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 (Mn) in mg/kg of complete feed with a moisture content of 12%			
Category: nutritional additives. Functional group: compounds of trace elements								
3b512	Manganese(II) - betaine complex	**Additive composition:** Manganese(II) - betaine complex with a minimum of 17% of manganese and a minimum of 42 % of betaine Nickel: maximum 84 mg/kg Solid form **Characterisation of the active substances:** Name: catena-[μ3-sulfato-(trimethylammonio)acetato-manganese(II)] Chemical formula: $[Mn(H_2O)_2((CH_3)_3NCH_2COO)(SO_4)]_n$ Specifications – Minimum of 17% of Manganese – Minimum 42% betaine, – Sulphur: 9-12% – Maximum 5 % moisture **Analytical methods[1]:** For the quantification of total manganese in the feed additive: – Inductively coupled plasma-atomic emission	Aquatic animals	-	-	100	1. The additive shall be incorporated into feed in the form of a premixture. 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.	[*10 years from the date of entry into force of this Regulation – Precise date to be completed by the OP*]
			Other animal species			150		

[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

		spectrometry, ICP-AES (EN 15621 or EN 15510) or – Atomic absorption spectrometry, AAS (ISO 6869). For the quantification of total manganese in premixtures: – Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or – Atomic absorption spectrometry, AAS (ISO 6869) or – Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053). For the quantification of total manganese in compound feed: – Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or – Atomic absorption spectrometry, AAS (ISO 6869 or Commission Regulation (EC) No 152/2009 - Annex IV-C) or – Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053). For the quantification of betaine in the feed additive: – High performance liquid chromatography with refraction index detection (HPLC-RI). For the quantification of sulphur and sulphate in the feed additive: – Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621). Proof of complex formation between iron, betaine and sulphate: Powder X-ray diffraction (XRD)[2].						

[2] Stoe Stadi P diffractometer in Guinier geometry using Cu-Kα1 radiation (Johann Gemonochromator) and a Stoe imageplate detector IP-PSD.