consistency (both within the text and with other pieces of legislation) and to clarify the text.

Amendment 241
Elisabetta Gardini, Sergio Berlato, Oreste Rossi

Council position
Article 42 – paragraph 4a (new)

Council position	*Amendment*
	4a. Where the Register for Biocidal Products shows that a competent authority is examining an application relating to the same or a similar biocidal product or has already authorised the same or a similar biocidal product, the Agency shall nominate the original evaluating competent authority to

evaluate the application.

For products or families of products already authorised, the original evaluating competent authority shall submit its evaluation report and its evaluation conclusions to the Agency within 90 days from the request of the Agency.

Or. en

Amendment 242
Cristian Silviu Buşoi

Council position
Article 42 – paragraph 4 a (new)

Council position	*Amendment*
	4 a. Where the Register for Biocidal Products shows that a competent authority is examining an application relating to the same biocidal product or has already authorised the same biocidal product, that competent authority shall be the evaluating competent authority.

Or. en

Justification

By minimising duplication of work, such provision will help both national competent authorities and applicants save time and resources thereby avoiding any unnecessary administrative burdens or delays in the placing on the market of biocidal products.

Amendment 243
Cristian Silviu Buşoi

Council position
Article 43 – paragraph 3 – subparagraph 1

Council position	*Amendment*
Within ***180*** days of receipt of the	Within ***90*** days of receipt of the

conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product.	conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product.

Or. en

Justification

180 days is too long for the Agency to prepare and submit an opinion which is based on an already available evaluation performed by the evaluating competent authority. 90 days would be a more appropriate time frame.

Amendment 244
Dan Jørgensen

Council position
Article 43 – paragraph 3 a (new)

Council position	*Amendment*
	3 a. 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;

Or. en

Justification

The Summary of Biocidal Product Characteristics should be available in all the languages of the EU for products, which will have access to all EU countries.

Amendment 245
Dan Jørgensen, Michèle Rivasi, Sabine Wils

Council position
Article 43 – paragraph 4 – subparagraph 2

Council position	*Amendment*
The Commission may, at the request of a	***A*** Member State ***shall inform the***

Member State***, decide*** to adjust certain conditions of a Union authorisation specifically for 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).	***Commission if it decides*** to adjust certain conditions of a Union authorisation specifically for the 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).

Or. en

(Reinstatement of amendment 158 from first reading.)

Amendment 246
Elisabetta Gardini, Sergio Berlato, Oreste Rossi

Council position
Article 44 – paragraph 2 – point a

Council position	*Amendment*
(a) ***a list of*** all relevant data that ***it*** has generated since the initial authorisation or, as appropriate, previous renewal; ***and***	(a) ***without prejudice to Article 20 (1),*** all relevant data ***required under Article 19*** that has ***been*** generated since the initial authorisation or, as appropriate, previous renewal***, or a letter of access to these data***;

Or. en

Amendment 247
Elisabetta Gardini, Sergio Berlato, Oreste Rossi

Council position
Article 45 – paragraph 1 – subparagraph 2

Council position	*Amendment*
The evaluating competent authority may at any time require the applicant to submit the data from the list referred to in Article 44(2)(a).	***deleted***

Or. en

Amendment 248
Michèle Rivasi

Council position
Article 47 – paragraph 1 – point a a (new)

Council position	*Amendment*
	(a a) the authorisation fails to comply with requirements of Directive 2008/56/EC establishing a framework for community action in the field of marine environmental policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration, Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 98/83/EC on groundwater and Directive 2008/1/EC concerning integrated pollution prevention and control;

Or. en

(Reinstatement of amendment 163 from first reading.)

Justification

It needs to be clarified that an authorisation shall be cancelled when it fails to comply with the requirements of relevant legislation for the protection of waters.

Amendment 249
Richard Seeber

Council position
Article 50– paragraph 1

Council position	*Amendment*
In order to ensure a harmonised approach to the cancellation and amendment of authorisations, the Commission shall lay	In order to ensure a harmonised approach to the cancellation and amendment of authorisations, the Commission shall lay

down rules for the application of Articles 46 to 49 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).	down rules for the application of Articles 46 to 49, ***including a dispute settlement mechanism,*** by means of implementing acts**.** Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

Or. en

Amendment 250
Dan Jørgensen

Council position
Article 53 – paragraph 1

Council position	*Amendment*
1. Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence (**'**the applicant**'**) shall submit an application to the Agency and pay the applicable fee.	1. Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence (***"***the applicant***"***) shall submit an application to the Agency ***in the correct format*** and pay the applicable fee ***in accordance with Article 79(1)***.

Or. en

Justification

In the assessment of technical equivalence, the Agency should have the possibility to ensure that applications are submitted according to the correct format. Applications not submitted according to the format or for which the required fee has not been paid, should be rejected.

Amendment 251
Dan Jørgensen

Council position
Article 53 – paragraph 2 a (new)

Council position	*Amendment*
	2 a. In the case where the Agency decides that the application has not been

submitted in the correct format or that the appropriate fee has not been paid it shall reject the application and inform the applicant accordingly.

Or. en

Justification

In the assessment of technical equivalence, the Agency should have the possibility to ensure that applications are submitted according to the correct format. Applications not submitted according to the format or for which the required fee has not been paid, should be rejected.

Amendment 252
Michèle Rivasi

Council position
Article 54 – paragraph 1 – subparagraph 1

Council position	*Amendment*
By way of derogation from Articles 17 and 18, a competent authority may permit, for a period not exceeding ***270 days***, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use, if such a measure is necessary because of a danger to public health or the environment which cannot be contained by other means.	By way of derogation from Articles 17 and 18, a competent authority may permit, for a period not exceeding ***four months***, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use, if such a measure is necessary because of a danger to public health or the environment which cannot be contained by other means***, and if all of the following conditions are met:*** ***(a) the active substances concerned are approved for inclusion in Annex I or evaluated according to Article 4 of this Regulation and a full dossier is provided;*** ***(b) if the relevant active substances fall under Article 5(1) or 10(1), a mandatory substitution plan is established and implemented by the applicant or competent authority in order to replace the relevant substances with non-hazardous chemical or non-chemical alternatives within two years of the date of***

	approval; and
	(c) the application of the product is restricted to professional users who are certified pursuant to the requirements for an integrated pest management and the use is appropriately monitored .

Or. en

(Reinstatement of amendment 175 from first reading.)

Amendment 253
Michèle Rivasi

Council position
Article 54 – paragraph 2

Council position	*Amendment*
2. By way of derogation from point (a) of Article 18(1) and until an active substance is approved, competent authorities and the Commission may authorise, for a period not exceeding three years, a biocidal product containing a new active substance.	***deleted***
Such a provisional authorisation may be issued only if, after dossiers have been evaluated in accordance with Article 8, the evaluating competent authority has submitted a recommendation for approval of the new active substance and the competent authorities which received the application for the provisional authorisation or, in the case of a provisional Union authorisation, the Agency, consider that the biocidal product may be expected to comply with points (b), (c) and (d) of Article 18(1) taking into account the factors set out in Article 18(2).	
The competent authorities or the Commission shall enter the information referred to in Article 29(4) in the Register for Biocidal Products.	

If the Commission decides not to approve the new active substance, the competent authorities which granted the provisional authorisation or the Commission shall cancel that authorisation.

Where a decision on the approval of the new active substance has not yet been adopted by the Commission when the period of three years expires, the competent authorities which granted the provisional authorisation, or the Commission, may extend the provisional authorisation for a period not exceeding one year, provided that there are good reasons to believe that the active substance will satisfy the requirements of Article 4(1) or, where applicable, Article 5(2). Competent authorities which extend the provisional authorisation shall inform the other competent authorities and the Commission of such action.

Or. en

(Reinstatement of amendment 176 from first reading.)

Amendment 254
Françoise Grossetête

Council position
Article 55 – paragraph 1 – subparagraph 1

Council position	*Amendment*
1. By way of derogation from Article 17, an experiment or a test for the purposes of research or development involving ***an unauthorised*** biocidal product or a non-approved active substance intended exclusively for use in a biocidal product ("experiment" or "test") may take place only under the conditions laid down in this Article.	1. By way of derogation from Article 17, an experiment or a test for the purposes of research or development involving ***a new*** biocidal product ***which cannot be deemed to be a minor change to a product that has already been authorised,*** or a non-approved active substance intended exclusively for use in a biocidal product ("experiment" or "test") may take place only under the conditions laid down in this Article.

Or. fr

Justification

Experiments or tests on unauthorised biocidal products that belong to an existing biocidal product family requiring only minor changes should not be subject to the conditions laid down in this Article.

Amendment 255
Françoise Grossetête

Council position
Article 55 – paragraph 2 – subparagraph 1

Council position	*Amendment*
2. Any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the relevant competent authority of the Member State where the experiment or test will occur. The notification shall include the information ***listed in the second subparagraph of paragraph 1***.	2. Any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the relevant competent authority of the Member State where the experiment or test will occur. The notification shall include the ***identity of the biocidal product or active substance, labelling data and quantities supplied. The person concerned shall also compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. They shall make this*** information ***available to the competent authorities on request.***

Or. fr

Justification

While it is important to maintain a record of the names and addresses of consumers, it is not feasible to supply these details in advance, particularly given that this article concerns release into the environment rather than human health.

Amendment 256
Miroslav Ouzký

Council position
Article 57 – paragraph 1

Council position	*Amendment*
1. This Article shall apply exclusively to treated articles within the meaning of Article 3(1)(l) that are not biocidal products within the meaning of Article 3(1)(a). It shall not apply to treated articles where the sole treatment undertaken was ***the*** fumigation or disinfection ***of premises or containers used for storage or transport*** and where no residues are expected to remain from such treatment.	1. This Article shall apply exclusively to treated articles within the meaning of Article 3(1)(l) that are not biocidal products within the meaning of Article 3(1)(a). It shall not apply to treated articles where the sole treatment undertaken was fumigation or disinfection and where no residues are expected to remain from such treatment.

Or. en

Justification

While it is necessary to exclude from the scope of this chapter the abovementioned treated articles, this exclusion should apply in a general manner to all articles where the sole treatment was fumigation or disinfection and where no residues are expected to remain regardless of the object of the treatment.

Amendment 257
Corinne Lepage

Council position
Article 57 – paragraph 2 a (new)

Council position	*Amendment*
	2 a. Member States, or where appropriate the Commission, may prohibit or restrict the making available on the market or the use of a treated article if an active substance contained in the biocidal product that it was treated with or incorporates is a candidate for substitution in accordance with Article 10(1).

Or. en

Justification

Member States or the Commission are allowed to prohibit or restrict the making available and use of biocidal product containing an active substance candidate for substitution (Article 22). There is also the need to make provisions to be able to do the same on treated articles.

Amendment 258
Julie Girling

Council position
Article 57 – paragraph 3 – introductory part

Council position	*Amendment*
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:	3. Where***, in order to exert a biocidal effect with*** the ***exception of in-can preservatives, 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:

Or. en

Justification

The current wording remains unclear, e.g. in the case of non-biocidal products treated with in-can preservatives. Such preservatives, designed to avoid product deterioration and bacterial growth in non-biocidal products during storage may be seen as "intended to be released" when the non-biocidal product is used for non-biocidal purposes. The definition of treated articles also covers substances and mixtures. Overlap with other legislation should be avoided.

Amendment 259
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 57 – paragraph 3 – introductory part

Council position	*Amendment*
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:	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 under normal or reasonably foreseeable conditions of use, ***or where*** the ***active substance contained in the biocidal product with which a treated article was treated, or which it incorporates, is classified or meets the criteria for classification in accordance with Regulation (EC) No 1272/2008, or meets the criteria of Article 5(1)(d) or (e), the*** person responsible for the placing on the market of that treated article shall ensure that the label provides the following information:

Or. en

(Attempt to find a compromise between Council and Parliament.)

Justification

Council has introduced two different bases for labelling - they hinge on whether the biocidal product is intended/expected to be released or not. However, especially the notion of an "expectation" is subjective and thus not a suitable basis for labelling. Any article that contains an active substance with a hazard classification, that is a PBT, vPvB or an endocrine disrupter should be labelled. This also clarifies that only those articles that still contain a biocidal product need to be labelled.

Amendment 260
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 57 – paragraph 3 – point c a (new)

Council position	*Amendment*
	(c a) the name of all nanomaterials being followed by the word "nano" in brackets;

Or. en

(Partial reinstatement of amendment 62 from first reading.)

Justification

In light of the lack of knowledge about the effects of nanomaterials in biocidal products, any article that has been treated with a biocidal product that contains nanomaterials and still contains this nanomaterial should be explicitly labelled to allow for an informed consumer choice.

Amendment 261
Julie Girling

Council position
Article 57 – paragraph 3 – subparagraph 1a (new)

Council position	*Amendment*
	Points (a) to (c) of subparagraph 1 shall not apply where labelling requirements for biocidal products or alternative means to meet information requirements concerning those active substances already exist under sector-specific legislation.

Or. en

Justification

The current wording remains unclear, e.g. in the case of non-biocidal products treated with in-can preservatives. Such preservatives, designed to avoid product deterioration and bacterial growth in non-biocidal products during storage may be seen as "intended to be released" when the non-biocidal product is used for non-biocidal purposes. The definition of treated articles also covers substances and mixtures. Overlap with other legislation should be avoided.

Amendment 262
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 57 – paragraph 4

Council position	*Amendment*
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:	***deleted***
(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 Regulation (EC) No 1272/2008.	
The label of such a treated article shall not lay claim to any biocidal property.	

Or. en

(Linked to the amendment by the same authors to Art. 57(3))

Justification

This is no longer necessary if the amendment to Art. 57(3) by the same authors is adopted.

Amendment 263
Julie Girling

Council position
Article 57 – paragraph 4 – subparagraph 2 a (new)

Council position	*Amendment*
	This paragraph shall not apply where labelling requirements for biocidal products or alternative means to meet information requirements concerning those active substances already exist under sector-specific legislation.

Or. en

Justification

Overlap with other legislation should be avoided. For instance, the Detergents Regulation (EC) No 648/2004 requires in its Annex VII Part A labelling of ingredients used in detergents, in particular preservatives must be listed irrespective of their concentration with their INCI names (INCI: International Nomenclature Cosmetic Ingredients).

Amendment 264
Michèle Rivasi

Council position
Article 57 – paragraph 7

Council position	*Amendment*
7. Where there are ***serious*** indications that an active substance contained in a biocidal product with which a treated article is treated or which it incorporates does not meet the conditions laid down in Article 4(1), 5(2) or 24, the Commission shall review the approval of that active substance or its inclusion in Annex I in accordance with Article 15(1) or 27(2).	7. Where there are ***significant*** indications that an active substance contained in a biocidal product with which a treated article is treated or which it incorporates does not meet the conditions laid down in Article 4(1), 5(2) or 24, the Commission shall review the approval of that active substance or its inclusion in Annex I in accordance with Article 15(1) or 27(2).

Or. en

(Amendment in line with part of amendment 74 of first reading in a modified form.)

Justification

New text by the Council. The Commission should review the approval of an active substance as soon as there are significant indications of non-compliance, not only when there are serious indications.

Amendment 265
Miroslav Ouzký

Council position
Article 58 – paragraph 1 – introductory part

Council position	*Amendment*
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:

Or. en

Justification

Since Article 59 extends data protection to data submitted under Directive 98/8/EC they should benefit from the same level of protection in all respects.

Amendment 266
Miroslav Ouzký

Council position
Article 58 – paragraph 1 – point a

Council position	*Amendment*
(a) the subsequent applicant has a letter of access; or	(a) the subsequent applicant has ***and submits*** a letter of access; or

Or. en

Justification

Point a) should include that the letter of access has to be submitted to the authorities in order to be used for the benefit of a subsequent applicant.

Amendment 267
Cristian Silviu Buşoi

Council position
Article 61 – paragraph 2 – subparagraph 1

Council position	*Amendment*
2. Any person intending to perform tests or studies involving vertebrate animals or	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. The ***competent authority or the*** Agency shall verify whether such tests or studies have already been submitted.	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 Agency shall verify whether such tests or studies have already been submitted.

Or. en

Justification

In order to ensure transparency of negotiations between prospective applicants and data owners and avoid free-ridership, the Agency shall determine whether technical equivalence can be established between the product of the data submitter (s) and of the prospective applicant or not. The data submitter (s) shall be informed of this equivalence before the prospective applicant is granted the possibility to request from the data owner the scientific and technical data.

Amendment 268
Cristian Silviu Buşoi

Council position
Article 61 – paragraph 2 – subparagraph 2

Council position	*Amendment*
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 ***prospective applicant as well as the outcome of the technical equivalence verification to the*** data ***submitter(s) and communicate the name and contact details of the data submitter(s)*** to the prospective applicant.

Or. en

Justification

In order to ensure transparency of negotiations between prospective applicants and data owners and avoid free-ridership, the Agency shall determine whether technical equivalence can be established between the product of the data submitter (s) and of the prospective applicant or not. The data submitter (s) shall be informed of this equivalence before the prospective applicant is granted the possibility to request from the data owner the scientific and technical data.

Amendment 269
Cristian Silviu Buşoi

Council position
Article 61 – paragraph 2 – subparagraph 3 – points a and b

Council position	*Amendment*
(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	(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 animals, request from the data owner the right to refer to ***those tests or studies***.	(b) may, in the case of data not involving tests on vertebrate 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***.

Or. en

Justification

In order to ensure transparency of negotiations between prospective applicants and data owners and avoid free-ridership, the Agency shall determine whether technical equivalence can be established between the product of the data submitter (s) and of the prospective applicant or not. The data submitter (s) shall be informed of this equivalence before the prospective applicant is granted the possibility to request from the data owner the scientific and technical data.

Amendment 270
Cristian Silviu Buşoi

Council position
Article 62 – paragraph 3

Council position	*Amendment*
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 two months after receipt, from the Agency, of the name and address of the data submitter(s)***. Within ***120*** 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 costs 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, which*** shall ***be enforceable before*** the ***national courts***.

Or. en

Justification

R&D companies invest large amounts of resources (human and financial) on tests and studies to develop new and innovative products over many years. In order to boost innovation, these investments should be protected in the new regulation in order to avoid free ridership. An extension from 4 to 6 months as maximum period before the prospective applicant can obtain the data will incentive R&D companies to keep investing and will still be a reasonable timing for prospective applicants.

Amendment 271
Cristian Silviu Buşoi

Council position
Article 64 – paragraph 2 – subparagraph 2

Council position	*Amendment*
In order to facilitate such enforcement, manufacturers of biocidal products placed on the Union market shall maintain a suitable system of quality control of the manufacturing process ***without causing disproportionate administrative burden*** to ***economic operators*** and Member ***States***.	In order to facilitate such enforcement, manufacturers of biocidal products placed on the Union market shall maintain a suitable system of quality control of the manufacturing process***. To that end they shall establish and maintain, as a minimum, appropriate documentation in paper or electronic format with respect*** to***:***
	(a) the input of the ingredients to be added to the biocidal product to include specifications, manufacturing formulae and safety data sheets which are relevant to compliance and the safety of the biocidal product to be placed on the market;
	(b) the various manufacturing operations performed which are relevant to compliance and safety of the biocidal product to be placed on the market and allow its traceability; and
	c) data concerning the results of the quality control and batch identification.
	A Member State does not need to undertake a system of official controls where a company holds an internationally recognised quality assurance certificate (e.g. ISO9001) that includes an audit to verify, as a minimum, that all of the above elements have been maintained.
	Where necessary in order to ensure uniform application of this paragraph, the Commission may adopt implementing acts in accordance with the procedure referred to in Article 81(3)".

Or. en

Justification

There are too many products on the market which are of poor quality. This amendment to the Council's text reinforces the possibility to secure an efficient control of the quality of products, as it is foreseen in other legislations. Furthermore, this provision will help to stimulate innovation with a view to have safer products on the market.

Amendment 272
Corinne Lepage

Council position
Article 64 – paragraph 3 – subparagraph 1 – introductory part

Council position	*Amendment*
Every three years, from …[47] , Member States shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The report shall include:	Every three years, from …[47] , Member States shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The ***implementation reports shall be published annually on the relevant website of the Commission. The*** report shall include:

Or. en

(Reinstatement of amendment 199 from first reading.)

Amendment 273
Corinne Lepage

Council position
Article 64 – paragraph 3 – subparagraph 1 – point b

Council position	*Amendment*
(b) information on any poisonings and, where available, occupational diseases involving biocidal products.	(b) information on any poisonings and, where available, occupational diseases involving biocidal products***, especially regarding vulnerable groups, and the actions undertaken to lower the risk of future cases***.

Or. en

(Reinstatement of amendment 200 from first reading.)

Amendment 274
Michèle Rivasi

Council position
Article 64 – paragraph 3 – subparagraph 1 – point b

Council position	*Amendment*
(b) information on any poisonings and, where available, occupational diseases involving biocidal products.	(b) information on any poisonings***, especially regarding vulnerable groups,*** and ***the actions taken to lower the risk of future cases***, ***and,*** where available, occupational diseases involving biocidal products.

Or. en

(Reinstatement of amendment 200 from first reading.)

Amendment 275
Corinne Lepage

Council position
Article 64 – paragraph 3 – subparagraph 1 – point b a (new)

Council position	*Amendment*
	(b a) information on the impact on the environment.

Or. en

(Reinstatement of amendment 201 from first reading.)

Amendment 276
Corinne Lepage

Council position
Article 64 – paragraph 4

Council position	*Amendment*
4. The Commission shall draw up a report on the implementation of this Regulation, in particular Article 57, by 1 January 2020. The Commission shall submit the report to	4. The Commission shall draw up a report on the implementation of this Regulation, in particular Article 57, by 1 January 2020 ***and every three years thereafter***. The

the European Parliament and to the Council.	Commission shall submit the report to the European Parliament and to the Council.

Or. en

(Partial reinstatement of amendment 350 from first reading.)

Amendment 277
Julie Girling

Council position
Article 64 – paragraph 4 a (new)

Council position	*Amendment*
	4a. The Commission shall review the suitability of the definition of nanomaterial for biocides as defined in Article 3 (aa) within two years of the entry into force of this Regulation and shall report to the European Parliament and the Council.

Or. en

Justification

As the Council has newly introduced the reference to a horizontal definition of nano materials the European Parliament has not been able to address this in 1st reading.

Amendment 278
Corinne Lepage

Council position
Article 64 – paragraph 4 a (new)

Council position	*Amendment*
	4 a. Not later than five years after the entry into force of this Regulation, the Commission shall draw up a report on the impact of the spread of biocidal products in the environment. The Commission

shall submit the report to the European Parliament and the Council.

Or. en

(Reinstatement of amendment 204 from first reading.)

Amendment 279
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 64 – paragraph 4 a (new)

Council position	*Amendment*
	4 a. At the latest two years after the entry into force of this Regulation, the Commission shall submit to the European Parliament and Council a report on the assessment of the risks to human health and the environment presented by the use of nanomaterials in biocidal products and on specific measures to be taken with regard to them.

Or. en

(Reinstatement of amendment 203 from first reading.)

Justification

Nanomaterials fall within the scope of the Regulation. However, a proper assessment may well lack the necessary methods. There should be full transparency about how this Regulation deals with nanomaterials. As such, there should be a dedicated Commission report on the matter.

Amendment 280
Mario Pirillo

Council position
Article 65 – paragraph 2 – subparagraph 2 – point ba (new)

Council position	*Amendment*
	(ba) the precise use, function or

application of a substance or mixture;

Or. en

Justification

The precise use, function or application of a substance or mixture are confidential information and they should not be disclosed in order to protect commercial interests.

Amendment 281
Cristian Silviu Buşoi

Council position
Article 65 – paragraph 2 – subparagraph 2 – point c a (new)

Council position	*Amendment*
	(c a) names and addresses of manufacturers of the active substances, including location of manufacturing sites;

Or. en

Justification

Name of active substances supplier and biocidal product's manufacturing site are confidential business information that should not be disclosed in order to protect commercial interests. The address of a biocidal product manufacturing site does not provide useful information to the public.

Amendment 282
Cristian Silviu Buşoi

Council position
Article 65 – paragraph 2 – subparagraph 2 – point c b (new)

Council position	*Amendment*
	(c b) the location of a biocidal product manufacturing site;

Or. en

Justification

Name of active substances supplier and biocidal product's manufacturing site are confidential business information that should not be disclosed in order to protect commercial interests. The address of a biocidal product manufacturing site does not provide useful information to the public.

Amendment 283
Mario Pirillo

Council position
Article 65 – paragraph 2 – subparagraph 2 – point da (new)

Council position	*Amendment*
	(da) names and addresses of manufacturers of the active substances, including location of manufacturing sites;

Or. en

Justification

This information is confidential and should not be disclosed in order to protect commercial interests.

Amendment 284
Mario Pirillo

Council position
Article 65 – paragraph 2 – subparagraph 2 – point db (new)

Council position	*Amendment*
	db) the location of a biocidal product's manufacturing site.

Or. en

Justification

This is a confidential information and it should not be disclosed in order to protect commercial interests.

Amendment 285
Mario Pirillo

Council position
Article 65 – paragraph 2 – subparagraph 3

Council position	*Amendment*
However, where urgent action is essential to protect human health, safety or the environment or for other reasons of overriding public interest, the Agency or the competent authorities shall disclose the information referred to in this paragraph**.**	However, where urgent action is essential to protect human health, safety or the environment or for other reasons of overriding public interest, the Agency or the competent authorities shall disclose the information referred to in this paragraph ***with the exception of point (d).***

Or. en

Amendment 286
Cristian Silviu Buşoi

Council position
Article 65 – paragraph 3 – point a

Council position	*Amendment*
(a) the name ***and address*** of the authorisation holder;	(a) the name of the authorisation holder;

Or. en

Justification

Name of active substances supplier and biocidal product's manufacturing site are confidential business information that should not be disclosed in order to protect commercial interests. The address of a biocidal product manufacturing site does not provide useful information to the public.

Amendment 287
Cristian Silviu Buşoi

Council position
Article 65 – paragraph 3 – point b

Council position	*Amendment*
(b) the name and address of the biocidal product manufacturer;	***deleted***

Or. en

Justification

Name of active substances supplier and biocidal product's manufacturing site are confidential business information that should not be disclosed in order to protect commercial interests. The address of a biocidal product manufacturing site does not provide useful information to the public.

Amendment 288
Christa Klaß

Council position
Article 65 – paragraph 3 – point c

Council position	*Amendment*
(c) the name and address of the active substance manufacturer;	***deleted***

Or. de

Justification

This information falls under data protection.

Amendment 289
Mario Pirillo

Council position
Article 65 – paragraph 4 – subparagraph 1a (new)

Council position	*Amendment*
	Information accepted as confidential by a competent authority or the Agency shall be treated as confidential by other competent authorities, the Agency and the

Commission.

Or. en

Amendment 290
Dan Jørgensen

Council position
Article 65 – paragraph 4 a (new)

Council position	*Amendment*
	4 a. The request shall be accompanied by a fee in accordance with Article 79(1). If the fee is not paid, the request shall not be considered.

Or. en

Justification

In the absence of a fee, requests for confidentiality are likely to be made on a routine basis using up the resources of the national authorities and the Agency.

Amendment 291
Elisabetta Gardini, Sergio Berlato, Oreste Rossi

Council position
Article 66 – paragraph 1 – subparagraph 1 – introductory part

Council position	*Amendment*
The following information held by the Agency or the Commission on active substances shall be made publicly ***and easily*** available ***free*** of ***charge***:	The following information held by the Agency or***, as appropriate,*** the Commission on active substances shall be made***, free of charge,*** publicly available ***in a single database, in a structured format on at least the relevant website*** of ***the Commission***:

Or. en

Amendment 292
Mario Pirillo

Council position
Article 66 – paragraph 1 – subparagraph 1 – point d

Council position	*Amendment*
(d) physicochemical ***data*** and data on pathways and environmental fate and behaviour;	(d) physicochemical ***endpoints*** and data on pathways and environmental fate and behaviour;

Or. en

Justification

The word "data" is too generic and means studies doesn't refers directly to endpoints. It is necessary to clarify between the specific results of studies (endpoints) from the generic word data. The aim of the amendment is to underline the difference between "end results" and "studies".

Amendment 293
Mario Pirillo

Council position
Article 66 – paragraph 1 – subparagraph 1 – point e

Council position	*Amendment*
(e) the ***result*** of each toxicological and ecotoxicological study;	(e) the ***endpoints*** of each toxicological and ecotoxicological study;

Or. en

Justification

Also in this case "endpoints" is more clear than the word "result".

Amendment 294
Corinne Lepage

Council position
Article 66 – paragraph 2 a (new)

Council position	*Amendment*
	2 a. Public access shall be granted free of charge to an inventory containing details of biocidal products authorised pursuant to Article 25 and of the corresponding manufacturers.

Or. en

(Reinstatement of amendment 211 from first reading.)

Justification

It is essential to establish a product list to inform consumers about biocidal products authorised according to the new simplified authorization (which replaces the low risk procedure).

Amendment 295
Corinne Lepage

Council position
Article 66 – paragraph 2 b (new)

Council position	*Amendment*
	2 b. The Commission shall make available on the internet a list of all active substances available within the internal market.
	The persons responsible for the placing on the market of biocidal products shall make available on the internet a list of such products. This website shall serve to increase transparency for consumers and to facilitate an easy and fast collection of data on the properties and conditions of use of these products.

Or. en

(Partial reinstatement of amendment 219 from first reading.)

Amendment 296
Julie Girling

Council position
Article 68 – paragraph 2 – subparagraph 1 – introductory part

Council position	*Amendment*
In addition to compliance with paragraph 1, authorisation holders shall ensure that labels are not misleading in respect of the risks from the product to human health or the environment or its efficacy and, in any case, do not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless***', 'natural***', 'environmentally friendly', 'animal friendly' or similar indications. In addition, the label must show clearly and indelibly the following information:	In addition to compliance with paragraph 1, authorisation holders shall ensure that labels are not misleading in respect of the risks from the product to human health or the environment or its efficacy and, in any case, do not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless', 'environmentally friendly', 'animal friendly' or similar indications. In addition, the label must show clearly and indelibly the following information:

Or. en

Justification

"Natural" is an easily understood term and consumers should be able to identify products which contain natural rather than synthetic ingredients.

Amendment 297
Françoise Grossetête, Gaston Franco

Council position
Article 68 – paragraph 2 – subparagraph 1 – introductory part

Council position	*Amendment*
In addition to compliance with paragraph 1, authorisation holders shall ensure that labels are not misleading in respect of the risks from the product to human health or the environment or its efficacy and, in any case, do not mention the indications "low-risk biocidal product", "non-toxic", "harmless", ***"natural",*** "environmentally friendly", "animal friendly" or similar indications. In addition, the label must	In addition to compliance with paragraph 1, authorisation holders shall ensure that labels are not misleading in respect of the risks from the product to human health or the environment or its efficacy and, in any case, do not mention the indications "low-risk biocidal product", "non-toxic", "harmless", "environmentally friendly", "animal friendly" or similar indications. In addition, the label must show clearly and

show clearly and indelibly the following information:	indelibly the following information:

Or. fr

Justification

Consumers and some market operators are increasingly demanding the possibility of taking informed decisions in favour of purchasing products containing more natural substances. The industry should therefore be authorised to provide information on the product's composition provided that this does not mislead consumers and no inaccurate or unscientific statements are made concerning safety, environmental protection or performance.

Amendment 298
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 68 – paragraph 2 – subparagraph 1 – point aa (new)

Council position	*Amendment*
	(aa) whether the product contains nanomaterials and any specific related risks, and, following each reference to nanomaterials, the word "nano" in brackets;

Or. en

(Reinstatement of amendment 213 from first reading.)

Justification

The impact of nanomaterials on health and the environment is largely unknown at present, yet they may pose specific problems. Any user of a biocidal product should therefore be informed via adequate labelling.

Amendment 299
Nessa Childers

Council position
Article 68 – paragraph 2 – subparagraph 1 – point n a (new)

Council position	*Amendment*
	(n a) the statement "Use biocides safely. Always read the label and product information before use".

Or. en

Amendment 300
Julie Girling

Council position
Article 71 – paragraph 3

Council position	*Amendment*
3. Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention 'low-risk biocidal product', 'non-toxic', 'harmless***', 'natural***', 'environmentally friendly', 'animal friendly' or any similar indication.	3. Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention 'low-risk biocidal product', 'non-toxic', 'harmless', 'environmentally friendly', 'animal friendly' or any similar indication.

Or. en

Justification

"Natural" is an easily understood term and consumers should be able to identify products which contain natural rather than synthetic ingredients.

Amendment 301
Françoise Grossetête, Gaston Franco

Council position
Article 71 – paragraph 3

Council position	*Amendment*
3. Advertisements for biocidal products	3. Advertisements for biocidal products

shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention "low-risk biocidal product", "non toxic", "harmless", ***"natural",*** "environmentally friendly", "animal friendly" or any similar indication.	shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention "low-risk biocidal product", "non toxic", "harmless", "environmentally friendly", "animal friendly" or any similar indication.

Or. fr

Justification

Consumers and some market operators are increasingly demanding the possibility of taking informed decisions in favour of purchasing products containing more natural substances. The industry should therefore be authorised to provide information on the product's composition provided that this does not mislead consumers and no inaccurate or unscientific statements are made concerning safety, environmental protection or performance.

Amendment 302
Elisabetta Gardini, Sergio Berlato, Oreste Rossi

Council position
Article 75 – paragraph 1 – point j a (new)

Council position	*Amendment*
	(j a) providing assistance to and coordinating between Member States in order to avoid the parallel assessment of applications relating to the same or similar biocidal products referred to in Articles 28 (4) and 42 (5).

Or. en

Amendment 303
Dan Jørgensen

Council position
Article 79 – paragraph 1 – subparagraph 1 – point a

Council position	*Amendment*
(a) the fees payable to the Agency, including an annual fee;	(a) the fees payable to the Agency, including an annual ***and a submission*** fee;

Or. en

Justification

It should be clarified that also a submission fee is required for covering the related Agency services.

Amendment 304
Richard Seeber

Council position
Article 79 – paragraph 1 – subparagraph 4

Council position	*Amendment*
The fees payable ***to the Agency*** shall be set at such a level as to 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.	The fees payable shall be set at such a level as to ensure that the revenue 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.***

Or. en

Amendment 305
Cristian Silviu Buşoi

Council position
Article 79 – paragraph 1 – subparagraph 1 – point a

Council position	*Amendment*
(a) the fees payable to the Agency***, including an annual fee***;	(a) the fees payable to the Agency;

Or. en

Justification

In absence of any justification an annual fee should not be applicable.

Amendment 306
Miroslav Ouzký

Council position
Article 79 – paragraph 3 – introductory part

Council position	*Amendment*
3. ***Both the*** implementing Regulation referred to in paragraph 1 ***and Member States' own rules*** concerning fees shall respect the following principles:	3. ***The*** implementing Regulation referred to in paragraph 1 concerning fees shall respect the following principles:

Or. en

Justification

The deletion of certain parts is triggered by establishing a fee regulation that covers fees payable to both the Agency and the Member State, as proposed in Amendments 155 and 156.

Amendment 307
Miroslav Ouzký

Council position
Article 79 – paragraph 3 – point a

Council position	*Amendment*
(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;***

Or. en

Justification

While it is evident that the applicant has to pay for services delivered by the competent authorities and by the Agency, it is disproportionate to devolve all costs to the industry.

Amendment 308
Miroslav Ouzký

Council position
Article 79 – paragraph 3 – point c

Council position	*Amendment*
(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 responsibility of the relevant competent authority to carry out a careful assessment in accordance with the provisions of this Regulation;***

Or. en

Justification

SMEs could benefit from a specific fee payment system, e.g. by allowing them to spread the fee over several months or years.

Amendment 309
Miroslav Ouzký

Council position
Article 79 – paragraph 3 – point f

Council position	*Amendment*
(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.

Or. en

Justification

Publication of the fee structure decided by the Agency and by Member States will allow companies to submit fee payment with their applications thereby shortening review times and minimising the risk that deadlines for payment will not be met.

Amendment 310
Andres Perello Rodriguez, Pilar Ayuso, Cristina Gutiérrez-Cortines

Council position
Article 88 – paragraph 3 – subparagraph 2

Council position	*Amendment*
To that effect, those wishing to apply for the authorisation or mutual recognition in parallel of biocidal products of that product-type containing no active substances other than existing active substances shall submit applications for authorisation or mutual recognition in parallel to Member States' competent authorities no later than the date of approval of the active substance(s). In the case of biocidal products containing more than one active substance, applications for authorisation shall be submitted no later than the date of approval of the last active substance for that product-type.	To that effect, those wishing to apply for the authorisation or mutual recognition in parallel of biocidal products of that product-type containing no active substances other than ***approved*** existing active substances shall submit applications for authorisation or mutual recognition in parallel to Member States' competent authorities no later than the date of approval of the active substance(s). In the case of biocidal products containing more than one active substance, applications for authorisation shall be submitted no later than the date of approval of the last active substance for that product-type.

Or. en

Amendment 311
Andres Perello Rodriguez, Pilar Ayuso, Cristina Gutiérrez-Cortines

Council position
Article 88 – paragraph 3 – subparagraph 3 – point a

Council position	*Amendment*
(a) the biocidal product shall no longer be made available on the market with effect from ***180 days after*** the date of approval of the active substance(s); and	(a) the biocidal product shall no longer be made available on the market with effect from the date of approval of the active substance(s); and

Or. en

Justification

In the absence of application for authorisation or mutual recognition in parallel, there should be no transitional period for biocidal products with the exception of existing stocks.

Amendment 312
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Article 89 – paragraph 2 – subparagraph 1

Council position	*Amendment*
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.	***deleted***

(Amendment to achieve coherence with the wording in Art. 88(1) third subparagraph.)

Or. en

Justification

From Article 88(1), one can see that the new cut-off criteria of this Regulation should apply for future approval decisions. However, unless this subparagraph is deleted, the provisions of this new regulation, in particular the cut-off criteria and the provisions on candidates for substitution, will not apply for the evaluation of all existing substances for at least a decade, as the evaluation of existing active substances will still take many years. That makes a mockery of the whole regulation.

Amendment 313
Cristian Silviu Buşoi

Council position
Article 95 – paragraph 1 – subparagraph 3

Council position	*Amendment*
For the purposes of this paragraph and for existing active substances listed in Annex II to Regulation (EC) No 1451/2007, the provisions on ***mandatory*** data sharing, as laid down in Articles 61 ***and*** 62 ***of this Regulation***, shall apply to all ***toxicological and ecotoxicological*** studies included in the dossier. The relevant person shall be required to apply for data sharing only for those data that it does not already possess.	For the purposes of this paragraph and for existing active substances listed in Annex II to Regulation (EC) No**.** 1451/2007, the provisions on data sharing, as laid down in Articles 61, 62, ***and 63*** shall apply to all studies included in the dossier. The relevant person shall be required to apply for data sharing only for those data that it does not already possess ***and that involves tests on vertebrate animals only***.

Or. en

Justification

Mandatory sharing of non-vertebrate data should not be allowed as this would not be consistent with other legislations (Regulation 1107/2009 on plant protection products, REACH) and would discriminate R&D investments.

Amendment 314
Jolanta Emilia Hibner, Bogusław Sonik

Council position
Annex I – Category 4 – Row 2a(new)

Council position

EC number	*Name/group*	*Restriction*	*Comment*

Amendment

EC number	*Name/group*	*Restriction*	*Comment*
Natural oil	***Tea tree oil***	***Maximum concentration in products should be limited to 1%***	***68647-73-4***

Or. en

Justification

We propose to include Tea tree oil into in Annex I. It was already included to Annex I of Commission Regulation (EC) No 1451/2007 of 4 December 2007. There are scientific justifications of antibacterial and antifungal activity in proposed concentration. Tea tree oil is effective in very low concentration, in which the substance is not harmful to human and the environment.

Amendment 315
Jolanta Emilia Hibner, Bogusław Sonik

Council position
Annex I – Category 4 – Row 2b(new)

Council position

EC number	*Name/group*	*Restriction*	*Comment*

Amendment

EC number	*Name/group*	*Restriction*	*Comment*
232-371-1	***Garlic extract***		

Or. en

Justification

We propose to include Garlic extract into in Annex I. It was already included into in Annex I and Annex II (product type 3,4,5,18,19) of Commission Regulation (EC) No 1451/2007of 4 December 2007. Garlic extract can be used as a repellent even in 99.9 per cent, however, an antibacterial and antifungal activity is observed for concentration to 10 per cent. According to Directive 2008/127/EC this active substance was included to Directive 91/414/EEC and the long term exposure of human was set at 3g/kg b.w./day, which mean that this substance is not harmful to human.

Amendment 316
Jolanta Emilia Hibner, Bogusław Sonik

Council position

Annex I – Category 4 – Row 2c (new)

Council position

EC number	*Name/group*	*Restriction*	*Comment*

Amendment

EC number	*Name/group*	*Restriction*	*Comment*
Natural oil	***Citronella oil***	***Maximum concentration in products should be limited to 0.15%***	***8000-29-1***

Or. en

Justification

We propose to include Citronella oil into in Annex I. It was already included to Annex I of Commission Regulation (EC) No 1451/2007 of 4 December 2007. There are scientific justifications of antifungal and repellent activity against ticks in proposed concentration. Citronella oil is effective in very low concentration, in which is not harmful to human and the environment.

Amendment 317
Jolanta Emilia Hibner, Bogusław Sonik

Council position
Annex I – Category 7 – Row 4a (new)

Council position

EC number	*Name/group*	*Restriction*

Amendment

EC number	*Name/group*	*Restriction*

223-095-2	***Denatonium benzoate***	***Maximum concentration in products should be limited to 500 ppm (0.050%).***

Or. en

Justification

We propose to include denatonium benzoate (Bitrex) to Annex I. It was already included to Annex I of Commission Regulation (EC) No 1451/2007 of 4 December 2007. Based on a discussion between EU Member States Bitrex has been approved as an active substance in biocidal products using as a repellent against pet animals (e.g. dogs, cats). It is also commonly use as aversive agent in rodenticides and important for their safe use. Denatonium benzoate is used in products in very low concentration, in which is not harmful to human and the environment.

Amendment 318
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Annex II – point 5

Council position	*Amendment*
5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[66] . However, if a method is inappropriate or not described, other methods shall be used which are***, whenever possible, internationally recognised*** and must be justified in the application.	5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[66] . ***Methods listed in Annex I do not cover nanomaterials, except where specifically mentioned.*** However, if a method is inappropriate or not described, other methods shall be used which are ***scientifically satisfactory*** and ***the validity of which*** must be justified in the application.

Or. en

(Reinstatement of amendment 346 from first reading)

Justification

The relevant scientific committee of the Commission concluded that the knowledge on the methodology for both exposure estimates and hazard identification of nanomaterials needs to be further developed and validated. As such, existing methods for bulk chemicals cannot be assumed to provide relevant data. Until the validity of standard test methods has been assessed for nanomaterials, a special justification has to be given for the use of these tests for the assessment of nanomaterials.

Amendment 319
Dan Jørgensen

Council position
Annex II – Title 1 – 7.5. – Column 1

Council position	*Amendment*
7.5. Likely tonnage to be placed on the market per year	7.5. Likely tonnage to be placed on the market per year ***and where relevant, for the envisaged major use categories.***

Or. en

Justification

Additional information is important at both active substance level (Annex II) and for the Biocidal Product (Annex III) in order to allow for a proper cumulative risk assessment for biocidal products where relevant.

Amendment 320
Julie Girling

Council position
Annex II – Title 1 – 8.7. Acute toxicity – Column 1

Council position	*Amendment*
8.7. Acute toxicity	8.7. Acute toxicity
In addition to the oral route (8.7.1), for substances other than gases, the information mentioned under 8.7.2 to 8.7.3 ***shall*** be provided for ***at least one*** other ***route.***	In addition to the oral route (8.7.1), for substances other than gases, the information mentioned under 8.7.2 to 8.7.3 ***may*** be provided for other ***routes***.
– The choice for the second route will depend on the nature of the substance and	– The choice for the second route will depend on the nature of the substance and

the likely route of human exposure.	the likely route of human exposure.
– Gases and volatile liquids should be administered by the inhalation route	– Gases and volatile liquids should be administered by the inhalation route
– If the only route of exposure is the oral route, then information for only that route need be provided. If dermal or inhalation route is the only route available then an oral test may be considered.	– If the only route of exposure is the oral route, then information for only that route need be provided. If dermal or inhalation route is the only route available then an oral test may be considered. ***Before a new dermal acute toxicity study is carried out, an in vitro dermal penetration study (OECD 428) should be conducted to assess the likely magnitude and rate of dermal bioavailability.***
– There may be ***specific*** circumstances where all routes of exposure are deemed necessary.	– There may be ***exceptional*** circumstances where all routes of exposure are deemed necessary.

Or. en

Justification

Acute toxicity studies can sometimes lead to morbidity or mortality in animal specimens. Requiring such studies by more than one exposure route (i.e. oral + skin + inhalation) should be the exception rather than the rule. This is especially true for dermal (skin) testing, which has been shown in several independent analyses to add nothing of value for classification purposes in more than 98% biocides and other substances examined.

Amendment 321
Julie Girling

Council position
Annex II – Title 1 – 8.7.3 Acute toxicity - by dermal route – Column 1

Council position	*Amendment*
8.7.3. By dermal route	8.7.3. By dermal route
Testing by the dermal route is ***appropriate*** if:	Testing by the dermal route ***may be indicated*** if:
– inhalation of the substance is unlikely; ***or***	– inhalation of the substance is unlikely;
– skin contact in production and/or use is likely; ***or***	– skin contact in production and/or use is likely;

– the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.	– the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin; ***and***
	– the oral LD50 is 300 mg/kg or less;
	– the results of an in vitro dermal penetration study (OECD 428) demonstrate high dermal bioavailability.

Or. en

Justification

Same scientific justification as for Amendment 328. This amendment refines the triggers for acute (lethal dose) testing by the skin route and introduces an intelligent testing strategy to prevent unnecessary animal use.

Amendment 322
Sabine Wils

Council position
Annex II – Title 1 – 8.9. Repeated dose toxicity – Column 1 – point(iii)

Council position	*Amendment*
8.9 Repeated dose toxicity	8.9 Repeated dose toxicity
(iii) dermal toxicity is recognised for structurally related substances and for example is observed at lower doses than in the oral toxicity test ***or*** dermal absorption is comparable or higher than oral absorption	(iii) dermal toxicity is recognised for structurally related substances and for example is observed at lower doses than in the oral toxicity test ***and*** dermal absorption is comparable or higher than oral absorption

Or. en

Justification

A repeated dose toxicity study by the dermal route should not be carried out if the results of an in vitro dermal absorption study are 1) not available and 2) do not demonstrate higher absorption via the skin vs. the oral route.

Amendment 323
Julie Girling

Council position
Annex II – Title 1 – 8.9.3. Long-term repeated dose toxicity (≥ 12 months) – Column 3

Council position	*Amendment*
8.9.3. The long-term toxicity study (≥ 12 months) does not need to be conducted if: – Long-term exposure can be excluded and no effects have been seen at limit dose in the 90-day study or	8.9.3. The long-term toxicity study (≥ 12 months) does not need to be conducted if: – Long-term exposure can be excluded and no effects have been seen at limit dose in the 90-day study, or ***– if the application of an uncertainty factor of up to ten-fold would be sufficiently protective for risk assessment purposes, or***
– a combined long-term repeated dose/carcinogencity study (section 8.11.1) is undertaken.	– a combined long-term repeated dose/carcinogencity study (section 8.11.1) is undertaken.

Or. en

Justification

Long-term general toxicity studies are costly in both economic and animal welfare terms and can often be avoided by extrapolating the results from a 90-day study data using conservative statistical techniques (i.e. dividing the "no effect level" from a 90 day study by 10, which assumes that humans could be up to 10-times more sensitive to long-term vs. short-term exposure). In practice, this approach usually leads to more conservative and health-protective risk assessments than can be achieved with animal testing.

Amendment 324
Julie Girling

Council position
Annex II – Title 1 – 8.9.4. Further repeat dose studies – Column 1– paragraph 1 – introductory part and indent 1

Council position	*Amendment*
8.9.4. Further repeat dose studies	8.9.4. Further repeat dose studies
Further repeat dose studies including testing on a second species (non-rodent), studies of longer duration or through a different route of exposure ***shall*** be undertaken in case of:	Further repeat dose studies including testing on a second species (non-rodent), studies of longer duration or through a different route of exposure ***may*** be undertaken in case of:

– no other information on toxicity for a second non-rodent species is provided for; or

Or. en

Justification

Testing on a second species (i.e. dogs) should be the exception rather than the rule. The first of the proposed triggers for further studies is not appropriate and should be deleted.

Amendment 325
Sirpa Pietikäinen

Council position
Annex II – Title 1 – 8.10.2 – Column 1

Council position	*Amendment*
8.10.2. Two-generation reproductive toxicity study, rat, oral route of administration is the preferred route.	8.10.2. Two-generation reproductive toxicity study, rat, oral route of administration is the preferred route.
If another reproductive toxicity test is used justification shall be provided.	If another reproductive toxicity test is used justification shall be provided. ***Now that an extended one-generation reproductive toxicity study has been adopted at OECD level it should be considered as an alternative approach to the multi-generation study.***

Or. en

Amendment 326
Julie Girling

Council position
Annex II – Title 1 – 8.11.2. Carcinogenicity testing in a second species – Column 1

Council position	*Amendment*
8.11.2. Carcinogenicity testing in a second species	***Delete***
– A second carcinogenicity study should normally be conducted using the mouse	

as test species.
– For evaluation of consumer safety of active substances that may end up in food or feed, it is necessary to conduct toxicity studies by the oral route.

Or. en

Amendment 327
Dan Jørgensen

Council position
Annex II – Title 1 – 8.13. – Column 1 – paragraph 1a (new)

Council position	*Amendment*
	Other available data: Available data from emerging methods and models, including toxicity pathway-based risk assessment, in vitro and 'omic (genomic, proteomic, metabolomic, etc.) studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening shall be submitted in parallel.

Or. en

Justification

The explosive growth of computing power and computational biology has made available a wide range of new tools for studying the effects of chemicals on cells, tissues and organisms in a rapid and cost-efficient manner. As companies begin to incorporate these tools and tests into their in-house product stewardship programmes, these data should be submitted in parallel to maximise the availability of mechanistic data to support regulation, and to build confidence in the use of new methods to replace or reduce animal use.

Amendment 328
Sabine Wils

Council position

Annex II – Title 1 – 8.13 – Column 1 – paragraph 1a(new)

Council position	*Amendment*
	Other available data
	Available data from emerging methods and models, including toxicity pathway-based risk assessment, in vitro and 'omic (genomic, proteomic, metabolomic, etc.) studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening shall be submitted in parallel.

Or. en

Justification

The explosive growth of computing power and computational biology has made available a wide range of new tools for studying the effects of chemicals on cells, tissues and organisms in a rapid and cost-efficient manner. As companies begin to incorporate these tools and tests into their in-house product stewardship programmes, these data should be submitted in parallel to maximise the availability of mechanistic data to support regulation, and to build confidence in the use of new methods to replace or reduce animal use.

Amendment 329
Julie Girling

Council position
Annex II – Title 1 – 8.13.3. – Column 1

Council position	*Amendment*
8.13.3. Endocrine ***disruption***	8.13.3. Endocrine***-mediated toxicity***
If there is any evidence from *in vitro*, repeat dose or reproduction toxicity studies, that the active substance may ***have*** endocrine ***disrupting*** properties then additional information or specific studies ***shall*** be required:	If there is any evidence from *in vitro*, repeat dose or reproduction toxicity studies, that the active substance may ***exhibit*** endocrine***-mediated toxic*** properties then additional information or specific studies ***may*** be required:

Or. en

Amendment 330
Julie Girling

Council position
Annex II – Title 1 – 8.13.4. – Column 1

Council position	*Amendment*
8.13.4. Immunotoxicity ***including developmental immunotoxicity***	8.13.4. Immunotoxicity
If there is any evidence, from skin sensitisation, repeat dose or reproduction toxicity studies, that the active substance may have immunotoxicity properties then additional information or specific studies ***shall*** be required:	If there is any evidence, from skin sensitisation, repeat dose or reproduction toxicity studies, that the active substance may have immunotoxicity properties then additional information or specific studies ***may*** be required:
– to elucidate the mode/mechanism of action	– to elucidate the mode/mechanism of action
– provide sufficient evidence for relevant adverse effects in humans	– provide sufficient evidence for relevant adverse effects in humans

Or. en

Amendment 331
Sirpa Pietikäinen

Council position
Annex II – Title 1 – 9.1.11. – Columns 1 and 2

Council position	*Amendment*
9.1.11. Amphibian metamorphosis assay - ADS	***Delete***

Or. en

Amendment 332
Julie Girling
Council position

Annex II – Title 1 – 9.9. – Column 3 (new)

Council position	*Amendment*
	Data are derived from the mammalian toxicological assessment. The most sensitive relevant mammalian long-term toxicological endpoint (NOAEL) expressed as mg test compound/kg bw/day shall be reported.

Or. en

Justification

Because it is standard to use rodent and other mammalian data developed for human health assessments in environmental toxicology assessments aimed at protecting wild mammals, this should be stated explicitly to avoid unnecessary additional animal testing. The language of the proposed amendment is derived from proposed new EU data requirements for plant protection products.

Amendment 333
Julie Girling

Council position
Annex II – Title 2 – 7. Effects on human and animal health – Column 3 (new)

Council position	*Amendment*
	Information requirements in this section may be adapted as appropriate in accordance with the specifications of Title 1 of this Annex.

Or. en

Justification

Adaptation of certain standard information requirements for microbial biocides through the addition of qualifying sentence to the introductory text.

Amendment 334
Julie Girling

Council position
Annex II – Title 2 – 7.2.2.2. Acute inhalatory toxicity– Column 2 (new)

Council position	*Amendment*
	ADS

Or. en

Justification

Acute toxicity studies can sometimes lead to morbidity or mortality in animal specimens. Requiring such studies by more than one exposure route (i.e. oral + inhalatory + intraperitoneal/subcutaneous) should be the exception rather than the rule. Accordingly, acute pulmonary toxicity should at most be a second-tier data requirement.

Amendment 335
Julie Girling

Council position
Annex II – Title 2– 7.2.2.3. Intraperitoneal/subcutaneous single dose – Column 2 (new)

Council position	*Amendment*
	ADS

Or. en

Justification

Acute toxicity studies involve literally poisoning animals to death, making them among the most severe and ethically objectionable type of toxicity test. Requiring such studies by more than one exposure route (i.e. oral + pulmonary + intraperitoneal/subcutaneous) should be the exception rather than the rule. Accordingly, acute pulmonary toxicity should at most be a second-tier data requirement. Accordingly, an acute injection study should at most be a second-tier data requirement.

Amendment 336
Julie Girling

Council position

Annex II – Title 2 – 8. Effects on non-target organisms – Column 3 (new)

Council position	*Amendment*
	Information requirements in this section may be adapted as appropriate in accordance with the specifications of Title 1 of this Annex.

Or. en

Justification

The Commission has expressed support in principle for the adaptation of certain standard information requirements for microbial biocides through the addition of qualifying sentence to the introductory text.

Amendment 337
Dan Jørgensen, Corinne Lepage, Michèle Rivasi, Sabine Wils

Council position
Annex III – point 5

Council position	*Amendment*
5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. However, if a method is inappropriate or not described, other methods shall be used which are***, whenever possible, internationally recognised and*** scientifically ***appropriate*** and must be justified in the application***.***	5. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Regulation (EC) No 440/2008. ***Methods listed in Annex I do not cover nanomaterials, except where specifically mentioned.*** However, if a method is inappropriate or not described, other methods shall be used which are scientifically ***satisfactory*** and ***the validity of which*** must be justified in the application

Or. en

(Reinstatement of amendment 293 from first reading.)

Justification

The relevant scientific committee of the Commission concluded that the knowledge on the methodology for both exposure estimates and hazard identification of nanomaterials needs to

be further developed and validated. As such, existing methods for bulk chemicals cannot be assumed to provide relevant data. Until the validity of standard test methods has been assessed for nanomaterials, a special justification has to be given for the use of these tests for the assessment of nanomaterials.

Amendment 338
Holger Krahmer, Christa Klaß

Council position
Annex III - Title 1 - point 2.3 - Column 1

Council position	*Amendment*
2.3. ***Complete*** quantitative (g/kg, g/l or % w/w (v/v)) composition of the biocidal product, ***i.e. declaration of all active substances and co-formulants (substance or mixture according to Article 3 of Regulation (EC) No 1907/2006), which are intentionally added to the biocidal product (formulation) as well as detailed quantitative and qualitative information on the composition of the active substance(s) contained. For co-formulants, a safety data sheet in compliance with Article 31 of Regulation (EC) No 1907/2006 has to be provided. In addition, all relevant information on individual ingredients, their function and, in case of a reaction mixture, the final composition of the biocidal product shall be given.***	2.3. ***Detailed*** quantitative ***and qualitative information on the*** composition of the biocidal product, ***e.g. active substance(s), impurities, adjutants, inert components, taking account of the concentrations referred to in Article 18(2)(ba)***

Or. en

(Reinstatement of amendment 296 from first reading.)

Justification

This Amendment would ensure the alignment to provisions for the Chemical Safety Report threshold under the REACH Regulation.

Amendment 339
Dan Jørgensen

Council position
Annex III – Title 1 – 7.5. – Column 1

Council position	*Amendment*
7.5 Likely tonnage to be placed on the market per year	7.5 Likely tonnage to be placed on the market per year ***and where relevant, for different use categories.***

Or. en

Justification

Additional information is important at both active substance level (Annex II) and for the Biocidal Product (Annex III) in order to allow for a proper cumulative risk assessment for biocidal products where relevant.

Amendment 340
Julie Girling

Council position
Annex III – Title 1 – 8.5.3. Acute toxicity – by dermal route – Column 1

Council position	*Amendment*
8.5.3. By dermal route	***delete***

Or. en

Justification

Acute toxicity studies can sometimes lead to morbidity or mortality in animal specimens. This is especially true for dermal (skin) testing, which has been shown in several independent analyses to add nothing of value for classification purposes in more than 98% biocides and other substances examined. Classification of biocidal products for acute dermal toxicity should therefore be based on direct "read-across" from the oral classification.

Amendment 341
Julie Girling

Council position

Annex III – Title 1 – 9.1. Testing of biocide formulations – Column 1 – indent 2

Council position	*Amendment*
- Where valid ***data*** on the components is not available or where synergistic effects may be expected ***then*** testing of components and/or the biocidal product itself may be necessary.	- Where valid ***information*** on the components is not available or where synergistic effects may be expected**,** testing of components and/or the biocidal product itself may be necessary. ***Vertebrate animal testing should be restricted to acute studies.***

Or. en

Justification

Testing of the finished product/formulation should not normally be needed due to the extensive data requirements for individual formulants and accepted "classification by calculation" approaches. If and when required, such testing can normally be limited to the acute exposure scenario.

Amendment 342
Sabine Wils

Council position
Annex III - Title 1 – 9.2 – Column 1

Council position	*Amendment*
9.2. Further Ecotoxicological studies Further studies chosen from among the endpoints referred to in Annex II, Section 9 for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product	9.2. Further Ecotoxicological studies Further studies chosen from among the endpoints referred to in Annex II, Section 9 for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product. ***Vertebrate animal testing should be restricted to acute studies.***

Or. en

Justification

Testing of the finished product/formulation should not normally be needed due to the

extensive data requirements for individual formulants and accepted "classification by calculation" approaches. If and when required, such testing can normally be limited to the acute exposure scenario.

Amendment 343
Julie Girling

Council position
Annex III – Title 2 – 8.5.3. Acute toxicity – by dermal route – Column 1

Council position	*Amendment*
Dermal	***delete***

Or. en

Justification

Acute toxicity studies can sometimes lead to morbidity or mortality in animal specimens. This is especially true for dermal (skin) testing, which has been shown in several independent analyses to add nothing of value for classification purposes in more than 98% biocides and other substances examined. Classification of biocidal products for acute dermal toxicity should therefore be based on direct "read-across" from the oral classification.

Amendment 344
Christa Klaß

Council position
Annex III – Title 2 – 8.7. – Column 1

Council position	*Amendment*
8.7. Available toxicological data relating to:	8.7. Available toxicological data relating to:
- co-formulants (i.e. substance(s) of concern), or	– co-formulants (i.e. substance(s) of concern), or
- a mixture that a substance(s) of concern is a component of	– a mixture that a substance(s) of concern is a component of**.**
If ***no*** data ***is*** available, ***then the appropriate*** test(s) described in Annex II,	If ***insufficient*** data ***are*** available ***for a coformulant(s) and cannot be inferred***

shall be carried out for the ***co-formulants (i.e.*** substance(s) of concern***)*** or a mixture that a substance(s) of concern is a component of	***through read-across or other accepted non-testing approaches***, ***targeted acute*** test(s) described in Annex II, shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of***.***

Or. de

Justification

Annex III sets out the requirements for biocidal products, including chemical products (Title 1) and micro-organisms (Title 2). The data requirement 8.7 appears in both titles. If the data requirement 8.7 in Title 1 is amended (Amendment 96), the same amendment needs to be made to the corresponding data requirement 8.7 in Title 2 to ensure consistency.

Amendment 345
Julie Girling

Council position
Annex III – Title 2 – 8.7. Co-formulant data – Column 1

Council position	*Amendment*
8.7. Available toxicological data relating to: – co-formulants (i.e. substance(s) of concern), or – a mixture that a substance(s) of concern is a component of – If ***no data is*** available, ***then the appropriate*** test(s) described in Annex II, shall be carried out for the ***co-formulants (i.e***. substance(s) of concern) or a mixture ***that a substance(s) of concern is a component of.***	8.7. Available toxicological data relating to: – co-formulants (i.e. substance(s) of concern), or – a mixture that a substance(s) of concern is a component of – if ***insufficient*** data ***are*** available ***for a co-formulant(s) and cannot be inferred through read-across or other accepted non-testing approaches, targeted*** test(s) described in Annex II, shall be carried out for the substance(s) of concern or a mixture that a substance(s) of concern is a component of. ***Vertebrate animal testing should be restricted to acute studies.***

Or. en

Justification

Identical to Rapporteur's Amendment 96 addressing an identical point in Annex III, Title 1 (chemicals vs. micro-organisms). For consistency the same language should be used in Title

2.

Amendment 346
Julie Girling

Council position
Annex III – Title 2 – 9.2. Testing of biocide formulations – Column 1

Council position	*Amendment*
9.2. Further ecotoxicological studies Further studies chosen from among the endpoints referred to in Annex II, Section 8, Micro- Organisms for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product.	9.2. Further ecotoxicological studies Further studies chosen from among the endpoints referred to in Annex II, Section 8, Micro- Organisms for relevant components of the biocidal product or the biocidal product itself may be required if the data on the active substance cannot give sufficient information and if there are indications of risk due to specific properties of the biocidal product. ***Vertebrate animal testing should be restricted to acute studies.***

Or. en

Justification

Testing of the finished product/formulation should not normally be needed due to the extensive data requirements for individual formulants and accepted "classification by calculation" approaches. If and when required, such testing can normally be limited to the acute exposure scenario.

Amendment 347
Nessa Childers

Council position
Annex V – Main group 1: Disinfectants – product-type 6 – paragraph 2

Council position	*Amendment*
Products used as preservatives for the storage or use of rodenticide or ***insecticide*** baits.	Products used as preservatives for the storage or use of rodenticide***, insecticide*** or ***other*** baits.

Or. en

Amendment 348
Nessa Childers

Council position
Annex V – Main Groups 2: Preservatives – Product type 9 – paragraph 1

Council position	*Amendment*
Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of ***microbiological deterioration***.	Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of ***fibrous/polymerised material destroying or disfiguring organisms, including insects***.

Or. en

Amendment 349
Julie Girling

Council position
Annex VI – Introduction – point 2

Council position	*Amendment*
2. The principles set out in this Annex can be applied in their entirety to the evaluation of biocidal products comprised of chemical substances. For biocidal products containing micro-organisms, these principles should be further developed in technical guidance taking into account practical experience gained, and be applied taking into account the nature of the product and the latest scientific information. In the case of biocidal products containing nanomaterials the principles set out in this Annex will also need to be adapted and elaborated in technical guidance to take account of the latest scientific information.	2. The principles set out in this Annex can be applied in their entirety to the evaluation of biocidal products comprised of chemical substances. For biocidal products containing micro-organisms, these principles should be further developed in technical guidance taking into account practical experience gained, and be applied taking into account the nature of the product and the latest scientific information. In the case of biocidal products containing nanomaterials the principles set out in this Annex will also need to be adapted and elaborated in technical guidance to take account of the latest scientific information. ***The guidance, for substances falling under Recommendation 20../…/EC of … shall not apply where these substances contain:*** ***- less than 10 wt-% of nano-objects***

OR

- less than 50 wt-% of aggregates /agglomerates consisting of nano-objects

OR

- have not been intentionally manufactured at the nanoscale in order to take advantage of their specific nano qualities

Or. en

Justification

Additional and readily available methods, capable of determining weight of nano-sized particles, should be used where suitable validated methodologies are not available for evaluating numbers of small particles in certain product types according to the definition for nanomaterials, as per Recommendation 20../.../EC. Developments regarding the definition of nanomaterial to be introduced in Commission Recommendation 20../.../EC of ...and its requirements are new and could not be addressed by the European Parliament in 1st reading.

Amendment 350
Holger Krahmer

Council position
Annex VI – Introduction – point 2

Council position	*Amendment*
2. The principles set out in this Annex can be applied in their entirety to the evaluation of biocidal products comprised of chemical substances. For biocidal products containing micro-organisms, these principles should be further developed in technical guidance taking into account practical experience gained, and be applied taking into account the nature of the product and the latest scientific information. In the case of biocidal products containing nanomaterials the principles set out in this Annex will also need to be adapted and elaborated in technical guidance to take account of the latest scientific information.	2. The principles set out in this Annex can be applied in their entirety to the evaluation of biocidal products comprised of chemical substances. For biocidal products containing micro-organisms, these principles should be further developed in technical guidance taking into account practical experience gained, and be applied taking into account the nature of the product and the latest scientific information. In the case of biocidal products containing nanomaterials the principles set out in this Annex will also need to be adapted and elaborated in technical guidance to take account of the latest scientific information. ***The guidance, for substances falling under Recommendation 20../…/EC of … with***

regard to specific requirements under this Regulation relating to their nature as nanomaterials shall not apply where these substances contain:

- less than 10 wt-% of nano-objects

or

- less than 50 wt-% of aggregates /agglomerates consisting of nano-objects

or

- have not been intentionally manufactured at the nanoscale in order to take advantage of their specific nano qualities

Or. en

Justification

Amends new provision introduced by Council. This approach is in line with ECHA Guidance Document for "identification and naming of substances under REACH" (June 2007). Furthermore, in line with the approach of Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetic products (article 2.1 (k)), only those substances which are intentionally manufactured to benefit from nanomaterial properties should fall under the requirements associated with the definition.

Amendment 351
Pilar Ayuso, Cristina Gutiérrez-Cortines, Andres Perello Rodriguez

Council position
Annex VI – Introduction – point 2

Council position	*Amendment*
2. The principles set out in this Annex can be applied in their entirety to the evaluation of biocidal products comprised of chemical substances. For biocidal products containing micro-organisms, these principles should be further developed in technical guidance taking into account practical experience gained, and be applied taking into account the nature of the product and the latest scientific information. In the case of biocidal	2. The principles set out in this Annex can be applied in their entirety to the evaluation of biocidal products comprised of chemical substances. For biocidal products containing micro-organisms, these principles should be further developed in technical guidance taking into account practical experience gained, and be applied taking into account the nature of the product and the latest scientific information. In the case of biocidal

products containing nanomaterials the principles set out in this Annex will also need to be adapted and elaborated in technical guidance to take account of the latest scientific information.	products containing nanomaterials the principles set out in this Annex will also need to be adapted and elaborated in technical guidance to take account of the latest scientific information. ***The guidance, for substances falling under Recommendation 20../.../EC of ... with regard to specific requirements under this Regulation relating to their nature as nanomaterials shall not apply where these substances contain:*** ***-less than 10 w-% of nano-objects as defined by ISO,*** ***or*** ***-have not been intentionally manufactured at the nanoscale in order to take advantage of their specific nano qualities.***

Or. en

Justification

Available methods, capable of measuring weight of nano-sized particles as indicated by ECHA Guidance Document for identification and naming of substances, should be used where suitable validated methodologies are not available for evaluating numbers of small particles in products according to the definition for nanomaterials. As in Regulation N°1223/2009, only substances which are intentionally manufactured to be nanomaterials should fall under the requirements associated with the definition

Amendment 352
Julie Girling

Council position
Annex VI– Introduction – point 3

Council position	*Amendment*
3. In order to ensure a high and harmonised level of protection of human and animal health and of the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of	3. In order to ensure a high and harmonised level of protection of human and animal health and of the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of

any risks that are identified. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product taking into account any cumulative and synergistic effects.	any risks that are identified. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product taking into account any cumulative and synergistic effects. ***Scientific definitions and methodologies for the assessment of cumulative or synergistic effects will be based on the technical guidance notes provided by the Commission as foreseen in Article 23.***

Or. en

Justification

At present, there is no single agreed scientific definition for the concepts of cumulative and synergistic effects, neither is there a common, agreed method of analysis. The Commission should adopt these definitions and methodologies by way of technical guidance notes, before the regulation's entry into force.

Amendment 353
Julie Girling

Council position
Annex VI – Assessment – point 15

Council position	*Amendment*
15. In carrying out the assessment, the possibility of cumulative or synergistic effects shall also be taken into account.	15. In carrying out the assessment, the possibility of cumulative or synergistic effects shall also be taken into account. ***Scientific definitions and methodologies for the assessment of cumulative or synergistic effects will be based on the technical guidance notes provided by the Commission as foreseen in Article 23.***

Or. en

Justification

At present, there is no single agreed scientific definition for the concepts of cumulative and synergistic effects, neither is there a common, agreed method of analysis. The Commission should adopt these definitions and methodologies by way of technical guidance notes, before

the regulation's entry into force.

Amendment 354
Dan Jørgensen

Council position
Annex VI – Assessment – point 47 a (new)

Council position	*Amendment*
	47 a. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) if it contains any substance of concern or of relevant metabolites or breakdown or reaction products fulfilling the criteria for being PBT or vPvB in accordance with Annex XIII of Regulation (EC) No 1907/2006, or have endocrine-disrupting properties unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

Or. en

Justification

In order to ensure proper consideration of potentially PBT and vPvB substances. The exclusion criteria in Article 5 give some security that the active substances do not have such properties; however this also applies for coformulants in biocidal products especially because the concentration of these substances normally exist in much higher concentrations compared to the active substances.

Amendment 355
Julie Girling

Council position
Annex VI – Assessment – point 52

Council position	*Amendment*
52. In each of the areas where risk assessments have been carried out, the evaluating body shall combine the results	52. In each of the areas where risk assessments have been carried out, the evaluating body shall combine the results

for the active substance together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This shall also take account of any cumulative or synergistic effects.	for the active substance together with the results for any substance of concern to produce an overall assessment for the biocidal product itself. This shall also take account of any cumulative or synergistic effects. ***Scientific definitions and methodologies for the assessment of cumulative or synergistic effects will be based on the technical guidance notes provided by the Commission as foreseen in Article 23.***

Or. en

Justification

At present, there is no single agreed scientific definition for the concepts of cumulative and synergistic effects, neither is there a common, agreed method of analysis. The Commission should adopt these definitions and methodologies by way of technical guidance notes, before the regulation's entry into force.

Amendment 356
Julie Girling

Council position
Annex VI – Conclusions – point 62

Council position	*Amendment*
62. If for non-professional users the wearing of personal protective equipment would be the only possible method for reducing exposure to an acceptable level for this population the product shall not normally be considered as complying with criterion (iii) under point (b) of Article 18(1) for this population.	62. If for non-professional users the wearing of personal protective equipment would be the only possible method for reducing exposure to an acceptable level for this population ***as a result of*** the ***biocidal*** product ***risk assessment, the product*** shall not normally be considered as complying with criterion (iii) under point (b) of Article 18(1) for this population.

Or. en

Justification

The requirements for personal protective equipment must be determined by the biocidal product risk assessment, and not be ascertained from precautionary statements derived from

the product classification under either the Dangerous Preparations Directive or the Classification, Labelling and Packaging Regulation, as these are solely hazard-based assessments.

Amendment 357
Michèle Rivasi

Council position
Annex VI – Conclusion – point 68 – introductory part

Council position	*Amendment*
68. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) if the foreseeable concentration of the active substance or a substance of concern or of relevant metabolites, breakdown or reaction products to be expected in surface water or its sediments after use of the biocidal product under the proposed conditions of use:	68. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 18(1) if the foreseeable concentration of the active substance or a substance of concern or of relevant metabolites, breakdown or reaction products to be expected in ***groundwater or*** surface water or its sediments after use of the biocidal product under the proposed conditions of use:

Or. en

(Reinstatement of amendment 328 from first reading)

Amendment 358
Michèle Rivasi

Council position
Annex VI – Conclusion – point 68 – indent 1 a (new)

Council position	*Amendment*
	– risks non-achievement of the objectives or standards fixed by:
	– Directive 98/83/EC, or
	– Directive 2000/60/EC, or
	– Directive 2006/118/EC, or
	– Directives 2008/56/EC, or
	– Directive 2008/105/EC, or

– international agreements containing important obligations on the protection of marine waters from pollution, or

Or. en

(*Reinstatement of amendment 329 from first reading.*)