Making available on the market and use of biocidal products

2009/0076(COD) - 11/10/2016 - Follow-up document

The Commission presented a report on the exercise of the delegation conferred on the Commission pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR).

The report shall be drawn up not later than nine months before the end of the five-year period of the delegation, running from 17 July 2012.

The BPR empowers the Commission to adopt delegated acts in order to supplement or amend certain non-essential elements of the Regulation.

Exercise of the delegation: during the period concerned by this report, the Commission adopted **four delegated acts:**

1. Commission Delegated Regulation (EU) No 736/2013: the BPR provides for the continuation of the work programme for the systematic examination of all existing active substances used in biocidal products commenced in accordance with Directive 98/8/EC. The Commission shall be empowered to adopt delegated acts concerning the extension of the duration of the work programme for a determined period.

The BPR provided the work programme to be achieved by 14 May 2014. However, the Commission pointed out that the examination of all existing active substances used in biocidal products will only be finalised by 31 December 2024. As a consequence, Regulation (EU) No 736/2013 amended the BPR in order to extend the duration of the work programme until 31 December 2024.

The Commission adopted the delegated act on 17 May 2013 and notified it to the European Parliament and the Council. Neither institution objected to the delegated act within the two-month period provided for in the BPR. The Delegated Regulation entered into force on 20 August 2013.

2. Commission Delegated Regulation (EU) No 837/2013: the Commission shall be empowered to adopt delegated acts concerning the adaptation of Annexes II, III and IV to such scientific and technical progress.

Regulation (EU) No 837/2013 amended Annex III to the BPR in order to include the proof of establishment of technical equivalence in the information requirement for authorisation of biocidal products. A biocidal product may be authorised even if one or more of the active substances contained therein has been manufactured in a different location or according a different process, including from different starting materials, than those of the substance evaluated for approval pursuant to Article 9 of the BPR. This delegated act was aimed at ensuring in such a situation that the active substance contained in a biocidal product does not have significantly more hazardous properties than the substance which has been evaluated for the purpose of approval.

The Commission adopted the delegated act on 25 June 2013 and notified it to the European Parliament and the Council. Neither institution objected to the delegated act within the two-month period provided for in the BPR. The Delegated Regulation entered into force on 23 September 2013.

3. Commission Delegated Regulation (EU) No 492/2014: the Commission shall be empowered to adopt delegated acts laying down supplementary rules for the renewal of authorisations subject to mutual recognition.

The Commission adopted Regulation (EU) No 492/2014 in order to lay down supplementary rules for the renewal of authorisations subject to mutual recognition procedures, both in the Member State having granted the first authorisation and in those Member States having granted an authorisation through mutual recognition of that first authorisation. The delegated act provides that the European Chemicals Agency shall draw up guidelines on the details related to the handling of renewals.

The Commission adopted the delegated act on 7 March 2014 and notified it to the European Parliament and the Council. Neither institution objected to the delegated act within the two-month period provided for in the BPR. The Delegated Regulation entered into force on 3 June 2014.

4. Commission Delegated Regulation (EU) No 1062/2014: the Commission adopted Regulation (EU) No 1062/2014 in order to supplement the BPR as regards the detailed rules for the continuation of the review programme which was previously carried out according to rules based on Directive 98/8/EC. S

Since the BPR repealed the Directive, the existing detailed rules had to be updated adapted to the provisions of the BPR. The delegated act defines the rights and obligations of competent authorities and of participants in the work programme. In addition, the delegated act specifies in which situations a prospective applicant would be allowed to join or replace an existing participant or to take over the support of an included substance in the review programme.

The Commission adopted the delegated act on 4 August 2014 and notified it to the European Parliament and the Council. Neither institution objected to the delegated act within the two-month period provided for in the BPR. The Delegated Regulation entered into force on 30 October 2014.

Other delegations: experts are currently discussing a draft delegated regulation in line with the new inter-institutional agreement. It is going to adopt as soon as possible the delegated regulation supplementing the BPR and specifying scientific criteria for the **determination of endocrine-disrupting properties**.

Conclusion: the Commission considered that the delegated powers conferred on it should **remain in force** . The implementation of the BPR is advancing and technical and scientific progress takes place. Therefore the Commission may be required to adopt further delegated acts in the future in order to keep the legal framework up to date.