

Brussels, XXX SANTE/12148/2020 Rev. 2 [...](2020) XXX draft

ANNEXES 1 to 2

## **ANNEXES**

to the

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

amending Implementing Regulations (EU) No 540/2011 and (EU) No 820/2011 as regards the conditions of approval of the active substance terbuthylazine

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ANNEX I

Annex I to Implementing Regulation (EU) No 820/2011 is replaced by the following:

Common Name, Identification Numbers	IUPAC Name	Purity <sup>1</sup>	Date of approval	Expiration of approval	Specific provisions
Terbuthylazine CAS No 5915-41-3 CIPAC No 234	N2-tert-butyl-6-chloro-N4-ethyl-1,3,5-triazine-2,4-diamine	≥ 950 g/kg  The following impurities are of toxicological concern and must not exceed the following levels in the technical material:  - Propazine: maximum of 9 g/kg  - Atrazine: maximum of 1 g/kg  - Simazine: maximum of 9 g/kg	1 January 2012	31 December 2024	PART A Only uses as herbicide may be authorised.  Use shall be limited to one application every three years on the same field at a maximum dose of 850 g terbuthylazine per hectare.  PART B 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 terbuthylazine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 and updated by the Standing Committee on Plants, Animals, Food and Feed on XX XXX 2021 shall be taken into account.  In this overall assessment Member States shall pay particular attention to:  (a) the consumer risk assessment from exposure to metabolites of terbuthylazine;  (b) the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;  (c) the risk to mammals and earthworms.

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

Common Name, Identification Numbers	IUPAC Name	Purity <sup>1</sup>	Date of approval	Expiration of approval	Specific provisions
					Conditions of use shall include risk mitigation measures and the obligation to carry out monitoring programmes to verify potential groundwater contamination in vulnerable zones, where appropriate.

**ANNEX II** 

Entry 16, on terbuthylazine, in Part B of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

Number	Common Name, Identification Numbers	IUPAC Name	Purity <sup>2</sup>	Date of approval	Expiration of approval	Specific provisions
16	Terbuthylazine CAS No 5915-41-3 CIPAC No 234	N2-tert-butyl-6-chloro-N4-ethyl-1,3,5-triazine-2,4-diamine	≥ 950 g/kg  The following impurities are of toxicological concern and must not exceed the following levels in the technical material:  - Propazine: maximum of 9 g/kg  - Atrazine: maximum of 1 g/kg  - Simazine: maximum of 9 g/kg	1 January 2012	31 December 2024	PART A Only uses as herbicide may be authorised.  Use shall be limited to one application every three years on the same field at a maximum dose of 850 g terbuthylazine per hectare.  PART B 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 terbuthylazine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011 and updated by the Standing Committee on Plants, Animals, Food and Feed on XX XXX 2021 shall be taken into account.  In this overall assessment Member States shall pay particular attention to:  (a) the consumer risk assessment from exposure to metabolites of terbuthylazine;  (b) the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;

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

Number	Common Name, Identification Numbers	IUPAC Name	Purity <sup>2</sup>	Date of approval	Expiration of approval	Specific provisions
						(c) the risk to mammals and earthworms.  Conditions of use shall include risk mitigation measures and the obligation to carry out monitoring programmes to verify potential groundwater contamination in vulnerable zones, where appropriate.