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### ANNEX

| Identi-<br>fication<br>number<br>of the<br>additive  | Name of the<br>additive  | Composition, chemical formula,<br>description, analytical method  | Species or<br>category of<br>animal | Maxim<br>um<br>age | Minimu<br>m<br>content  | Maximu<br>m<br>content | Other provisions   | End of<br>period of<br>authorisa-<br>tion   |
|--|--|---|-------------------------------------|--------------------|---|------------------------|--|---|
|  |  |   |                                     |                    | mg of active<br>substance/kg of<br>complete feed with<br>a moisture content<br>of 12% |                        |  |   |
| Category: Nutritional additives. Functional group: Vitamins, pro-vitamins and chemically well-defined substances having a similar effect |  |   |                                     |                    |   |                        |  |   |
| 3a710  | Menadione<br>sodium<br>bisulphite' or<br>'Vitamin K <sub>3</sub> ' | <b>Additive composition</b><br>Menadione sodium bisulphite (MSB)<br>Chromium III and IV ≤ 45 mg/kg<br>Solid form<br><br><b>Characterisation of the active substance</b><br>Menadione sodium bisulphite<br>Produced by chemical synthesis<br>C <sub>11</sub> H <sub>9</sub> NaO <sub>5</sub> S·3H <sub>2</sub> O<br>CAS number: 6147-37-1<br>Purity: min. 96 % MSB complex which<br>corresponds to min. 50 % of menadione. | All animal<br>species               | -                  | -   | -                      | <div>1. In the directions for use of the additive and premixtures, the storage conditions, and the stability to heat treatment shall be indicated.</div> <div>2. The additive shall be incorporated into feed in the form of a premixture.</div> <div>3. The following equivalency shall be used if the amount of the additive is labelled: 1 mg vitamin K<sub>3</sub> = 1 mg of menadione = 2 mg of menadione sodium bisulphite.</div> <div>4. 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. In particular, the exposure to chromium by inhalation or dermal</div> | <i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i> |

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|--|-------------------------|---|-------------------------------------|--------------------|---|------------------------|---|---|
|  |                         |   |                                     |                    | mg of active<br>substance/kg of<br>complete feed with<br>a moisture content<br>of 12% |                        |   |   |
| Category: Nutritional additives. Functional group: Vitamins, pro-vitamins and chemically well-defined substances having a similar effect |                         |   |                                     |                    |   |                        |   |   |
|  |                         | <p>Analytical method<sup>1</sup></p> <p>For the determination of menadione sodium bisulphite in the feed additive: a spectrophotometric method using a visible detector at 635 nm (VDLUFA -Bd. III 13.7.1).</p> <p>— For the determination of menadione sodium bisulphite in premixtures and compound feed: Normal Phase High-Performance Liquid Chromatograph coupled to UV detector - Decreto 29/4/2010, Gazzetta Ufficiale della Repubblica Italiana n. 120, 25/5/2010.</p> <p>— For the determination of total chromium:- atomic absorption spectrometry (AAS) — GB/T 13088</p> |                                     |                    |   |                        | route. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with skin, personal breathing, eye and skin protective equipment. |   |

<sup>1</sup> Details of the analytical methods for the additives 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).

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|--|---|--|-------------------------------------|--------------------|---|------------------------|--|---|
|  |   |  |                                     |                    | mg of active<br>substance/kg of<br>complete feed with<br>a moisture content<br>of 12% |                        |  |   |
| Category: Nutritional additives. Functional group: Vitamins, pro-vitamins and chemically well-defined substances having a similar effect |   |  |                                     |                    |   |                        |  |   |
| 3a711  | ‘Menadione<br>nicotinamide<br>bisulphite’ or<br>‘Vitamin K <sub>3</sub> ’ | <b>Additive composition</b><br>Menadione nicotinamide bisulphite<br>Chromium III and IV≤ 142 mg/kg<br>Solid form<br><br><b>Characterisation of the active substance</b><br>Menadione nicotinamide bisulphite<br>C <sub>11</sub> H <sub>9</sub> O <sub>5</sub> S·C <sub>6</sub> H <sub>7</sub> N <sub>2</sub> O<br>CAS number: 73581-79-0<br>Produced by chemical synthesis<br>Purity: min. 96 % menadione nicotinamide<br>bisulphite complex which corresponds to min.<br>43,9 % menadione and min. 31,2 %<br>nicotinamide | All animal<br>species               | -                  | -   | -                      | <div><div>1.</div><div>In the directions for use of the additive and premixtures, the storage conditions, and the stability to heat treatment shall be indicated.</div></div> <div><div>2.</div><div>The additive shall be incorporated into feed in the form of a premixture.</div></div> <div><div>3.</div><div>The following equivalency shall be used if the amount of the additive is labelled: 1 mg vitamin K<sub>3</sub> = 1 mg of menadione = 2.27 mg of menadione nicotinamide bisulphite</div></div> <div><div>4.</div><div>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. In particular, the exposure to chromium by inhalation or dermal</div></div> | <i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i> |

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|--|-------------------------|---|-------------------------------------|--------------------|---|------------------------|---|---|
|  |                         |   |                                     |                    | mg of active<br>substance/kg of<br>complete feed with<br>a moisture content<br>of 12% |                        |   |   |
| Category: Nutritional additives. Functional group: Vitamins, pro-vitamins and chemically well-defined substances having a similar effect |                         |   |                                     |                    |   |                        |   |   |
|  |                         | <p><b>Analytical method<sup>2</sup></b></p> <p>— For the determination menadione nicotinamide bisulphite in the feed additive: a spectrophotometric method using a visible detector at 635 nm (VDLUFA — Bd.III 13.7.1).</p> <p>— For the determination of menadione nicotinamide bisulphite in premixtures and compound feed: Normal Phase High-Performance Liquid Chromatograph - Decreto 29/4/2010, Gazzetta Ufficiale della Repubblica Italiana n. 120, 25/5/2010</p> <p>— For the determination of total chromium:- atomic absorption spectrometry (AAS) — GB/T 13088</p> |                                     |                    |   |                        | route. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with skin, personal breathing, eye and skin protective equipment. |   |

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