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**ANNEX**

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

1. in Table 1 (Authorised novel foods), the entry for ‘Protein extract from pig kidneysʼ is replaced by the following:

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| **Authorised novel food** | **Conditions under which the novel food may be used** | | **Additional specific labelling requirements** | **Other requirements** |
| **Protein extract from pig kidneys** | ***Specified food category*** | ***Maximum levels*** |  |  |
| Food Supplements as defined in Directive 2002/46/EC | 3 capsules or tablets/day; equalising 12,6 mg pig kidney extract a day Diamine oxidase (DAO) content: 0,9 mg/day (3 capsules or 3 tablets with a content of DAO of 0,3 mg/capsule or 0,3 mg/tablet) |
| Food for special medical purposes as defined in Regulation (EU) No 609/ 2013 |

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1. in Table 2 (Specifications), the entry for ‘Protein extract from pig kidneysʼ is replaced by the following:

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| **Authorised Novel Food** | **Specification** |
| **Protein extract from pig kidneys** | **Description/Definition:**  The protein extract is obtained from homogenised pig kidneys through a combination of salt precipitation and high speed centrifugation. The obtained precipitate contains essentially proteins with 7 % of the enzyme diamine oxidase (enzyme nomenclature E.C. 1.4.3.22) and is resuspended in a physiologic buffer system. The obtained pig kidney extract is formulated as encapsulated enteric coated pellets or enteric coated tablets to reach the active sites of digestion.  Basic Product:  Specification: pig kidney protein excerpt with natural content of Diamine oxidase (DAO):  Physical condition: liquid  Colour: brownish  Appearance: slightly turbid solution  pH value: 6,4-6,8  Enzymatic activity: > 2 677 kHDU DAO/ml (DAO REA (DAO Radioextractionassay))  **Microbiological criteria:** *Brachyspira* spp.: negative (Real Time PCR)  *Listeria monocytogenes*: negative (Real Time PCR)  *Staphylococcus aureus*: < 100 CFU/g  Influenza A: negative (Reverse Transcription Real Time PCR)  *Escherichia coli*: < 10 CFU/g  Total aerobic microbiological count: < 105 CFU/g  Yeasts/moulds count: < 105 CFU/g  *Salmonella*: Absence/10g  Bile salt resistant enterobacteriaceae: < 104 CFU/g  **Final product:**  Specification pig kidney protein excerpt with natural content of DAO (E.C. 1.4.3.22) in an enteric coated formulation:  Physical condition: solid  Colour: yellow grey  Appearance: micropellets or tablets  Enzymatic activity: 110-220 kHDU DAO/g pellet or g tablet (DAO REA (DAO Radioextractionassay))  Acid stability 15 min 0,1M HCl followed by 60 min Borat pH = 9,0: > 68 kHDU DAO/g pellet or g tablet (DAO REA (DAO Radioextractionassay))  Humidity: < 10 %  *Staphylococcus aureus*: < 100 CFU/g  *Escherichia coli*: < 10 CFU/g  Total aerobic microbiological count: < 104 CFU/g  Total combined yeasts/moulds count: < 103 CFU/g  *Salmonella*: Absence/10g  Bile salt resistant enterobacteriaceae: < 102 CFU/g |

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