Making available on the market and use of biocidal products

2009/0076(COD) - 21/06/2011 - Council position

The Council adopted its position on first reading with a view to the adoption of a regulation of the European Parliament and of the Council concerning the making available on the market and use of biocidal products.

The European Parliament adopted several hundred amendments to the Commission proposal. Many are acceptable to the Council and it has therefore included them in its position at first reading (wholly, in part, or in principle).

The following points should be mentioned:

- while the Council accepts the need to address nanomaterials, because of rapid developments in the field, at this stage it has only included a definition, a statement that approval of active substances does not cover nanomaterials, except where explicitly mentioned, and a reference to the need for technical guidance to be elaborated to take account of the latest scientific information;
- the Council considers that requiring a substitution plan for biocidal products containing active substances meeting the exclusion criteria would unnecessarily duplicate the requirement for a comparative assessment ;
- the Council’s position at first reading would open the Union authorisation procedure to all other biocidal products except for those of certain product-types. It also provides for the Commission to make a report on the application of the Union authorisation procedure by the end of 2017, in which report the Commission can review whether adjustments are needed to the scope in 2020;
- only those Annexes containing technical provisions (i.e., Annexes II, III and IV) should be adapted to scientific and technical progress via delegated acts;
- helpdesks should not be mandatory, but an option that Member States can choose as a way to fulfil their obligation to provide advice to applicants.

The Council's position at first reading also includes a number of changes other than those envisaged in the European Parliament's position. The changes of substance compared to the Commission's initial proposal concern principally the following points:

1) Consequences of the Lisbon Treaty: like the European Parliament, the Council had to adapt the text of the original proposal to the new regime laid down by the Lisbon Treaty regarding powers conferred by the legislator on the Commission. However, the Council considered certain matters which the Parliament was prepared to delegate to the Commission, to be of such importance that they should be decided at the legislative level, i.e. by Parliament and Council jointly. The Council also considered certain decisions for which the Parliament had considered delegated acts appropriate to be in the nature of implementing measures rather than acts which supplement or amend the basic act.

2) Procedure for the approval of active substances: approval of active substances will, as at present, require the Commission to adopt a legal act. However, rather than amending the basic act repeatedly, the Council considered free-standing implementing measures preferable to a list of approved active substances in an annex to the basic act. This change to the procedure for the approval of active substances parallels that recently agreed for plant protection products. While they were listed in Annex I to Directive 91/414/EEC, Regulation (EC) No 1107/2009 provides for their approval via implementing acts, for their compilation into a free-standing list and for electronic public access to that list.

3) ECHA's role: ECHA will have an essential coordination role to play in the approval of active substances and the Union authorisation of biocidal products. However, the Council considers that:

- all stages of the evaluation of an application should remain the responsibility of the evaluating competent authority;
- all Member States be able to appoint a member of the Biocidal Products Committee and that there be close links between this committee and Member States' competent authorities.

4) Products subject to a simplified authorisation procedure: the Council suggests the establishment of a specific list of active substances presenting low concern and a simplified authorisation procedure for biocidal products containing those active substances. To encourage widespread marketing and use of such products, they could as a general rule circulate throughout the Union after authorisation by a single Member State and a simple notification procedure in other Member States. If another Member State raises objections, the dispute settlement mechanisms of the mutual recognition procedure would be applicable.

5) Fees: the Council considers that a different approach needs to be taken for fees payable to ECHA from those payable to Member States' competent authorities. While it is appropriate for the Commission to adopt an implementing act laying down the fees payable to ECHA (rather than delegated acts, as the Commission proposed), Member States should be free to set national fees.