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ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ¹	Expiry date of approval	Prod uct type	Specific conditions
Difenacoum	IUPAC Name: 3-(3-biphenyl-4-yl-1,2,3,4- tetrahydro-1-naphthyl)-4- hydroxycoumarin EC No: 259-978-4 CAS No: 56073-07-5	960g/kg Sum of isomers in a ratio of 50-80% cis and 20-50% trans isomers	30 June 2024	14	Difenacoum is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following general conditions: 1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. 2) Products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied. 3) The nominal concentration of difenacoum in the products shall not exceed 75 mg/kg. 4) Products shall contain an aversive agent and a dye. 5) Products shall not be authorised in the form of tracking powder. 6) Products in the form of contact formulations, other than

¹ The purity indicated in this column was the minimum degree of purity of the active substance evaluated. 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.

					<p>tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals.</p> <p>7) Only ready-to-use products shall be authorised.</p> <p>8) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category.</p> <p>9) Dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.</p> <p>In addition to the general conditions, the authorisations of biocidal products to be used by the general public are subject to the following conditions:</p> <p>1) Products shall only be authorised for use in tamper-resistant bait stations.</p> <p>2) Products shall only be supplied with a maximum quantity of bait per pack of:</p> <p>a) For products against mice only:</p> <p>i) For grain, pellet or paste baits: 50 g.</p> <p>ii) For wax block baits: 100g.</p> <p>b) For products against rats only, or mice and rats:</p> <p>i) For grain, pellet or paste baits: 150 g.</p> <p>ii) For wax block baits: 300g.</p> <p>3) Products against <i>Rattus norvegicus</i> and <i>Rattus rattus</i> shall only be authorised for use indoors or in and around buildings.</p> <p>4) Products against <i>Mus musculus</i> shall only be authorised for use indoors.</p>
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					<p>treatments.</p> <p>4) Products may only be authorised for use in permanent baiting treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient.</p> <p>5) Persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.</p>
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