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ANNEXES 1 to 2

## ANNEXES

to the

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

**renewing the approval of the active substance methoxyfenozide, as a candidate for substitution, 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**

## ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity <sup>1</sup>	Date of approval	Expiration of approval	Specific provisions
Methoxyfenozide CAS No 161050-58-4 CIPAC No 656	N-tert-Butyl-N'-(3-methoxy-o-toluoyl)-3,5-xylohydrazide	<p>≥ 970 g/kg</p> <p>Tert-butylhydrazine &lt; 0.001 g/kg</p> <p>RH-116267 &lt; 2 g/kg</p>	1 February 2019	31 January 2026	<p>Only uses on fruiting vegetables of solanaceae in greenhouse shall be authorised.</p> <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 review report on methoxyfenozide, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In their overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>- the protection of groundwater when the substance is applied in regions with vulnerable soil and/or climate conditions;</li> <li>- the risk of accumulation in soil;</li> <li>- the protection of non-target arthropods, sediment dwelling and aquatic organisms.</li> </ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> <li>1. a comparative in vitro metabolism study on methoxyfenozide, by <i>1 February 2020</i>;</li> <li>2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water, within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater;</li> <li>3. the endocrine disrupting potential of methoxyfenozide as regards the thyroid modality/pathway, providing in particular mechanistic data to clarify in accordance with Points 3,6,5 and 3,8,2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605<sup>2</sup>, whether there is a thyroid endocrine disrupting mode of action, by 10 November 2020.</li> </ol>

<sup>1</sup> Further details on identity and specification of active substance are provided in the review report.

<sup>2</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.).

## ANNEX II

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

- (1) in Part A, entry 96 on methoxyfenozide is deleted;  
 (2) in Part E, the following entry is added:

No.	Common Name, Identification Numbers	IUPAC Name	Purity <sup>3</sup>	Date of approval	Expiration of approval	Specific provisions
"xx	Methoxyfenozide CAS No 161050-58-4 CIPAC No 656	N-tert-Butyl-N'-(3-methoxy-o-toluoyl)-3,5-xylohydrazide	<p>≥ 970 g/kg</p> <p>Tert-butylhydrazine &lt; 0.001 g/kg</p> <p>RH-116267 &lt; 2 g/kg</p>	1 February 2019	31 January 2026	<p>Only uses on fruiting vegetables of solanaceae in greenhouse shall be authorised.</p> <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 review report on methoxyfenozide, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In their overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>- the protection of groundwater when the substance is applied in regions with vulnerable soil and/or climate conditions;</li> <li>- the risk of accumulation in soil;</li> <li>- the protection of non-target arthropods, sediment dwelling and aquatic organisms.</li> </ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> <li>1. a comparative in vitro metabolism study on methoxyfenozide, by <i>1 February 2020</i>;</li> <li>2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water, within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater;</li> <li>3. the endocrine disrupting potential of methoxyfenozide as regards the thyroid modality/pathway, providing in particular mechanistic data to clarify in accordance with Points 3,6,5 and 3,8,2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605<sup>4</sup>, whether there is a thyroid endocrine disrupting mode of action, by 10 November 2020." </li></ol>

<sup>3</sup> Further details on identity and specification of active substance are provided in the review report.

<sup>4</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.).