



2024/2186

4.9.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2186

of 3 September 2024

renewing the approval of the active substance captan in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending 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 ⁽¹⁾, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2007/5/EC ⁽²⁾ included captan as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (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 ⁽⁴⁾.
- (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 15 November 2024.
- (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 ⁽⁵⁾ within the time period provided for in that Article.
- (5) The applicants submitted the supplementary dossiers required to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the the Authority and the Commission on 4 December 2017. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of captan.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

⁽²⁾ 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. 11, ELI: <http://data.europa.eu/eli/dir/2007/5/oj>).

⁽³⁾ 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, ELI: <http://data.europa.eu/eli/dir/1991/414/oj>).

⁽⁴⁾ 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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

⁽⁵⁾ 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, ELI: http://data.europa.eu/eli/reg_impl/2012/844/oj).

- (7) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments 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 ⁽⁶⁾ 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 the determination of endocrine disrupting properties set in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009.
- (9) The Commission presented a draft renewal report on 14 July 2022 and the draft Regulation on 13 October 2022 to the Standing Committee on Plants, Animals, Food and Feed.
- (10) Some Member States requested to explore the possibility to refine the assessment for certain non-target species for field uses. The rapporteur Member State conducted such assessment and the Authority was requested to analyse that assessment. In the absence of agreed harmonised values for regulatory purposes, in 2024 the Authority did not consider the information available as sufficiently robust to demonstrate a significant variation of the level of risk to those non-target species compared to the one identified in the EFSA Conclusion ⁽⁷⁾.
- (11) In March 2024, the Standing Committee on Plants, Animals, Food and Feed endorsed a compendium ⁽⁸⁾ which lists techniques and pesticide application equipment, which include innovations used in precision agriculture, and are recognised by risk managers as reducing exposure of the environment to pesticides. That compendium sets a harmonised sound basis for risk managers to select particular application equipment which leads to the reduction of exposure as risk mitigation measures. Consequently, while acknowledging the Authority's assessment of the literature studies, the Standing Committee considered that the risk mitigation measures leading to the refined risk assessment could be considered appropriate and achieving the reduction of exposure necessary to protect wild mammals, bees, and the aquatic environment. Taking into account the new information, the Commission presented a revised draft renewal report to the Standing Committee on Plants, Animals, Food and Feed on 24 June 2024.
- (12) The Commission invited the applicants to submit their 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 Commission also shared the further assessment for certain non-target species for field uses with further refinements provided by the rapporteur Member State with the applicants and the other Member States. The applicants submitted their comments on both versions of the renewal report and on the further assessment provided by the rapporteur Member State. Those comments have been carefully examined and taken into due consideration.
- (13) 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. It is therefore appropriate to renew the approval of captan.
- (14) It is however necessary to provide for certain conditions and restrictions, 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. It is, in particular, appropriate that the use of plant protection products containing captan be restricted to uses outside flowering of the crop and when no flowering weeds are present in the rows of the treated crops. Furthermore, for outdoor applications on orchards (e.g. apples, cherries), in order to ensure the protection of non-target organisms, in particular wild mammals, aquatic organisms and bees, only certain uses should be authorised. Those are uses via pesticide application equipment that increases the precision and accuracy of the application and, while maintaining the application rate on the target surfaces, achieves an average reduction of at

⁽⁶⁾ *EFSA Journal* 2020;18(9):6230 (revised on 11 November 2020). Available online: www.efsa.europa.eu.

⁽⁷⁾ Statement on the refined environmental risk assessment and impact on the new classification for captan EFSA (European Food Safety Authority), 2024; 10.2903/j.efsa.2024.8576.

⁽⁸⁾ Compendium of conditions of use to reduce exposure and risk from plant protection products.

least 61 % of the applied plant protection product (per hectare) and a minimum of 20 % reduction of plant protection product loss to the ground, compared to applications via conventional application equipment and practices, therefore, minimises the drift to areas outside the target surface of the crop (e.g. canopy).

- (15) In order to increase confidence in the regulatory decision making, the applicants should submit information and exposure data demonstrating that the pesticide application equipment (e.g. emission shields, shielded sprayers, hooded sprayers, tunnel sprayers, sensor-controlled sprayers) used on orchards achieves a reduction of exposure of at least 61 % of the applied plant protection product (per hectare) and a minimum of 20 % reduction of plant protection product loss to the ground compared to applications via conventional equipment.
- (16) It is further appropriate to require further confirmatory information as regards the effect of water treatment processes on the nature of residues of captan's metabolites THPI and THPAM present in ground water, when it is abstracted for drinking water.
- (17) Taking into account the Opinion of the Risk Assessment Committee of the European Chemicals Agency of 14 September 2023 ⁽⁹⁾, which proposed to classify captan as toxic to reproduction Category 2 and as STOT-RE Category 1, it is also appropriate to require further confirmatory information concerning the relevance of metabolites THPI and THPAM that may occur in groundwater.
- (18) Furthermore, it is also appropriate to require further confirmatory information as regards the storage stability of captan in high acidic content matrices to confirm the existing applicable maximum residue level for strawberries.
- (19) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (20) Commission Implementing Regulation (EU) 2023/918 ⁽¹⁰⁾ extended the approval period of captan to 15 November 2024 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on the renewal has been taken ahead of that extended expiry date, this Regulation should start to apply earlier than that date.
- (21) 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.

⁽⁹⁾ <https://chesar.echa.europa.eu/documents/10162/61dcb37e-ab22-e25e-9891-181ae09413ef>.

⁽¹⁰⁾ Commission Implementing Regulation (EU) 2023/918 of 4 May 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aclonifen, ametoctradin, beflubutamid, benthialdicarb, boscalid, captan, clethodim, cycloxydim, cyflumetofen, dazomet, diclofop, dimethomorph, ethephon, fenazaquin, fluopicolide, fluoxastrobin, flurochloridone, folpet, formetanate, *Helicoverpa armigera nucleopolyhedrovirus*, hymexazol, indolylbutyric acid, mandipropamid, metalaxyl, metaldehyde, metam, metazachlor, metribuzin, milbemectin, paclobutrazol, penoxsulam, phenmedipham, pirimiphos-methyl, propamocarb, proquinazid, prothioconazole, S-metolachlor, *Spodoptera littoralis nucleopolyhedrovirus*, *Trichoderma asperellum* strain T34 and *Trichoderma atroviride* strain I-1237 (OJ L 119, 5.5.2023, p. 160, ELI: http://data.europa.eu/eli/reg_impl/2023/918/oj).

*Article 2***Amendment 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 November 2024.

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

Done at Brussels, 3 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

| Common Name, Identification Numbers | IUPAC Name | Purity (%) | Date of approval | Expiration of approval | Specific provisions |
|---|---|---|------------------|------------------------|--|
| Captan CAS No 133-06-2 CIPAC No 40 | N-[(trichloromethyl)thio]cyclohex-4-ene-1,2-dicarboximide | <p>≥ 930 g/kg</p> <p>perchloromethyl-mercaptan: ≤ 5 g/kg</p> <p>folpet: ≤ 10 g/kg</p> <p>carbon tetrachloride: ≤ 0,1 g/kg</p> | 1 November 2024 | 31 October 2039 | <p>For outdoor uses the following conditions shall apply:</p> <ul style="list-style-type: none"> — only uses outside flowering of the crop and when no flowering weeds are present in the rows of the treated crops may be authorised, — Member States shall require that applications in orchards (e.g. apples, cherries) are only done with application equipment that increases the precision and accuracy of the application (e.g. emission shields, shielded sprayers, hooded sprayers, tunnel sprayers, sensor-controlled sprayers), and, while maintaining the application rate on the target surfaces, achieves an average reduction of at least 61 % of the applied plant protection product (per hectare) and a minimum of 20 % reduction of plant protection product loss to the ground compared to applications via conventional application equipment and practice. <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on captan, and in particular Appendices I and II thereto, shall be taken into account. In addition, risk mitigations such as no-spray buffer zones from field margins, shall be required, when appropriate, by the Member States on the basis of their risk assessment to protect bees and aquatic organisms.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the compliance with the technical specification of the active substance contained in the plant protection product for which applications for authorisation are submitted, — the protection of operators and workers ensuring that conditions of use include the application of adequate personal protective equipment taking into account the high skin sensitising potential of the active substance, — the protection of bystanders and residents ensuring that conditions of use include adequate risk mitigation measures taking into account the high skin sensitising potential of the active substance. |

| Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|-------------------------------------|------------|-----------------------|------------------|------------------------|--|
| | | | | | <p>In addition, Member States may set monitoring requirements when granting authorisations, in order to supplement the monitoring under Directives 2000/60/EC ⁽²⁾ and 2009/128/EC ⁽³⁾ of the European Parliament and of the Council.</p> <p>Within two years from 24 September 2024, the applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> (1) the effect of water treatment processes on the nature of residues of captan's metabolites THPI and THPAM present in ground water, when it is abstracted for drinking water; (2) the relevance of metabolites THPI and THPAM that may occur in groundwater, taking into account the proposal of classification of captan as toxic to reproduction Category 2 and as STOT-RE Category 1 in the Opinion of the Risk Assessment Committee of the European Chemicals Agency of 14 September 2023; (3) the storage stability of captan in high acid content matrices, in compliance with the relevant OECD Test Guideline; and <p>Furthermore, within 18 months from 24 September 2024, the applicant shall submit to the Commission, the Member States and the Authority:</p> <ol style="list-style-type: none"> (4) information and exposure data demonstrating that the pesticide application equipment used on orchards increases the precision and accuracy of the application and achieves a reduction of exposure of at least 61 % of the applied plant protection product (per hectare) and a minimum of 20 % reduction of plant protection product loss to the ground compared to applications via conventional equipment and practices. |

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.

⁽²⁾ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: <http://data.europa.eu/eli/dir/2000/60/oj>).

⁽³⁾ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71, ELI: <http://data.europa.eu/eli/dir/2009/128/oj>).

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, entry 145 on captan is deleted;
- (2) in Part B, the following entry is added:

| No | Common Name, Identification Numbers | IUPAC Name | Purity (1) | Date of approval | Expiration of approval | Specific provisions |
|-----|---|---|---|------------------|------------------------|---|
| 170 | Captan CAS No 133-06-2 CIPAC No 40 | N-[(trichloromethyl)thio]cyclohex-4-ene-1,2-dicarboximide | <p>≥ 930 g/kg</p> <p>perchloro methylmercaptan: ≤ 5 g/kg</p> <p>folpet: ≤ 10 g/kg</p> <p>carbon tetrachloride: ≤ 0,1 g/kg</p> | 1 November 2024 | 31 October 2039 | <p>For outdoor uses the following conditions shall apply:</p> <ul style="list-style-type: none"> — only uses outside flowering of the crop and when no flowering weeds are present in the rows of the treated crops may be authorised, — Member States shall require that applications in orchards (e.g. apples, cherries) are only done with application equipment that increases the precision and accuracy of the application (e.g. emission shields, shielded sprayers, hooded sprayers, tunnel sprayers, sensor-controlled sprayers), and, while maintaining the application rate on the target surfaces, achieves an average reduction of at least 61 % of the applied plant protection product (per hectare) and a minimum of 20 % reduction of plant protection product loss to the ground compared to applications via conventional application equipment and practice. <p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on captan, and in particular Appendices I and II thereto, shall be taken into account. In addition, risk mitigations such as no-spray buffer zones from field margins, shall be required, when appropriate, by the Member States on the basis of their risk assessment to protect bees and aquatic organisms.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the compliance with the technical specification of the active substance contained in the plant protection product for which applications for authorisation are submitted, |

| No | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|----|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | <p>— the protection of operators and workers ensuring that conditions of use include the application of adequate personal protective equipment taking into account the high skin sensitising potential of the active substance,</p> <p>— the protection of bystanders and residents ensuring that conditions of use include adequate risk mitigation measures taking into account the high skin sensitising potential of the active substance.</p> <p>In addition, Member States may set monitoring requirements when granting authorisations, in order to supplement the monitoring under Directives 2000/60/EC ⁽²⁾ and 2009/128/EC ⁽³⁾ of the European Parliament and of the Council.</p> <p>Within two years from 24 September 2024, the applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> (1) the effect of water treatment processes on the nature of residues of captan's metabolites THPI and THPAM present in ground water, when it is abstracted for drinking water; (2) the relevance of metabolites THPI and THPAM that may occur in groundwater, taking into account the proposal of classification of captan as toxic to reproduction Category 2 and as STOT-RE Category 1 in the Opinion of the Risk Assessment Committee of the European Chemicals Agency of 14 September 2023; (3) the storage stability of captan in high acid content matrices, in compliance with the relevant OECD Test Guideline; and <p>Furthermore, within 18 months from 24 September 2024, the applicant shall submit to the Commission, the Member States and the Authority:</p> |

| No | Common Name, Identification Numbers | IUPAC Name | Purity ⁽¹⁾ | Date of approval | Expiration of approval | Specific provisions |
|----|-------------------------------------|------------|-----------------------|------------------|------------------------|---|
| | | | | | | (4) information and exposure data demonstrating that the pesticide application equipment used on orchards increases the precision and accuracy of the application and achieves a reduction of exposure of at least 61 % of the applied plant protection product (per hectare) and a minimum of 20 % reduction of plant protection product loss to the ground compared to applications via conventional equipment and practices. |

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.

⁽²⁾ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: <http://data.europa.eu/eli/dir/2000/60/oj>).

⁽³⁾ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71, ELI: <http://data.europa.eu/eli/dir/2009/128/oj>).