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**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of **XXX****

**renewing the approval of the active substance captan in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011**

(Text with EEA relevance)

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## **renewing the approval of the active substance captan in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC<sup>1</sup>, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2007/5/EC<sup>2</sup> included captan as an active substance in Annex I to Council Directive 91/414/EEC<sup>3</sup>.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011<sup>4</sup>.
- (3) The approval of the active substance captan, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2023.
- (4) An application for the renewal of the approval of the active substance captan was submitted to the rapporteur Member State and the co-rapporteur Member State in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012<sup>5</sup> within the time period provided for in that Article.
- (5) The applicants submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

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<sup>1</sup> OJ L 309, 24.11.2009, p. 1.

<sup>2</sup> Commission Directive 2007/5/EC of 7 February 2007 amending Council Directive 91/414/EEC to include captan, folpet, formetanate and methiocarb as active substances (OJ L 35, 8.2.2007, p. 14).

<sup>3</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

<sup>4</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

<sup>5</sup> Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 4 December 2017.
- (7) The Authority communicated the draft renewal assessment report to the applicants and made it available to the public and forwarded the comments received to the Commission. The Authority made the supplementary summary dossier available to the public.
- (8) On 24 July 2020, the Authority communicated to the Commission its conclusion<sup>6</sup> on whether captan can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority concluded that captan does not meet the criteria for identifying endocrine disrupting properties set in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605<sup>7</sup>.
- (9) The Commission presented a renewal report and the draft Regulation regarding captan to the Standing Committee on Plants, Animals, Food and Feed on 24 March 2020 and 13 October 2022 respectively and a revised version of the renewal report on 14 July 2022.
- (10) The Commission invited the applicants to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on both versions of the renewal report. The applicant submitted its comments on both versions of the renewal report, which have been carefully examined.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance captan that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) The risk assessment for the renewal of the approval of the active substance captan is based on representative uses as fungicide. While it is not necessary, in the light of this risk assessment, to maintain the restriction to use only as a fungicide, it is necessary to provide, in accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, for certain conditions and restrictions. It is, in particular, appropriate to restrict the use of plant protection products containing captan to use in greenhouses with the obligation that they remain closed from the time of application until harvest to mitigate the risk to wild mammals, fish, aquatic invertebrates, bees and non-target arthropods other than bees and to require further confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water.
- (13) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (14) Commission Implementing Regulation (EU) 2022/708<sup>8</sup> extended the approval period of captan to 31 July 2023 in order to allow the renewal process to be completed before

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<sup>6</sup> EFSA Journal 2020;18(9):6230 (revised on 11 November 2020). Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu).

<sup>7</sup> Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

<sup>8</sup> Commission Implementing Regulation (EU) 2022/708 of 5 May 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances

the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date. [

- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*  
***Renewal of the approval of the active substance***

The approval of the active substance captan, as specified in Annex I to this Regulation, is renewed subject to the conditions laid down in that Annex.

*Article 2*  
***Amendments to Implementing Regulation (EU) No 540/2011***

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

*Article 3*  
***Entry into force and date of application***

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

It shall apply from 1 March 2023.

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

Done at Brussels,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*

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2,5-dichlorobenzoic acid methylester, acetic acid, aclonifen, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, beflubutamid, benthialdicarb, boscalid, calcium carbide, captan, cymoxanil, dimethomorph, dodemorph, ethephon, ethylene, extract from tea tree, fat distillation residues, fatty acids C7 to C20, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, hydrolysed proteins, iron sulphate, magnesium phosphide, metam, metamidron, metazachlor, metribuzin, milbemectin, phenmedipham, pirimiphos-methyl, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, propamocarb, proquinazid, prothioconazole, pyrethrins, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, sulcotrione, tebuconazole and urea (OJ L 133, 10.5.2022, p. 1).