EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10877/2016 ANNEX
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ANNEX.doc)
[…](2016) XXX draft

ANNEXES 1 to 2

**ANNEXES**

**to the**

**COMMISSION IMPLEMENTING DECISION**

**authorising the placing on the market of UV-treated milk as a novel food under Regulation (EC) No 258/97 of the European Parliament and of the Council**

## ANNEX I

### Specification of UV-treated milk

**Definition:**

UV-treated milk is cow's milk (whole and semi-skimmed) to which a treatment with ultraviolet (UV) radiation via turbulent flow is applied after pasteurisation. The treatment of the pasteurised milk with UV radiation results in an increase in the vitamin $D_3$ (cholecalciferol) concentrations by conversion of 7-dehydrocholesterol to vitamin $D_3$.

UV radiation: a process of radiation in ultraviolet light within the wavelength of 200-310 nm with energy input of 1045 J/l.

**Vitamin $D_3$:**

| | |
|---|---|
| **Chemical name** | (1S,3Z)-3-[(2E)-2-[(1R,3aS,7aR)-7a-methyl-1-[(2R)-6-methylheptan-2-yl]-2,3,3a,5,6,7-hexahydro-1H-inden-4-ylidene]ethylidene]-4-methylidenecyclohexan-1-ol |
| **Synonym** | Cholecalciferol |
| **CAS No** | 67-97-0 |
| **Molecular weight** | 384.6377g/mol |

**Contents:**

| | |
|---|---|
| Vitamin $D_3$ in the final product | Whole milk[1]: 0.5–3.2 μg/100 g[2]<br>Semi-skimmed milk[1]: 0.1–1.5 μg/100 g[2] |

[1] As defined by Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671-854).

[2] HPLC

## ANNEX II

### Authorised uses of UV-treated milk

| Food category | Range of vitamin $D_3$ |
|---|---|
| Pasteurised whole milk[3] | 5–32 μg/kg for general population excluding infants |
| Pasteurised semi-skimmed milk[3] | 1–15 μg/kg for general population excluding infants |

[3] Consumed as such.