EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10783/2016 ANNEX
(POOL/E4/2016/10783/10783-EN
ANNEX.doc)
[…](2016) XXX draft

ANNEX 1

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION (EU) …/...

approving chlorocresol as an existing active substance for use in biocidal products of product-types 1, 2, 3, 6 and 9

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance[1]	Date of approval	Expiry date of approval	Product type	Specific conditions
Chlorocresol	IUPAC Name: 4-chloro-3-methylphenol EC No: 200-431-6 CAS No: 59-50-7	99.8% w/w	1 May 2018	30 April 2028	1	The authorisations of biocidal products are subject to the following condition: The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.
					2	The authorisations of biocidal products are subject to the following conditions: 1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. 2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: a) industrial and professional users; b) children for products used in private and institutional areas.
					3	The authorisations of biocidal products are subject to the following conditions: 1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. 2) In view of the risks identified for the uses assessed, the

[1] The purity indicated in this column was the minimum degree of purity of the active substance evaluated in accordance with Article 89(1) of Regulation (EU) No 528/2012. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

						product assessment shall pay particular attention to: a) professional users; b) soil compartment. 3) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council[2] or Regulation (EC) No 396/2005 of the European Parliament and of the Council[3] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					6	The authorisations of biocidal products are subject to the following conditions: 1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. 2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: a) professional users during the formulation of product to be preserved and during the application of the preserved product in paper production; b) infants crawling on a surface that has been cleaned with the preserved product.
					9	The authorisations of biocidal products are subject to the following conditions: 1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use

[2] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

						covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. 2) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.