

*Status: Point in time view as at 31/01/2020.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX. (See end of Document for details)*

## ANNEX

Annex I to Regulation (EU) No 10/2011 is amended as follows:

(1) Table 1 is amended as follows:

(a) the entries concerning FCM substances Nos 161, 241, 344, 364, 410, 713, 784, 799, 880 and 881 are replaced by the following:

|     |       |       |                              |     |     |    |      |    |                     |   |
|-----|-------|-------|------------------------------|-----|-----|----|------|----|---------------------|---|
| 161 | 92160 | 00008 | 7-69-4<br>(+)-tartaric acid  | yes | no  | no |      |    |                     |   |
| 241 | 22960 | 00001 | 08-95-2<br>phenol            | no  | yes | no | 3    |    |                     |   |
| 344 | 13810 | 00005 | 05-46-7<br>butanediol        | no  | yes | no | 0,05 | 15 |                     | (21)  |
|     | 21821 |       | formal                       |     |     |    |      | 30 |                     |   |
| 364 | 15404 | 00006 | 52-46-6<br>dianhydrosorbitol | no  | yes | no | 5    |    | Only to be used as: |   |
|     |       |       |                              |     |     |    |      |    | (a)                 | a co-monomer in poly(ethylene-co-isosorbide terephthalate);   |
|     |       |       |                              |     |     |    |      |    | (b)                 | a co-monomer at levels of up to 40 mole % of the diol component in combination with ethylene glycol |

**a** Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).'

*Status: Point in time view as at 31/01/2020.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX. (See end of Document for details)*

|     |       |       |         |    |     |    |    |  |  |  |
|-----|-------|-------|---------|----|-----|----|----|--|--|--|
|     |       |       |         |    |     |    |    |  |  | and/<br>or<br>1,4-<br>bis(hydroxymethyl)cycl<br>for<br>the<br>production<br>of<br>polyesters.<br>Polyesters<br>made<br>using<br>dianhydrosorbitol<br>together<br>with<br>1,4-<br>bis(hydroxymethyl)cyclohexane<br>shall<br>not<br>be<br>used<br>in<br>contact<br>with<br>foods<br>containing<br>more<br>than<br>15 %<br>alcohol. |
| 410 | 62720 | 00013 | 12-58-7 | no | yes | no | no |  |  | Particles<br>can<br>be<br>thinner<br>than<br>100<br>nm<br>only<br>if<br>incorporated<br>at a<br>quantity<br>of<br>less<br>than<br>12 %<br>w/w<br>in an<br>ethylene   |

**a** Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).'

*Status: Point in time view as at 31/01/2020.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX. (See end of Document for details)*

|     |       |       |                     |    |    |  |  |  |  |
|-----|-------|-------|---------------------|----|----|--|--|--|--|
|     |       |       |                     |    |    |  |  |  | vinyl alcohol copolymer (EVOH) inner layer of a multi-layer structure, in which the layer in direct contact with the food provides a functional barrier preventing migration of particles into the food. |
| 713 | 43480 | 00643 | Charcoal, activated | no | no |  |  |  | Only for use in PET at maximum 10 mg/kg of polymer. Same purity requirements as for Vegetable Carbon   |

**a** Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).'

*Status: Point in time view as at 31/01/2020.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX. (See end of Document for details)*

|     |       |       |   |     |    |    |     |  |   |
|-----|-------|-------|---|-----|----|----|-----|--|---|
|     |       |       |   |     |    |    |     |  | (E 153) set out by Commission Regulation (EU) No 231/2012 <sup>a</sup> with exception of ash content which can be up to 10 % (w/w).   |
| 784 | 95420 | 07450 | 70361-5   | yes | no | no | 5   |  |   |
|     |       |       | tris (2,2-dimethylpropanamido) benzene  |     |    |    |     |  |   |
| 799 | 77708 |       | polyethylene glycol (EO = 1-50) ethers of linear and branched primary (C <sub>8</sub> -C <sub>22</sub> ) alcohols | yes | no | no | 1,8 |  | In compliance with the maximum ethylene oxide content as laid down in the purity criteria for food additives in Commission Regulation |

<sup>a</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).<sup>7</sup>

*Status: Point in time view as at 31/01/2020.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX. (See end of Document for details)*

|     |       |       |   |     |     |    |   | (EU)<br>No<br>231/2012.     |  |
|-----|-------|-------|---|-----|-----|----|---|-----------------------------|--|
| 880 | 31348 |       | acids, fatty (C <sub>8</sub> -C <sub>22</sub> ), esters with pentaerythritol' | yes | no  | no |   |                             |  |
| 881 | 25187 | 00030 | 02964<br>tetramethylcyclobutane-1,3-diol                                      | no  | yes | no | 5 | Only for:<br>(a)<br><br>(b) | repeated use articles for long term storage at room temperature or below and hotfill; single use materials and articles as a co-monomer at a maximum use level of 35 mole % of the diol component of |

**a** Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).'

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX. (See end of Document for details)

|  |  |  |  |  |  |  |  |  |  |  |
|--|--|--|--|--|--|--|--|--|--|--|
|  |  |  |  |  |  |  |  |  |  | polyesters, and if such materials and articles are for long term storage at room temperature or below of food types which have an alcohol content of up to 10 % and for which Table 2 of Annex III does not assign simulant D2. Hot fill conditions are allowed for such |
|--|--|--|--|--|--|--|--|--|--|--|

**a** Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).<sup>7</sup>

*Status: Point in time view as at 31/01/2020.*

**Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX. (See end of Document for details)

|          |   |  |  |  |  |  |  |  |  |                                    |
|----------|---|--|--|--|--|--|--|--|--|------------------------------------|
|          |   |  |  |  |  |  |  |  |  | single use materials and articles. |
| <b>a</b> | Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1). <sup>7</sup> |  |  |  |  |  |  |  |  |                                    |

(b) the following entries are inserted in numerical order of the FCM substance numbers:

|     |  |  |  |     |    |    |  |  |  |  |
|-----|--|--|--|-----|----|----|--|--|--|--|
| 859 |  |  | (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with divinylbenzene, in nanoform | yes | no | no |  |  |  | Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 998 and/or the substance |
|-----|--|--|--|-----|----|----|--|--|--|--|

*Status: Point in time view as at 31/01/2020.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX. (See end of Document for details)*

|     |            |  |     |    |    |  |  |  |
|-----|------------|--|-----|----|----|--|--|--|
|     |            |  |     |    |    |  |  | with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm. |
| 903 | 37486-20-4 | perfluoro-[(5,8,11,14-tetraethylpropyl ether)]-tetraethyleneglycol | yes | no | no |  |  | Only to be used as a polymer production aid in the polymerisation of fluoropolymers intended for:<br>(a) repeated and single   |

*Status: Point in time view as at 31/01/2020.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX. (See end of Document for details)*

|     |  |            |                |    |    |  |  |            |   |
|-----|--|------------|----------------|----|----|--|--|------------|---|
|     |  |            |                |    |    |  |  |            | use materials and articles when sintered or processed (non-sintered) at temperatures at or above 360 °C for at least 10 minutes or at higher temperatures for equivalent shorter times; repeated use materials and articles when processed (non-sintered) at temperatures from 300 °C and up to 360 °C for at least 10 minutes. |
| 969 |  | 24937-78-8 | Styrenes vinyl | no | no |  |  | Only to be |   |

*Status: Point in time view as at 31/01/2020.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX. (See end of Document for details)*

|     |  |   |    |    |  |  |  |
|-----|--|---|----|----|--|--|--|
|     |  | acetate copolymer wax   |    |    |  |  | used as a polymeric additive up to 2 % w/w in polyolefins. The migration of low molecular weight oligomeric fraction below 1 000 Da shall not exceed 5 mg/kg food. |
| 998 |  | (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross-linked, in nanoform | no | no |  |  | Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including                           |



*Status: Point in time view as at 31/01/2020.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX. (See end of Document for details)*

|      |  |            |   |    |    |  |  |  |
|------|--|------------|---|----|----|--|--|--|
| 1017 |  | 25618-55-7 | polyglycerol  | no | no |  |  | To be processed under conditions preventing the decomposition of the substance and up to a maximum temperature of 275 °C.  |
| 1043 |  |            | (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with 1,3-butanediol dimethacrylate, in nanoform | no | no |  |  | Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with |



---

*Status: Point in time view as at 31/01/2020.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX. (See end of Document for details)*

---

|    |                   |   |                             |
|----|-------------------|---|-----------------------------|
| 30 | 254<br>344<br>672 | 5 | expressed as 1,4-butanediol |
|----|-------------------|---|-----------------------------|

(3) In Table 3, the following entry is added:

|      |  |
|------|--|
| (21) | In case of reaction with foods or simulants verification of compliance shall include verification that the migration limits of the hydrolysis products, formaldehyde and 1,4-butanediol, are not exceeded. |
|------|--|

**Status:**

Point in time view as at 31/01/2020.

**Changes to legislation:**

There are currently no known outstanding effects for the Commission Regulation (EU) 2015/174, ANNEX.