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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercice of the delegation conferred in 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

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1. INTRODUCTION AND LEGAL BASIS

The EU legal framework for biocidal products is intended 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. The framework works on the principle that biocidal products can be placed on the market only if a marketing authorisation is granted by the competent authorities.

The requirements and procedures for authorising the marketing of biocidal products are laid down principally in Regulation (EU) No 528/2012[1] (hereinafter, "the BPR") , as amended by Regulation (EU) No 736/2013[2], Regulation (EU) No 837/2013[3] and Regulation (EU) No 334/2014[4]. This report is to meet the obligation set for the Commission by Article 83(2) of the BPR. Article 83(2) requires the Commission to present to the European Parliament and to the Council a report on the exercise of the delegation conferred on the Commission by the 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 delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

Article 83(1) of the BPR empowers the Commission to adopt delegated acts subject to the conditions laid down in this Article in order to:

- adapt the definition of nanomaterial set out in the BPR in view of technical and scientific progress [Article 3(4)],

- specify scientific criteria for the determination of endocrine-disrupting properties [Article 5(3)],

[1] 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, OJ L 167, 27.6.2012, p. 1.
[2] Commission Delegated Regulation (EU) No 736/2013 of 17 May 2013 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the duration of the work programme for examination of existing biocidal active substances, OJ L 204, 31.7.2013, p. 25.
[3] Commission Delegated Regulation (EU) No 837/2013 of 25 June 2013 amending Annex III to Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the information requirements for authorisation of biocidal products, OJ L 234, 3.9.2013, p. 1.
[4] Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market, OJ L 103, 5.4.2014, p. 22.

- specify criteria for determining what constitutes adequate justification to adapt the data requirements for an application for approval of an active substance in case the data are not necessary owing to the exposure associated with the proposed use of the product [Article 6(4)],

- specify criteria for defining when the exposure associated with the proposed uses of the product would justify adapting the data requirements for the applications for biocidal products authorisations [Article 21(3)],

- specify the criteria for determining when comparative assessments of biocidal products involve questions better addressed at Union level and the procedures for such comparative assessments [Article 23(5)],

- amend Annex I in order to include active substances that do not give rise to concern [Article 28(1)],

- amend Annex I in order to restrict or to remove the entry for an active substance if there is evidence that biocidal products containing that substance do give rise to concerns [Article 28(3)],

- adopt supplementary rules for the renewal of authorisations subject to mutual recognition [Article 40],

- adopt specific rules supplementing the BPR provisions on research and development [Article 56(4)],

- adopt acts supplementary the BPR rules for the use of the Register for Biocidal Products [Article 71(9)],

- adapt Annexes II, III and IV to scientific and technical progress [Article 85],

- establish the rules on the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC[5] and specification of the related rights and obligations of the competent authorities and the participants in the programme extension of the duration of the work programme for a determined period [Article 89(1)].

2. EXERCISE OF THE DELEGATION

During the period concerned by this report, the Commission adopted four delegated acts in order to supplement or amend certain non-essential elements of the BPR. The following acts were adopted:

2.1. 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

[5] OJ L 123, 24.4.1998, p. 1.

accordance with Article 16(2) of Directive 98/8/EC. The second subparagraph of Article 89(1) of the BPR states that "*Depending upon the progress of the work programme, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 concerning the extension of the duration of the work programme for a determined period*".

Initially, the first paragraph of Article 89(1) of the BPR provided the work programme to be achieved by 14 May 2014. However, as pointed out in the Communication from the Commission to the European Parliament pursuant to Article 294(6) of the Treaty on the Functioning of the European Union concerning the position of the Council on the adoption of a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products[6], the examination of all existing active substances used in biocidal products will only be finalised by 31 December 2024.

As a consequence, on the basis of the second subparagraph of Article 89(1) of the BPR, Regulation (EU) No 736/2013 amended the first subparagraph of Article 89(1) of the BPR in order to extend the duration of the work programme until 31 December 2024.

The Biocides competent authorities expert group ("hereinafter, "Biocides CA expert group") served as expert group in accordance with the applicable inter-institutional arrangements. In this setting the draft delegated act was discussed in the meetings of 19-21 September 2012 and of 12-14 December 2012. The Biocides CA Expert Group was consulted on the draft Commission Delegated Regulation and an updated draft of the delegated act was made public in advance of each of those meetings. 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 Article 83(5) of the BPR. Commission Delegated Regulation (EU) No 736/2013 was published in the Official Journal of 31 July 2013 and entered into force on 20 August 2013.

2.2. Commission Delegated Regulation (EU) No 837/2013

This legal act was adopted on the basis of Article 85 of the BPR specifying:, "*In order to allow the provisions of this Regulation to be adapted to scientific and technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 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 pursuant to Article 54 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 Biocides CA Expert Group was consulted on the draft Commission Delegated Regulation in the meetings of 19-21 September 2012 and of 12-14 December 2012. An

[6] COM(2011) 498 final.

updated draft of the draft delegated act was made public in advance of each of those meetings. 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 Article 83(5) of the BPR. Commission Delegated Regulation (EU) No 837/2013 was published in the Official Journal of 3 September 2013 and entered into force on 23 September 2013.

2.3 Commission Delegated Regulation (EU) No 492/2014[7]

The legal act was adopted on the basis of the first subparagraph of Article 40 of the BPR, specifying "*The Commission shall be empowered to adopt delegated acts in accordance with Article 83 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 Biocides CA Expert Group was consulted on the draft Commission Delegated Regulation in meetings of 15-17 May 2013, 10-12 July 2013 and 25-27 September 2013. An updated draft of the delegated act was made public in advance of each of those meetings. 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 Article 83(5) of the BPR. Commission Delegated Regulation (EU) No 492/2014 was published in the Official Journal of 14 May 2014 and entered into force on 3 June 2014.

2.4 Commission Delegated Regulation (EU) No 1062/2014[8]

In relation to the work programme for the systematic examination of all existing active substances commenced in accordance with Article 16(2) of Directive 98/8/EC, the first subparagraph of Article 89(1) of the BPR empowers the Commission "*to adopt delegated acts in accordance with Article 83 concerning the carrying out of the work programme and specification of the related rights and obligations of the competent authorities and the participants in the programme*".

On the basis of this provision, 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. 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

[7] Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition (OJ L 139, 14.5.2014, p. 1).

[8] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1)

allowed to join or replace an existing participant or to take over the support of an included substance in the review programme.

The Biocides CA Expert Group was consulted on the draft Commission Delegated Regulation in meetings of 25-27 September 2013, 11-13 December 2013, 12-13 March 2014 and of 14-15 May 2014. An updated draft of the delegated act was made public in advance of each of those meetings. 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 Article 83(5) of the BPR. Commission Delegated Regulation (EU) No 492/2014 was published in the Official Journal of 10 October 2014 and entered into force on 30 October 2014.

3e. Other delegations

The BPR provides for further delegated powers.

As regards the delegation in Article 5(3) of the BPR, experts are currently discussing a draft delegated regulation in line with the new inter-institutional agreement[9]. Following these discussions, the Commission 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.

So far the Commission has not yet exercised the delegated powers provided for other legal bases[10]. With the exception of Article 5(3) the BPR allows – but does not oblige – the Commission adopt delegated acts. It is important to note that the BPR has only been applied since 1 September 2013.

CONCLUSION

To date the Commission has exercised the delegated powers provided for by the BPR in four occasions. One draft delegated act is currently being discussed by experts.

The Commission is of the view that the delegated powers conferred by Article 83(2) 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.

[9] The draft Commission Delegated Regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 was endorsed by the College of Commissioners on 15 June 2016. More information on the dedicated web portal: http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm.

[10] Article 3(4), Article 6(4), Article 21(3), Article 23(5), Article 28(1), Article 28(3), Article 56(4), Article 71(9) and Article 85.