EUROPEAN COMMISSION

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2009/0076 (COD)

OPINION OF THE COMMISSION

pursuant to Article 294(7)(c) of the Treaty on the Functioning of the European Union, on the European Parliament's amendment[s] to the Council's position regarding the proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the placing on the market and use of biocidal products.

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1. INTRODUCTION

Article 294(7)(c) of the Treaty on the Functioning of the European Union provides that the Commission is to deliver an opinion on the amendments proposed by the European Parliament at second reading. The Commission sets out its opinion below on the amendments proposed by the Parliament.

2. BACKGROUND

On 12 June 2009 the Commission submitted a proposal for a Regulation concerning the placing on the market and use of biocidal products to the European Parliament and the Council for adoption by co-decision procedure as laid down in Article 251 of the EC Treaty.

The Economic and Social Committee gave its opinion on 17 February 2010.

The European Parliament adopted its first reading position on 22 September 2010.

The Council reached a political agreement on the proposal on 20 December 2010 and adopted its common position on 21 June 2011.

COREPER gave its agreement on the second reading compromise on 23 November 2011.

The European Parliament adopted its Legislative Resolution at second reading on 19 January 2012.

3. OBJECTIVE OF THE PROPOSAL FROM THE COMMISSION

The objective of the proposed Regulation is to improve the functioning of the internal market in biocidal products whilst ensuring a high level of environmental and human health protection. The proposal intends to remedy a number of weaknesses that were identified during the first 8 years of the implementation of Directive 98/8/EC, to reduce compliance costs, to pre-empt problems with the upcoming product authorisation and mutual recognition procedure, and to update and adapt the instrument to recent policy developments

4. OPINION OF THE COMMISSION ON THE AMENDMENTS PROPOSED BY THE EUROPEAN PARLIAMENT

At its Plenary Session of 19 January 2012, the European Parliament adopted a compromise package which had been agreed with the Council in view of reaching a second reading agreement.

These amendments concern essentially:

– the criteria for the exclusion of active substances from the approval process;

– the scope of the EU centralized procedure for biocidal products,

– greater flexibility in relation to the data requirements and a reduction in the testing of vertebrate animals,

– the labelling requirements for treated articles;

– the publication of reports and the dissemination of information,

– the tasks attributed of the European Chemicals Agency and the basis for the payment of fees to that Agency.

The Commission will not stand against the compromise package as it is generally in line with the overall purpose and the general characteristics of the proposal. Regarding the use of implementing acts for the setting of the fees payable to the European Chemicals Agency, the definition of nanomaterial and the fees for mutual recognition applications, declarations have been made by the Commission and are annexed to the present opinion.

5. CONCLUSION

Pursuant to Article 293(2) of the Treaty on the Functioning of the European Union, the Commission will not stand against the amendments voted by the Europan Parliament in second reading according to the above described compromise text.

Annex: Commission Declarations

Commission declaration concerning the use of implementing acts for the setting of the fees

The Commission considers that the setting of the fees to be paid to ECHA cannot be determined via implementing acts. However, in a spirit of compromise, the Commission will not stand against the final text as agreed between the Council and the European Parliament. Nevertheless, on this specific issue, the Commission reserves its right to avail itself of the legal remedies provided by the Treaty with a view to seeking clarification by the Court on the issue of delimitation between Articles 290 and 291.

Commission declaration concerning the definition of nanomaterial

While the Commission can accept the final text as agreed between the Council and the European Parliament, it continues to believe that a direct reference to the Commission Recommendation 2011/696/EU on the definition of nanomaterial would have been more appropriate in view of the need for a harmonised definition of nanomaterial to apply throughout the EU legislation and the possibility to easily adapt it to technical and scientific developments. To this effect, the Commission will take the necessary steps to ensure that this is reflected in any future proposals.

Commission declaration concerning the fee for mutual recognition applications

In making its proposal for a Regulation on fees in accordance with Article 80(1), the Commission will seek to ensure that the level of the fee for applications for mutual recognition payable to the European Chemicals Agency takes into account the level of fees charged in the different Member States and does not constitute a disproportionate burden for companies, in particular SMEs.