Commission Implementing Regulation (EU) 2018/660 of 26 April 2018 renewing the approval of the active substance bentazone 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/660

of 26 April 2018

renewing the approval of the active substance bentazone 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[(1)], and in particular Article 20(1) thereof,

Whereas:

(1) Commission Directive 2000/68/EC[(2)] included bentazone 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 bentazone, as set out in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011, expires on 30 June 2018.

(4) An application for the renewal of the inclusion of bentazone in Annex I to Council Directive 91/414/EEC was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010[(5)] within the time period provided for in that Article.

(5) The applicants submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. The application was found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a 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 8 January 2014.

(7) The Authority communicated the renewal assessment report to the applicants and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(8) On 20 April 2015, the Authority communicated to the Commission its conclusion[(6)] on whether bentazone can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft review report for bentazone to the Standing Committee on Plants, Animals, Food and Feed on 8 October 2015.

(9) The applicants were given the opportunity to submit comments on the draft review report.

(10) It has been established with respect to one or more representative uses of at least one plant protection product containing bentazone 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 bentazone.

(11) Nevertheless, several Member States have identified bentazone in the groundwater in their national groundwater monitoring programmes and EFSA indicated that for certain uses and under vulnerable soil conditions groundwater contamination cannot be excluded.

(12) Therefore, in light of the results of national groundwater monitoring programmes, and bearing in mind the need to ensure a level of safety and protection consistent with the high level of protection that is sought within the Union, it is appropriate to provide for a renewal of the approval of bentazone for a period of seven years which ensures a priority re-assessment of bentazone over other active substances thereby also allowing to take into consideration updated results of national groundwater monitoring programmes.

(13) The risk assessment for the renewal of the approval of bentazone is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing bentazone may be authorised. It is therefore appropriate to remove the restriction for use only as a herbicide.

(14) 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, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

(15) The Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

(16) Commission Implementing Regulation (EU) 2017/841[(7)] extended the approval period of bentazone until 30 June 2018 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision on renewal has already been taken ahead of that date, this Regulation should apply from 1 June 2018.

(17) 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 bentazone is renewed as set out in Annex I.

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 June 2018.

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

Done at Brussels, 26 April 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/660. (See end of Document for details)*

ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Bentazone CAS No 25057-89-0 CIPAC No 366	3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide	≥ 960 g/kg 1,2-dichloroethane < 3 mg/kg	1 June 2018	31 May 2025	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on bentazone, and in particular Appendices I and II thereof, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the technical specification, — the protection of operators and workers, — the risk to birds and mammals, — the protection

a Further details on the identity and specification of the active substance are provided in the review report.

					of groundwater, particularly but not only in drinking water protected areas, and shall carefully consider the timing of application, soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit by 1 February 2019 to the Commission, the Member States and the Authority confirmatory information as regards Level 2/3 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-

a Further details on the identity and specification of the active substance are provided in the review report.