

**ANNEX**

| Identi-<br>fication<br>number<br>of the<br>additive                                       | Name of the<br>additive | Composition, chemical formula,<br>description, analytical method  | Species<br>or<br>category<br>of<br>animal | Maximum<br>age | Minimum<br>content                                      | Maximum<br>content | Other provisions   | End of<br>period of<br>authorisa-<br>tion   |
|---|-------------------------|---|---|----------------|---|--------------------|--|---|
|   |                         |   |   |                | mg/kg of complete feed<br>with 12 % moisture<br>content |                    |  |   |
| Category: nutritional additives. Functional group: amino acids, their salts and analogues |                         |   |   |                |   |                    |  |   |
| 3c366i  | L-arginine              | <b>Additive composition:</b><br>L-arginine<br>Solid form<br>-----<br><b>Characterisation of the active<br/>substance:</b><br>L-arginine ≥ 98,5 % (on a dry matter<br>basis) produced with <i>Escherichia coli</i><br>CCTCC M 20231961<br>IUPAC name: (S)-2-amino-5-<br>guanidinopentanoic acid<br>Chemical formula: C <sub>6</sub> H <sub>14</sub> N <sub>4</sub> O <sub>2</sub><br>CAS number: 74–79-3<br>-----<br><b>Analytical method<sup>1</sup>:</b><br>For the identification of L-arginine in the<br>feed additive:<br>– Food Chemical Codex “L-arginine<br>monograph”<br><br>For the determination of arginine in the<br>feed additive:<br>– Ion-exchange chromatography coupled<br>to post-column derivatisation and optical | All animal<br>species                     | -              | -   | -                  | 1.In the directions for use of the<br>additive and premixtures, the<br>storage conditions, the stability to<br>heat treatment and in water for<br>drinking shall be indicated.<br><br>2.The additive may be used via<br>water for drinking.<br><br>3.Feed business operators shall<br>ensure that L-arginine is rumen<br>protected, when fed to ruminants.<br><br>4.The moisture content shall be<br>indicated on the label of the<br>additive.<br><br>5.The label of the additive and<br>premixtures shall indicate the<br>following: ‘The supplementation<br>with L-arginine, in particular via<br>water for drinking, shall take into<br>account all essential and<br>conditionally essential amino | [10 years<br>from the date<br>of entry into<br>force of this<br>Regulation.<br>To be<br>completed by<br>the OP] |

<sup>1</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: [https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\\_en](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en).

|  |  |   |  |  |  |  |  |  |
|--|--|---|--|--|--|--|--|--|
|  |  | <p>detection (IEC-VIS/FLD or IEC-VIS)</p> <p>For the determination of arginine in premixtures:</p> <ul style="list-style-type: none"> <li>– Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS/FLD) or</li> <li>– Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009</li> </ul> <p>For the determination of arginine in compound feed:</p> <ul style="list-style-type: none"> <li>– Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009</li> </ul> <p>For the determination of arginine in water for drinking:</p> <ul style="list-style-type: none"> <li>– Ion-exchange chromatography coupled to post-column derivatisation and optical detection (IEC-VIS)</li> </ul> |  |  |  |  | <p>acids in order to avoid imbalances.’</p> <p>6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address 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 skin and eye protective equipment.</p> |  |
|--|--|---|--|--|--|--|--|--|