EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Food and feed safety, innovation
Pesticides and biocides

Chlorothalonil
SANTE/10186/2018 Rev 1
22 March 2019

Final Renewal report for the active substance **chlorothalonil**

finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 22 March 2019
in view of the non-renewal of the approval of chlorothalonil as active substance
in accordance with Regulation (EC) No 1107/2009[1]

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the evaluation of **chlorothalonil**, in accordance with Regulation (EC) No 1107/2009[2] and Commission Implementing Regulation (EU) No 844/2012[3] following the submission of an application to renew the approval of this active substance expiring in October 2018.

Chlorothalonil is a substance that was included in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, by Commission Directive 2005/53/EC[4]. Chlorothalonil is deemed to have been approved under Regulation (EC) No 1107/2009 and is listed in Part A of the Annex to Commission Implementing Regulation (EU) No 40/2011[5].

An application for renewal of the approval of chlorothalonil was submitted by Arysta LifeScience S.A.S, Oxon Italia S.p.A. and Syngenta Crop Protection AG in accordance with Article 1 of Regulation No. 844/2012.

Commission Implementing Regulation 2018/1262[6] extended until 31 October 2019 the period of approval of chlorothalonil to allow the completion of its review.

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1 Renewal Report established in accordance with Art. 14 of Regulation (EU) No 844/2012; does not necessarily represent the views of the European Commission.
2 OJ L 309, 24.11.2009, p. 1.
3 OJ L 252, 19.9.2012, p. 26.
4 Commission Directive 2005/53/EC of 16 September 2005 amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances (OJ L 241, 17.9.2005, p. 51).
5 OJ L 153, 11.6.2011, p. 1.
6 Commission Implementing Regulation (EU) 2018/1262 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, clomazone, cypermethrin, daminozide, deltamethrin, dimethenamid-p, diuron, fludioxonil, flufenacet, flurtamone, fosthiazate, indoxacarb, MCPA, MCPB, prosulfocarb, thiophanate-methyl and tribenuron (OJ L 238, 21.9.2018, p. 62).

Commission Implementing Regulation (EU) No 686/2012[7] designated the rapporteur Member States and the co-rapporteur Member States which had to submit the relevant renewal assessment reports and recommendations to the European Food Safety Authority (EFSA).

For chlorothalonil the rapporteur Member State was the Netherlands and the co-rapporteur Member State was Belgium.

The Netherlands finalised in September 2016 its examination, in the form of a renewal assessment report. This Report was sent to the Commission and the European Food Safety Authority on 2 September 2016 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of chlorothalonil for the supported uses.

In accordance with Article 13 of Implementing Regulation (EU) No 844/2012, the EFSA organised an intensive consultation of technical experts from Member States, to review the renewal assessment report and the comments received thereon (peer review).

The EFSA sent to the Commission its conclusion on the risk assessment (Conclusions regarding the peer review of the pesticide risk assessment of the active substance)[8] on 6 December 2017. This conclusion refers to to several background documents: the draft assessment report including its addendum and the EFSA peer review report.

According to the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 5 June 2018. The draft renewal report was finalised in the meeting of the Standing Committee on 22 March 2019.

The present renewal report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and its background documents, these documents are also considered to be part of this review report.

2. Purposes of this review report

This renewal report, including the background documents and appendices hereto, has been developed and finalised in support of **Commission Implementing Regulation (EU) 2019/677**[9] concerning the non-renewal of approval of chlorothalonil as active substance under Regulation (EC) No 1107/2009.

This review report will be made available to the public.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this review report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

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7 OJ L 200, 27.7.2012, p. 5.

8 EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance chlorothalonil. EFSA Journal 2018;16(1):5126, 47 pp. https://doi.org/10.2903/j.efsa.2018.5126.

9 OJ L 114, 30.4.2019, p. 15.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

As part of the updated evaluation of chlorothalonil the following reference values have been finalised:

ADI: 0.015 mg/kg bw per day,
ARfD: 0.05 mg/kg bw,
AOEL: 0.003 mg/kg bw per day,
AAOEL: 0.01 mg/kg bw.

To note, the ARfD and AOEL have changed compared to the previous EU agreed reference value (0.05 mg/kg bw compared to 0.6 mg/kg bw for the ARfD and 0.003 mg/kg bw per day compared to 0.009 mg/kg bw per day for the AOEL) and an AAOEL has been set for the first time.

The overall conclusion of the evaluation, based on the information available and the proposed conditions of use, is that:

- **the information available indicates that the approval criteria** as set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009 are not satisfied as **concerns were identified** with regards to:

    - The contamination of groundwater by metabolites of chlorothalonil. In particular, metabolites R417888, R419492, R471811, SYN507900, M3, M11, M2, M7 and M10 are predicted to occur above the parametric value of 0.1 µg/L in all scenarios.
    - A genotoxicity concern could not be excluded for residues to which consumers will be exposed.
    - The risk to amphibians and fish.
    - The proposed classification of chlorothalonil by the peer review as carcinogen category 1B in accordance to the provisions of Regulation (EC) No 1272/2008 (while harmonised classification is category 2).

- **the information available is insufficient** to satisfy the requirements set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009, in particular with regard to:

    - The analytical methods used in the toxicological studies were not identified and therefore not validated, this questions the validity of the studies, in particular repeated-dose dietary studies.
    - The need for further tests and risk assessment to unique human metabolites could not be finalised whilst an *in vitro* comparative metabolism study was not submitted.
    - The chronic risk to amphibians could not be finalised.
    - The consumer risk assessment from the consumption of water could not be finalised, whilst satisfactory information was not available to address the effect of water treatment processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water.
    - The consumer risk assessment could not be finalised as the residue definitions for risk assessment in plant and animal commodities are preliminary. In the absence of toxicological reference values for R182281 even an indicative consumer risk assessment using the preliminary residue definitions cannot be conducted.

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general the requirements laid down in Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

The approval of chlorothalonil in accordance with Regulation (EC) No 1107/2009 should therefore not be renewed.