Amendment 341  
Michèle Rivasi  
on behalf of the Verts/ALE Group  

Report  
Christa Klaß  
Placing on the market and use of biocidal products  

Proposal for a regulation  
Article 1 - paragraph 1 a (new)  

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market and use of biocidal products. The provisions of this Regulation are underpinned by the precautionary principle, in order to ensure that active substances or products placed on the market do not have harmful effects on humans, non-target species and the environment. Special attention shall be paid to protecting children, pregnant women and the sick.</td>
<td></td>
</tr>
</tbody>
</table>
| Or. en  

Justification  

It needs to be clear that the application of the precautionary principle should serve the protection of human health, non-target species and the environment against the adverse effects of biocides.
15.9.2010   A7-0239/342

Amendment 342
Michèle Rivasi
on behalf of the Verts/ALE Group

Report   A7-0239/2010
Christa Klaß
Placing on the market and use of biocidal products

Proposal for a regulation
Article 29 - paragraph 2 - subparagraph 2

Text proposed by the Commission

The Commission shall adopt a decision on
the proposed adjustment of the conditions
of the national authorisation to local
circumstances in accordance with the
procedure referred to in Article 72(3). The
competent authority of the concerned
Member State shall without delay adopt
all appropriate measures to comply with
that decision.

Amendment

deleted

Or. en

Justification

Adjustments to local circumstances by the competent authorities should be respected. It is
against the subsidiarity principle to grant the Commission the power to decide on adjustments
to local circumstances.
Amendment 343
Michèle Rivasi
on behalf of the Verts/ALE Group

Report
Christa Klaß
Placing on the market and use of biocidal products

Proposal for a regulation
Article 31

Text proposed by the Commission

By way of derogation from *Articles 25 and 28*, competent authorities of Member States may refuse mutual recognition of national authorisations granted for product types 15, 17 and 23 of Annex V provided that such a refusal can be justified on grounds of the protection of health of humans, animals or plants, the protection of national treasures possessing artistic, historic or archaeological value, or the protection of industrial and commercial property. Competent authorities of Member States shall without delay inform each other and the Commission of any decision taken in this respect and shall indicate the reasons thereof.

Amendment

By way of derogation from *Articles 25 to 29*, competent authorities of Member States may refuse mutual recognition of national authorisations granted for *biocidal products containing active substances referred to in Articles 5 and 9 and for product types 15, 17 and 23 of Annex V* provided that such a refusal can be justified on grounds of the protection of health of humans, *particularly of vulnerable groups, the protection of the health of animals or plants, the protection of the environment, national treasures possessing artistic, historic or archaeological value, or the protection of industrial and commercial property*. Competent authorities of Member States shall without delay inform each other and the Commission of any decision taken in this respect and shall indicate the reasons thereof.

Correction of amendment 151.

*Member States should be allowed to refuse mutual recognition for biocidal products that contain substances that fall under the exclusion criteria and for substances that are*
candidates for substitution.
15.9.2010

**Amendment 344**

Michèle Rivasi

on behalf of the Verts/ALE Group

**Report**

Christa Klaß

Placing on the market and use of biocidal products


**Proposal for a regulation**

**Article 47 - paragraph 2 - point a**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
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<tbody>
<tr>
<td>(a) the name of all active substances that were used to treat the article or materials or that were incorporated in the articles or materials;</td>
<td>(a) the words &quot;treated with biocides&quot;, followed by the name of all active substances, using wherever possible common nomenclature (e.g. INCI), that were used to treat the article or materials or that were incorporated in the articles or materials, unless at least equivalent labelling requirements already exist under sector-specific legislation; the names of all nanomaterials shall be followed by the word &quot;nano&quot; in brackets;</td>
</tr>
</tbody>
</table>

**Justification**

As consumers may not necessarily be familiar with the names of biocides, the label should clearly indicate that the articles have been treated with biocides before listing the names of the active substances. All articles treated with biocides should be labelled, unless at least equivalent labelling requirements already exist in other legislation. Nanomaterials should be labelled as such, as already adopted for cosmetics.
15.9.2010

Amendment 345
Michèle Rivasi
on behalf of the Verts/ALE Group

Report
Christa Klaß
Placing on the market and use of biocidal products

Proposal for a regulation
Article 70 - paragraph 2 - point a

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>(a) a reduced <strong>fee</strong> shall be set for small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises</td>
<td>(a) reduced <strong>fees</strong> shall be set for small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises; <strong>in particular, micro and small-sized enterprises shall receive a significant reduction in the annual fee;</strong></td>
</tr>
</tbody>
</table>

Justification
Compromise amendment to replace amendment 224.

The annual fee should be maintained to ensure adequate funding of ECHA, which has to provide continuous work on biocides. That work has to be done irrespective of the size of the applicant. This is all the more important if the scope of central authorisation and thus the resources required for ECHA are to increase significantly. However, to account for the special situation of micro and small enterprises, a significant reduction of the annual fee for them should be laid down explicitly.
15.9.2010

Amendment 346
Michèle Rivasi
on behalf of the Verts/ALE Group

Report
Christa Klaß
Placing on the market and use of biocidal products

Proposal for a regulation
Annex II - point 4

Text proposed by the Commission

4. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Council 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 must be justified in the application.

Amendment

4. Tests submitted for the purpose of authorisation shall be conducted according to the methods described in Council 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

Justification

Amendment in analogy to amendment 293. Nanomaterials are used due to their different or enhanced properties as compared to substances in bulk form. Due to their miniscule size and the resulting increase of relative surface area, they may pose new risks. The relevant scientific committee of the Commission concluded that the knowledge on the methodology for both exposure estimates and hazard identification needs to be further developed and validated for nanomaterials. As such, existing methods for bulk chemicals cannot be assumed to provide relevant data, unless clearly specified.
15.9.2010 A7-0239/347

Amendment 347
Michèle Rivasi
on behalf of the Verts/ALE Group

Report
Christa Klaß
Placing on the market and use of biocidal products

Proposal for a regulation
Annex II - point 1

Text proposed by the Commission

1. Dossiers on active substances shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL), Predicted Environmental Concentration (PEC) and Predicted No-Effect Concentration (PNEC).

Amendment

1. Dossiers on active substances shall contain the information needed to establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL), Predicted Environmental Concentration (PEC) and Predicted No-Effect Concentration (PNEC).

Dossiers for Tier 1 shall contain all information necessary for identifying the properties and risks of active substances over their life cycle, in particular pursuant to Article 5, 9 and 17 of this Regulation.

Or. en

Justification

The data requirements need to be such that sufficient information is provided to allow proper identification of the risks of active substances.
The applicant may propose to adapt the data requirements set out in Annexes II and III according to the general rules set out in this Annex. The reasons for such adaptations to the data requirements must be clearly stated under the appropriate heading of the dossier referring to the specific rule(s) of this Annex. The applicant may propose to adapt the data requirements set out in Annexes II and III according to the general rules set out in this Annex. The reasons for such adaptations to the data requirements must be clearly stated under the appropriate heading of the dossier referring to the specific rule(s) of this Annex, and must be approved by the competent authority.

Justification

The adaptations to the data requirements proposed by the applicant need to be confirmed by the competent authority.
### Amendment 349

on behalf of the Committee on the Internal Market and Consumer Protection

**Report**
Christa Klaß
Placing on the market and use of biocidal products

**Proposal for a regulation**
Article 28 - paragraph 9 - subparagraph 2 a (new)

<table>
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<tr>
<td><em>This decision shall be taken within three months of the notification by the competent authority referred to in subparagraph 1. If the Commission requests an opinion from the Agency pursuant to Article 30, the three-month period shall be suspended until the Agency submits its opinion.</em></td>
<td></td>
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Or. en

**Justification**

The legislative text should clearly specify the timeframe required for a procedure that can effectively resolve disputes related with the mutual recognition of national authorisations in parallel. Three months is an adequate period of time for the Commission to make a decision setting out the grounds for refusing to recognise authorisations or recognising them with restrictions.
15.9.2010 A7-0239/350

**Amendment 350**

on behalf of the Committee on the Internal Market and Consumer Protection

**Report**
Christa Klaß
Placing on the market and use of biocidal products

**Proposal for a regulation**
**Article 54 - paragraph 4**

<table>
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<tr>
<td>4. The Commission shall draw up a report on the implementation of this Regulation and, in particular, on the functioning of the Community authorisation procedure and mutual recognition, by <strong>1 January 2023</strong>. The Commission shall submit the report to the European Parliament and the Council.</td>
<td>4. The Commission shall draw up a report on the implementation of this Regulation and, in particular, on the functioning of the Community authorisation procedure and mutual recognition, by <strong>1 January 2019 and every three years thereafter</strong>. The Commission shall submit the report to the European Parliament and the Council.</td>
</tr>
</tbody>
</table>

*On the basis of the report, the Commission shall assess the desirability of proposing amendments to this Regulation.*

**Justification**

The Commission report should be the basis for a process of revision with the aim of remedying as much as possible the main difficulties identified.