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## SCHEDULE 11

Regulation 3

## Authorisation of Decoquinate (Avi-Deccox<sup>®</sup> 60G) (identification number 51756ii) as a feed additive for chickens for fattening

The substance of Decoquinate (Avi-Deccox<sup>®</sup> 60G), belonging to the additive 'coccidiostats and histomonostats', is authorised as an additive in animal nutrition in accordance with the specifications in the following table(1).

Additive	Decoquinate (Avi-Deccox <sup>®</sup> 60G)
Identification number of the additive	51756ii
Authorisation holder	Zoetis Belgium SA
Additive category	Coccidiostats and Histomonostats
Functional group	Not applicable
Additive composition	<ul> <li>Decoquinate, 60.0 g/kg</li> <li>Colloidal silica, 0.6 g/kg</li> <li>Silicon dioxide, 4.0 g/kg</li> <li>Carboxymethylcellulose sodium, 30.0 g/kg</li> <li>Calcium sulphate dihydrate, q.s. ad 1,000 g</li> </ul>
Characterisation of the active substance(s)	<ul> <li>Decoquinate: (Ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate)</li> <li>— Chemical Formula: C<sub>24</sub>H<sub>35</sub>NO<sub>5</sub></li> <li>— CAS No: 18507-89-6<sup>(1)</sup></li> <li>Related impurities:</li> <li>— Methyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: &lt; 1.0%</li> <li>— 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: &lt; 0.5%</li> <li>— Diethyl-4-decycloxy-3-ethoxyanilinomethylene-malonate: &lt; 0.5%</li> </ul>
Analytical methods <sup>(2)</sup>	<ul> <li>For quantification of decoquinate in the feed additive, premixtures feed materials and compound feed:</li> <li>— Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) in accordance with BS EN 16162:2012<sup>(3)</sup>.</li> </ul>
	<ul> <li>For quantification of decoquinate in tissues:</li> <li>Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS<sup>(4)</sup>) or any other analytical method complying with the requirements set by Commission Decision 2002/657/EC(2).</li> </ul>

This authorisation is a modified form of decoquinate, which was previously authorised under Regulation (EC) No 1289/2004, (1) and now authorised under Schedule 10 to these Regulations.
 (2) EUDN 2002/657, as amended by S.I 2020/1461.

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Species or category of animal	Chickens for fattening
Maximum age	Not applicable
Minimum content <sup>(5)</sup>	30 mg/kg
Maximum content <sup>(5)</sup>	40 mg/kg
Other provisions	<ol> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment must be indicated.</li> <li>The additive must be incorporated in compound feed in the form of a premixture.</li> <li>Decoquinate must not be mixed with other coccidiostats.</li> <li>Decoquinate must not be used in feed containing bentonite.</li> <li>A post-market monitoring programme must be carried out by the holder of the authorisation for resistance to bacteria and <i>Eimeria</i> spp. A report containing the outcome of the post market monitoring programme must be submitted to the Secretary of State before 25th November 2031.</li> </ol>

(1) This is a reference to the CAS Registry Number assigned to this substance by the Chemical Abstracts Service https://cas.org/ cas-data/cas-registry.

- (2) Details of the analytical methods set out in the document referenced "Ares(2013)3639174 04/12/2013" and last updated 6th June 2016. The document is available at the following address: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2013-0034.
- (3) BS EN 16162:2012. "Animal feeding stuffs. Determination of decoquinate by HPLC with fluorescence detection". Published by the British Standards Institution on 31st March 2012 (ISBN 978 0 580 67002 2). Available from the British Standards Institution https://knowledge.bsigroup.com.
- (4) "Safety and efficacy of Deccox<sup>®</sup> (decoquinate) for chickens for fattening". Published by the European Food Safety Authority in the EFSA Journal, Volume 17, Issue 1 on 14th January 2019. This document is available at the following address https://www.efsa.europa.eu/en/efsajournal/pub/5541.
- (5) Content of Decoquinate (Avi-Deccox<sup>®</sup>): mg/kg of complete feed with a moisture content of 12%.