

## SCHEDULE 1

Regulation 3

Authorisation of a preparation of Manganese chelate of lysine and glutamic acid (identification number 3b509) as feed additive for all animal species

The preparation of Manganese chelate of lysine and glutamic acid, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>	Manganese chelate of lysine and glutamic acid
<i>Identification number of the additive</i>	3b509
<i>Authorisation holder<sup>(1)</sup></i>	
<i>Additive category</i>	Nutritional additives
<i>Functional group</i>	Compounds of trace elements
<i>Additive composition</i>	A preparation of chelates of manganese with lysine and chelates of manganese with glutamic acid in a ratio of 1:1 as a powder with the following components: <ul style="list-style-type: none"> <li>— Manganese 15-17%</li> <li>— Lysine 20-21.5%</li> <li>— Glutamic acid 22-24%</li> <li>— Moisture 3.5% maximum</li> <li>— Nickel 4 ppm maximum</li> </ul>
<i>Characterisation of the active substance(s)</i>	Manganese-2,6-diaminohexanoic acid, chloride and hydrogen sulphate salt (C <sub>6</sub> H <sub>19</sub> ClN <sub>2</sub> O <sub>8</sub> SMn).  Manganese-2-aminopentanedioic acid, sodium and hydrogen sulphate salt (C <sub>5</sub> H <sub>10</sub> NNaO <sub>9</sub> SMn).
<i>Analytical methods<sup>(2)</sup></i>	For quantification of total manganese in the feed additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry (AAS) in accordance with BS EN ISO 6869:2001<sup>(3)</sup>;</li> <li>— Inductively Coupled Plasma-Atomic Emission Spectrometry after pressure digestion (ICP-AES) in accordance with European standard in accordance with BS EN 15621:2017<sup>(4)</sup>.</li> </ul> For the quantification of total manganese in premixtures, feed materials and compound feed: <ul style="list-style-type: none"> <li>— Inductively Coupled Plasma-Atomic Emission Spectrometry, (ICP-AES) in accordance with BS EN 15510<sup>(5)</sup>;</li> <li>— Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) in accordance with European standard BS EN 17053:2018.</li> </ul> For quantification of total manganese in feed materials and compound feed: <ul style="list-style-type: none"> <li>— Atomic Absorption Spectrometry (AAS) –Commission Regulation (EC) 152/2009 laying down the methods of</li> </ul>

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>Additive</i>	Manganese chelate of lysine and glutamic acid sampling and analysis for the official control of feed (Annex 4-C)(1). For quantification of lysine and glutamic acid in the feed additive: — Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) in accordance with BS EN ISO 13903:2005 <sup>(6)</sup> . For determination of the chelated form of the feed additive: — Mid-infrared (IR) spectrometry together with the determination of the content of trace element and lysine and glutamic acid in the feed additive.
<i>Species or category of animal</i>	All animal species.
<i>Maximum age</i>	Not applicable.
<i>Minimum content<sup>(7)</sup></i>	No minimum.
<i>Maximum content<sup>(7)</sup></i>	Fish 100 (total). All other animal species 150 (total).
<i>Other provisions</i>	The additive must be incorporated into the feed in form of a premixture.

(1) There is no requirement to include the name of the holder of this authorisation as this authorisation does not fall within the scope of Article 9(5) of Regulation (EC) 1831/2003.

(2) Details of the analytical methods are set out in the document referenced “Ares(2018)3918699 - 24/07/2018” and the document referenced “Ares(2019)7167892 - 20/11/2019” and last updated 28th January 2020. These documents are available at the following address:

[https://joint-research-centre.ec.europa.eu/publications/fad-2018-0009\\_en](https://joint-research-centre.ec.europa.eu/publications/fad-2018-0009_en)

(3) BS EN ISO 6869:2001 “Animal feeding stuffs. Determination of the contents of calcium, copper, iron, magnesium, manganese, potassium, sodium and zinc. Method using atomic absorption spectrometry”. Published by the British Standards Institution on 15th March 2001 (ISBN 0 580 36933 1). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

(4) BS EN 15621:2017 “Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES”. Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

(5) BS EN 15510:2017 “Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES”. Published by the British Standards Institution on 31st August 2017 (ISBN 978 0 539 09335 3). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

(6) BS EN ISO 13903:2005 “Animal feeding stuffs – Determination of amino acids content”. Published by the British Standards Institution on 24th October 2005 (ISBN 0 580 46218 8). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

(7) Content of element (Mn) in mg/kg of complete feed with a moisture content of 12%.

(1) EUR 2009/152, as amended by S.I. 2019/654. S.I. 2019/654 was itself amended by S.I. 2020/1504.