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COMMISSION IMPLEMENTING REGULATION (EU) No .../..

of **XXX**

**approving copper pyrithione as an active substance for use in biocidal products for
product-type 21**

(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard 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 products¹, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014² establishes a list of active substances to be evaluated with a view to their possible approval for use in biocidal products or inclusion into Annex I to Regulation (EU) No 528/2012. That list includes copper pyrithione.
- (2) Copper pyrithione has been evaluated in accordance with Article 90(2) of Regulation (EU) No 528/2012 for use in biocidal products for product-type 21, antifouling products, as defined in Annex V to Regulation (EU) No 528/2012.
- (3) Sweden was designated as evaluating competent authority and submitted an assessment report, together with its recommendations, to the Commission on 28 January 2011 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007³.
- (4) The opinion of the European Chemicals Agency was formulated on 3 October 2014 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to that opinion, biocidal products used for product-type 21 and containing copper pyrithione may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC of the European Parliament and of the Council⁴ provided that certain specifications and conditions relating to its use are satisfied.

¹ OJ L 167, 27.6.2012, p. 1.

² 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).

³ Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).

⁴ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

- (6) Nevertheless, the acceptability of the risks related to the use of antifouling products, as well as the suitability of the proposed risk mitigation measures, needs to be further confirmed. In order to facilitate, at the time of the renewal of the approvals of existing antifouling active substances, the review and comparison of the risks and benefits of those substances as well as of the risk mitigation measures applied, the expiry date of approval of those substances should be the same.
- (7) It is therefore appropriate to approve copper pyrithione for use in biocidal products for product-type 21 subject to compliance with certain specifications and conditions.
- (8) Since the evaluations did not address nanomaterials, the approval should not cover such materials in accordance with Article 4(4) of Regulation (EU) No 528/2012.
- (9) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Copper pyrithione shall be approved as an active substance for use in biocidal products for product-type 21, subject to the specifications and conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President