

ANNEX

Identification number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Content of the element (Fe) in mg/kg of complete feed with a moisture content of 12% or in mg element (Fe)/day			
Category: nutritional additives. Functional group: compounds of trace elements								
3b112	Iron(II) – betaine complex	<p>Additive composition: Iron betaine complex with a minimum of 14 % of iron and a minimum of 36 % of betaine. Nickel: maximum 58 mg/kg. Solid form.</p> <p>Characterisation of the active substances: Name: catena-[diaqua sulfato-μ2-(trimethylammonio)acetato-iron(II)] Chemical formula: [Fe (H₂O)₂((CH₃)₃NCH₂COO)(SO₄)_n]</p> <p><u>Specifications:</u> Minimum of 14% of iron, Minimum 36% betaine, 9%–12% sulphur, Maximum 5% moisture.</p> <p>Analytical methods¹: For the quantification of total iron in the feed additive: – Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or</p>	Ovines	-	-	500 mg/kg (total)	<p>1. The additive shall be incorporated into feed in the form of a premixture.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.</p>	[10 years from the date of entry into force of this Regulation – Precise date to be completed by the OP]
			Bovines	-	-	450 mg/kg (total)		
			Piglets	Until one week before weaning		250 mg/day (total)		
			Poultry			450 mg/kg (total)		
			Pets	-	-	600 mg/kg (total)		
			Other animal species	-	-	750 mg/kg (total)		

¹ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

		<p>– Atomic absorption spectrometry, AAS (ISO 6869).</p> <p>For the quantification of total iron in premixtures:</p> <p>– Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or</p> <p>– Atomic absorption spectrometry, AAS (ISO 6869) or</p> <p>– Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053).</p> <p>For the quantification of total iron in compound feed:</p> <p>– Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or</p> <p>– Atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 (Annex IV-C) or ISO 6869) or</p> <p>– Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053).</p> <p>For the quantification of betaine in the feed additive:</p> <p>– High performance liquid chromatography with refraction index detection (HPLC-RI).</p> <p>For the quantification of sulphur and sulphate in the feed additive:</p> <p>– Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621).</p> <p>Proof of complex formation between iron, betaine and sulphate²: Powder X-ray diffraction (XRD)</p>						
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² Stoe Stadi P diffractometer in Guinier geometry using Cu-K α 1 radiation (Johann Gemonochromator) and a Stoe imageplate detector IP-PSD.

